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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-4202; Directorate Identifier 2014-NM-016-AD; Amendment 39-18583; AD 2016-14-02]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2012-18-12 for certain Airbus Model A318, A319, and A320 series airplanes. AD 2012-18-12 required modifying the off-wing escape slide (OWS) enclosures on the left-hand (LH) side and right-hand (RH) side of the fuselage. This new AD retains the requirements of AD 2012-18-12 and expands the applicability to all Airbus Model A318, A319, and A320 series airplanes. This AD was prompted by reports that additional OWS part numbers have been affected. We are issuing this AD to prevent off-wing exits on the LH and RH sides of the fuselage from becoming inoperative. During an emergency, inoperative off-wing exits could impair the safe evacuation of occupants, possibly resulting in personal injuries.

DATES: This AD becomes effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of October 22, 2012 (77 FR 57003, September 17, 2012).

ADDRESSES: For Airbus service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet <http://www.airbus.com>.

For Air Cruisers service information identified in this final rule, contact Air Cruisers Company, Cage Code 70167, 1747 State Route 34, Wall Township, NJ 07727-3935; telephone 732-681-3527; fax 732-681-9163; Internet <http://www.zodiac aerospace.com/en/our-activities/aerosafety/zodiac-evacuation-systems>.

For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4202.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4202; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M 30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2012-18-12, Amendment 39-17189 (77 FR 57003, September 17, 2012) (“AD 2012-18-12”). AD 2012-18-12 applied to certain Airbus Model A318, A319, and A320 series airplanes. The NPRM published

in the **Federal Register** on October 23, 2015 (80 FR 64375) (“the NPRM”). The NPRM was prompted by reports that additional OWS part numbers have been affected. The NPRM proposed to retain the requirements of AD 2012-18-12, and to expand the applicability to all Airbus Model A318, A319, and A320 series airplanes. We are issuing this AD to prevent off-wing exits on the LH and RH sides of the fuselage from becoming inoperative. During an emergency, inoperative off-wing exits could impair the safe evacuation of occupants, possibly resulting in personal injuries.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014-0025R1, dated May 26, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition on all Airbus Model A318, A319, and A320 series airplanes. The MCAI states:

One operator reported a torn out aspirator during scheduled deployment (for on ground testing purposes) of the Left Hand (LH) off-wing [escape] slide (OWS). Investigation results revealed that the aspirator of the OWS system interfered with the extrusion lip of the OWS enclosure during the initial stage of the deployment sequence.

This condition, if not corrected, could lead to an off-wing exit, either LH or Right Hand (RH), becoming unserviceable, which, during an emergency situation, could impair the safe evacuation of occupants, possibly resulting in personal injuries.

To address this potential unsafe condition, Airbus issued Service Bulletin (SB) A320-25-1649 containing modification instructions for certain part number (P/N) OWS enclosures. Consequently, EASA issued [EASA] AD 2010-0210 [<http://ad.easa.europa.eu/ad/2010-0210>], which corresponds to FAA AD 2012-18-12 to require modification of the affected OWS enclosures.

Since that [EASA] AD was issued, several other OWS P/N[s] have been identified as potentially impacted.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2010-0210, which is superseded, expands the Applicability to all A318, A319 and A320 aeroplanes, and expands the batch of affected P/N[s] prohibited to be installed on an aeroplane.

For the reason described above, EASA issued AD 2014-0025, retaining the requirements of EASA AD 2010-0210, which was superseded, expanding the Applicability to all A318, A319 and A320 aeroplanes, and expanding the batch of affected P/N[s]

prohibited to be installed on an aeroplane. That [EASA] AD also retained the requirements of * * * [an AD, which was superseded], which required modification of the OWS and its aspirator.

This [EASA] AD is revised to amend paragraphs (1) and (3) to restore the original applicability of [a Direction Générale de l'Aviation Civile] DGAC France AD and EASA AD 2010–0210, respectively, and to correct paragraph (2) to give credit for certain production modifications that were equivalent for the in-service actions previously required by [a] DGAC France AD.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–4202.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Change Parts Installation Prohibitions

United Airlines (United) asked for clarification of the language in paragraph (k) of the proposed AD, which would prohibit the installation of OWS part numbers (P/Ns) including D31865–109, D31865–110, D31865–209, and D31865–210, as identified in paragraph (h)(2) of the proposed AD, but also specifies accomplishing the modification required by paragraph (g) of the proposed AD. United stated that the modification converts those part numbers into D31865–309, D31865–311, D31865–310, and D31865–312, respectively. Therefore, United suggested we remove any language allowing installation of P/Ns D31865–109, D31865–110, D31865–209, and D31865–210 from the proposed AD.

We agree that clarification is necessary. We have moved the language in paragraph (h)(1) of the proposed AD into paragraph (h) of this AD and removed paragraph (h)(2) from this AD. We have also removed the language in paragraph (k) of the proposed AD which specified “except as required by paragraph (h)(2) of this AD for the OWS enclosures identified in paragraph (h) of this AD.” And where paragraph (l)(2) of the proposed AD referred to “paragraph (h)(2),” we have changed this reference to paragraph (h) of this AD.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD with the changes described previously,

and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information.

- Airbus Service Bulletin A320–25–1156, Revision 03, dated December 5, 2001. This service information describes procedures for modifying OWS enclosures having P/Ns D31865–101, D31865–102, D31865–103, D31865–104, D31865–105, D31865–106, D31865–107, or D31865–108 of certain Airbus Model A319 and A320 series airplanes.

- Airbus Service Bulletin A320–25–1649, dated February 16, 2010. This service information describes procedures for modifying and installing OWS enclosures having P/Ns D31865–109, D31865–110, D31865–209, or D31865–210, on the LH and RH sides of the fuselage on certain Airbus Model A318, A319, and A320 series airplanes.

Air Cruisers has issued Service Bulletin A320 004–25–84, Revision 4, dated November 9, 2012. This service information describes procedures for modifying the LH and RH OWS.

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

Costs of Compliance

We estimate that this AD affects 851 airplanes of U.S. registry.

The actions required by AD 2012–18–12 and retained in this AD take about 14 work-hours per product, at an average labor rate of \$85 per work-hour. Required parts will cost \$0 per product. Based on these figures, the estimated cost of the actions that are required by AD 2012–18–12 is \$1,190 per product.

We also estimate that it takes about 48 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts will cost \$0 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$3,472,080, or \$4,080 per product.

Authority for This Rulemaking

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

detail the scope of the Agency's authority.

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

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2012–18–12, Amendment 39–17189 (77 FR 57003, September 17, 2012), and adding the following new AD:

2016–14–02 Airbus: Amendment 39–18583. Docket No. FAA–2015–4202; Directorate Identifier 2014–NM–016–AD.

(a) Effective Date

This AD becomes effective August 12, 2016.

(b) Affected ADs

This AD replaces (AD) 2012–18–12, Amendment 39–17189 (77 FR 57003, September 17, 2012) (“AD 2012–18–12”).

(c) Applicability

This AD applies to the Airbus airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model 320–211, –212, –214, –231, –232, and –233 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Reason

This AD was prompted by reports that additional OWS part numbers have been affected. We are issuing this AD to prevent off-wing exits on the left-hand (LH) and right-hand (RH) sides of the fuselage from becoming inoperative. During an emergency, inoperative off-wing exits could impair the safe evacuation of occupants, possibly resulting in personal injuries.

(f) Compliance

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

(g) Retained Modification

This paragraph restates the requirements of paragraph (g) of AD 2012–18–12, with no changes. For airplanes equipped with OWS enclosures having part number (P/N) D31865–109, D31865–110, D31865–209, or D31865–210, except as provided by paragraph (i)(1) of this AD: Within 36 months after October 22, 2012 (the effective date of AD 2012–18–12), modify the OWS enclosures and install an OWS enclosure having P/N D31865–309, D31865–311, D31865–310, or D31865–312 on the LH side and RH side of the fuselage, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–25–1649, dated February 16, 2010.

(h) New Modification of Affected OWS Enclosures and Aspirators

For airplanes equipped with an OWS enclosure having P/N D31865–101, D31865–102, D31865–103, D31865–104, D31865–105, D31865–106, D31865–107, or D31865–108, except as provided by paragraph (i)(2) of this AD: Within 36 months after the effective date of this AD, modify the OWS enclosures and their aspirators in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–25–1156, Revision 03, dated December 5, 2001.

(i) Exceptions to the Requirements of Paragraphs (g) and (h) of This AD

(1) Airplanes having Airbus Modification 30088 embodied in production using an OWS enclosure having P/N D31865–111 or D31865–112 are not affected by the requirements of paragraph (g) of this AD, unless a replacement OWS enclosure, having a part number listed in paragraphs (k)(9) through (k)(12) of this AD, has been installed on that airplane since first flight.

(2) Airplanes on which Airbus Modifications 24850, 25844, and 27275 have been embodied in production, or on which modifications of the LH and RH OWS enclosures and their aspirators have been accomplished using Airbus Service Bulletin A320–25–1156, Revision 01, dated February 2, 1999; or Revision 02, dated October 26, 1999; and Airbus Service Bulletin A320–25–1265, dated June 6, 2001, are compliant with the modification requirement of paragraph (h) of this AD.

(j) Optional Method of Compliance for Paragraph (g) of This AD

Installing both LH and RH OWS that have been modified in accordance with the Accomplishment Instructions of Air Cruisers Service Bulletin A320 004–25–84, Revision 4, dated November 9, 2012, is an acceptable method of compliance with the modification required by paragraph (g) of this AD.

(k) Part Installation Prohibition

As of the effective date of this AD, do not install on any airplane an OWS enclosure having a part number listed in paragraphs (k)(1) through (k)(12) of this AD.

- (1) D31865–101.
- (2) D31865–102.
- (3) D31865–103.
- (4) D31865–104.
- (5) D31865–105.
- (6) D31865–106.
- (7) D31865–107.
- (8) D31865–108.
- (9) D31865–109.
- (10) D31865–110.
- (11) D31865–209.
- (12) D31865–210.

(l) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraph (l)(1)(i) or (l)(1)(ii) of this AD, which is not incorporated by reference in this AD.

(i) Airbus Service Bulletin A320–25–1156, Revision 01, dated February 2, 1999.

(ii) Airbus Service Bulletin A320–25–1156, Revision 02, dated October 26, 1999.

(2) This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–25–1265, dated June 6, 2001, which is not incorporated by reference in this AD.

(3) This paragraph provides credit for the actions specified in paragraph (j) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraph (l)(3)(i),

(l)(3)(ii), (l)(3)(iii), or (l)(3)(iv) of this AD, which is not incorporated by reference in this AD.

(i) Air Cruisers Service Bulletin A320 004–25–84, dated February 5, 2010.

(ii) Air Cruisers Service Bulletin A320 004–25–84, Revision 1, dated April 9, 2010.

(iii) Air Cruisers Service Bulletin A320 004–25–84, Revision 2, dated February 11, 2011.

(iv) Air Cruisers Service Bulletin A320 004–25–84, Revision 3, dated October 28, 2011.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(ii) AMOCs approved previously for AD 2012–18–12 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

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

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0025R1, dated May 26, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–4202.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(5), (o)(6), and (o)(7) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(3) The following service information was approved for IBR on August 12, 2016.

(i) Airbus Service Bulletin A320-25-1156, Revision 03, dated December 5, 2001.

(ii) Air Cruisers Service Bulletin A320 004-25-84, Revision 4, dated November 9, 2012.

(4) The following service information was approved for IBR on October 22, 2012 (77 FR 57003, September 17, 2012).

(i) Airbus Service Bulletin A320-25-1649, dated February 16, 2010.

(ii) Reserved.

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

(6) For Air Cruisers service information identified in this AD, contact Air Cruisers Company, Cage Code 70167, 1747 State Route 34, Wall Township, NJ 07727-3935; telephone 732-681-3527; fax 732-681-9163; Internet <http://www.zodiac aerospace.com/en/our-activities/aerosafety/zodiac-evacuation-systems>.

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

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

Issued in Renton, Washington, on June 23, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-15902 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-5578; Directorate Identifier 2016-CE-005-AD; Amendment 39-18587; AD 2016-14-06]

RIN 2120-AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2006-13-05 for certain Pacific Aerospace Limited Model 750XL (type certificate previously held by Pacific Aerospace Corporation Ltd.) airplanes. 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 some critical rivets on the wing not being fully age-hardened and being installed in specific locations where reduction in rivet strength reduces wing strength. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of July 31, 2006 (71 FR 35509, June 21, 2006).

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5578; or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; facsimile: +64 7 843 6134; email: pacific@aerospace.co.nz; Internet: www.aerospace.co.nz. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the Internet at <http://www.regulations.gov> by searching for Docket No. FAA-2016-5578.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4123; fax: (816) 329-4090; email: karl.schletzbaum@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Pacific Aerospace Limited Model 750XL (type certificate previously held by Pacific Aerospace Corporation Ltd.) airplanes. That NPRM was published in the **Federal Register** on April 12, 2016 (81 FR 21489), and proposed to supersede AD 2006-13-05, Amendment 39-14658 (71 FR 35509, June 21, 2006) (“AD 2006-13-05”).

Since we issued AD 2006-13-05, additional airplanes have been identified that need to be added to the applicability of the AD.

The Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, has issued AD No. DCA/750XL/7B, dated February 25, 2016 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

DCA/750XL/7B revised to introduce PACSB/XL/018 issue 4, dated 20 January 2016, which reduces the applicability to S/N 101 through to 131 with no change to the requirements. Aircraft with S/N 132 onwards have been modified in accordance with PACSB/XL/018 at manufacture, which is a terminating action for the requirements of this AD.

This AD requires you to remove rivets that have not been fully age hardened and replace them with bolts, washers, and nuts in specific locations where reduction in rivet strength affects overall structural capability. The AD retains the airplane weight AFM limitations until the rivets are replaced with the bolts, washers, and nuts. You may examine the MCAI on the Internet at <https://www.regulations.gov/#!docketDetail;D=FAA-2016-5578-002>.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (81 FR 21489, April 12, 2016) or on the determination of the cost to the public.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (81 FR 21489, April 12, 2016) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (81 FR 21489, April 12, 2016).

Related Service Information

We reviewed Pacific Aerospace Limited Service Bulletin PACSB/XL/018, Issue 4, dated January 20, 2016. The service bulletin describes procedures for removing rivets (part number (P/N) MS20470 DD6) and installing bolts (P/N NAS 6203-7X or NAS 6203-6X), washers (P/N AN960-10), and nuts (P/N MS21044N3) in place of the rivets to restore airplane to full take-off weight of 7,500 pounds. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of the AD.

Costs of Compliance

We estimate that this AD will affect 9 products of U.S. registry. We also estimate that it will take about 32 work-hours per product to comply with the replacement requirements of this AD. The average labor rate is \$85 per work-hour. Required parts will cost about \$519 per product.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$29,151, or \$3,239 per product.

AD 2006-13-05 affected 8 of the 9 U.S.-registered airplanes reflected in the above cost information. This AD will only increase the cost already required by AD 2006-13-05 by one additional airplane. The FAA has a report that the additional airplane is already in compliance, thus this AD will impose no additional cost impact on U.S. operators.

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),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5578; 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 the NPRM, 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.

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 39-14658 (71 FR 35509, June 21, 2006), and adding the following new AD:

2016-14-06 Pacific Aerospace Limited: Amendment 39-18587; Docket No.

FAA-2016-5578; Directorate Identifier 2016-CE-005-AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective August 12, 2016.

(b) Affected ADs

This AD replaces AD 2006-13-05, Amendment 39-14658 (71 FR 35509, June 21, 2006) ("AD 2006-13-05").

(c) Applicability

This AD applies to the following Pacific Aerospace Limited Model 750XL airplanes (type certificate previously held by Pacific Aerospace Corporation Ltd.), that are certificated in any category.

(1) *Airplanes previously affected by AD 2006-13-05:* Serial numbers 101, 102, 104 through 120, and 125.

(2) *Airplanes new to this AD:* Serial numbers 103, 121, 122, 123, 124, and 126 to 131.

(d) Subject

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

(e) Reason

This 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 some critical rivets on the wing not being fully age-hardened and being installed in specific locations where reduction in rivet strength reduces wing strength. We are issuing this AD to add airplane serial numbers to the Applicability section, paragraph (c) of this AD, and to ensure wing ultimate load requirements are met. If wing ultimate load requirements are not met, wing failure could result with consequent loss of control.

(f) Actions and Compliance

Unless already done, do the following actions:

(1) Insert the following information into the Limitations section of the airplane flight manual (AFM) at the compliance time specified in paragraphs (f)(1)(i) and (ii) of this AD. You may do this by inserting a copy of this AD into the Limitations section of the AFM: "The maximum takeoff weight is reduced from 7,500 pounds to 7,125 pounds." The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do the flight manual changes requirement of this AD. Make an entry in the aircraft records showing compliance with this portion of the AD following section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(i) *For airplanes previously affected by AD 2006-13-05:* Before further flight after January 16, 2006 (the effective date retained from AD 2005-26-53, Amendment 39-14451 (71 FR 2453, January 17, 2006), which was replaced by AD 2006-13-05).

(ii) *For airplanes new to this AD:* Before further flight after August 12, 2016 (the effective date of this AD).

(2) Remove rivets, part number (P/N) MS20470 DD6, on the main spar web and

replace with bolts, P/N NAS 6203-6X or -7X, as indicated for the position, assembled with washers, P/N AN960-10, and nut, P/N MS21044N3, at the compliance time specified in paragraphs (f)(2)(i) and (ii) of this AD.

(i) *For airplanes previously affected by AD 2006-13-05:* Within the next 100 hours time-in-service (TIS) after July 31, 2006 (the effective date retained from AD 2006-13-05). Do the removal and replacement actions following Pacific Aerospace Corporation Ltd. Service Bulletin PACSB/XL/018, Issue 3, dated December 23, 2005, and amended January 16, 2006.

(ii) *For airplanes new to this AD:* Within the next 100 hours TIS after August 12, 2016 (the effective date of this AD) or within the next 12 months after August 12, 2016 (the effective date of this AD), whichever occurs first. Do the removal and replacement actions following Pacific Aerospace Limited Service Bulletin PACSB/XL/018, Issue 4, dated January 20, 2016.

(3) *For all affected airplanes:* Before further flight after doing the action required in paragraph (f)(2) of this AD, remove the restrictive information from the Limitations section of the AFM that you were required to insert in paragraph (f)(1) of this AD. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do the flight manual changes requirement of this AD.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4123; fax: (816) 329-4090; email: karl.schletzbaum@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(h) Related Information

Refer to MCAI Civil Aviation Authority (CAA) AD No. DCA/750XL/7B, dated February 25, 2016, for related information. You may examine the MCAI on the Internet at <https://www.regulations.gov/>#!/docketDetail;D=FAA-2016-5578-002.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(3) The following service information was approved for IBR on August 12, 2016.

(i) Pacific Aerospace Limited Service Bulletin PACSB/XL/018, Issue 4, dated January 20, 2016.

(ii) Reserved.

(4) The following service information was approved for IBR on July 31, 2006 (71 FR 35509, June 21, 2006).

(i) Pacific Aerospace Corporation Ltd. Service Bulletin PACSB/XL/018, Issue 3, dated December 23, 2005, and amended January 16, 2006.

(ii) Reserved.

(5) For Pacific Aerospace Limited service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; facsimile: +64 7 843 6134; email: pacific@aerospace.co.nz; Internet: www.aerospace.co.nz.

(6) You may view this service information at 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. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5578.

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

Issued in Kansas City, Missouri, on June 28, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-15864 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2016-0460; Directorate Identifier 2015-NM-078-AD; Amendment 39-18577; AD 2016-13-13]

RIN 2120-AA64

Airworthiness Directives; Beechcraft Corporation (Type Certificate Previously Held by Hawker Beechcraft Corporation; Raytheon Aircraft Company) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Beechcraft Corporation Model BAe.125 Series 1000A and 1000B airplanes and Model Hawker 1000 airplanes. This AD was prompted by reports of inadvertent stowage of the thrust reversers, which can result in high forward engine thrust even though the throttle is commanding reverse thrust. This AD requires installing kits that include relays, associated wiring, and a thrust reverser fail annunciator. We are issuing this AD to prevent inadvertent stowage of the thrust reversers, which could cause a runway overrun during a rejected takeoff or landing, and consequent structural failure and possible injury to occupants.

DATES: This AD is effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 12, 2016.

ADDRESSES: For service information identified in this final rule, contact Beechcraft Corporation, TMDC, P.O. Box 85, Wichita, KS 67201-0085; telephone: 316-676-8238; fax: 316-671-2540; email: tmdc@beechcraft.com; Internet: <http://pubs.beechcraft.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-0460.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-0460; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jeffrey Englert, Aerospace Engineer, Systems and Propulsion Branch, ACE-116W, FAA, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Dwight D. Eisenhower

National Airport, Wichita, KS 67209; phone: 316-946-4167; fax: 316-946-4107; email: jeffrey.englert@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Beechcraft Corporation Model BAe.125 series 1000A and 1000B airplanes and Model Hawker 1000 airplanes. The NPRM published in the **Federal Register** on January 21, 2016 (81 FR 3348) (“the NPRM”). The NPRM was prompted by reports of inadvertent stowage of the thrust reversers, which can result in high forward engine thrust even though the throttle is commanding reverse thrust. The NPRM proposed to require installing kits that include relays, associated wiring, and a thrust reverser fail annunciator. We are issuing this AD to prevent inadvertent stowage of the thrust reversers, which could cause a runway overrun during a rejected takeoff or landing, and consequent structural failure and possible injury to occupants.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Support for the NPRM

Mr. Kevin Maher expressed support for the NPRM.

Request To Revise NPRM Requirement

Mr. Kenneth Rittenhouse of Becker Aviation LLC requested that we not require installation of the service kits,

but leave the installation decision up to the individual owner/operator. Mr. Rittenhouse stated that the NPRM mentions that there have not been any issues reported involving Model BAe.125 airplanes but does mention that those airplanes have a similar engine/thrust reverser system to airplanes on which the problem was reported. Mr. Rittenhouse explained that if you examine the Learjet Model 60 and the Model Hawker 1000 systems, the Hawker 1000 is much more robust with redundant capabilities. Mr. Rittenhouse stated that he does not believe the unsafe condition has ever been an issue with the Model Hawker 1000 airplanes, and that it is extremely unjust to force operators to comply with this modification that costs 15 percent of the total value of the airplane.

We do not agree with the commenter’s request. We recognize that maintaining airplanes in an airworthy condition is vital, but sometimes expensive. Installation of the service kit corrects a potential unsafe condition that could cause a runway overrun during a rejected takeoff or landing, and consequent structural failure and possible injury to occupants. The service kit was designed and proposed by the airplane original equipment manufacturer as its best correction option. The root cause of the unsafe condition is incorrect software logic within the engine’s electronic control unit. We acknowledge the commenter’s statement indicating that “the Hawker 1000 is much more robust with redundant capabilities,” however, the commenter did not submit any substantiating data to support that statement. We have determined that this unsafe condition exists on the Model

Hawker 1000 airplanes as well as Beechcraft Corporation Model BAe.125 Series 1000A and 1000B airplanes. We might approve requests to revise the applicability of this AD if the request includes data that justifies such a revision and provides an acceptable level of safety. We have not changed this AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Beechcraft Service Bulletin 78-4133, dated May 2015. The service information describes procedures for installing kits having part numbers 140-9005 and 140-9006, which include relays, associated wiring, and a thrust reverser fail annunciator. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 38 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation	340 work-hours × \$85 per hour = \$28,900	\$100,000	\$128,900	\$4,898,200

Authority for This Rulemaking

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

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a

substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016-13-13 Beechcraft Corporation (Type Certificate Previously Held by Hawker Beechcraft Corporation; Raytheon Aircraft Company): Amendment 39-18577; Docket No. FAA-2016-0460; Directorate Identifier 2015-NM-078-AD.

(a) Effective Date

This AD is effective August 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Beechcraft Corporation (type certificate previously held by Hawker Beechcraft Corporation; Raytheon Aircraft Company) airplanes, certificated in any category, as identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model BAe.125 series 1000A and 1000B airplanes, serial numbers 258151, 258159, and 259004 through 259042 inclusive.

(2) Model Hawker 1000 airplanes, serial numbers 259003 and 259043 through 259052 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by reports of inadvertent stowage of the thrust reversers, which can result in high forward engine thrust even though the throttle is commanding reverse thrust. We are issuing this AD to prevent inadvertent stowage of the thrust reversers, which could cause a runway overrun during a rejected takeoff or landing, and consequent structural failure and possible injury to occupants.

(f) Compliance

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

(g) Installation

Within 600 flight hours or 12 months after the effective date of this AD, whichever occurs first: Install kits having part numbers 140-9005 and 140-9006, in accordance with the Accomplishment Instructions of Beechcraft Service Bulletin 78-4133, dated May 2015, except as specified in paragraph (h) of this AD.

(h) Exception to Service Information

A note in the Accomplishment Instructions of Beechcraft Service Bulletin 78-4133, dated May 2015, instructs operators to contact Beechcraft Corporation if any difficulty is encountered in accomplishing the service bulletin. However, any deviation from the actions required by paragraph (g) of this AD must be approved as an alternative method of compliance (AMOC) under the provisions of paragraph (i)(1) of this AD.

(i) Alternative Methods of Compliance

(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 paragraph (j) 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.

(j) Related Information

For more information about this AD, contact Jeffrey Englert, Aerospace Engineer, Systems and Propulsion Branch, ACE-116W, FAA, Wichita ACO, 1801 Airport Road, Room 100, Dwight D. Eisenhower National Airport, Wichita, KS 67209; phone: 316-946-4167; fax: 316-946-4107; email: jeffrey.englert@faa.gov.

(k) Material Incorporated by Reference

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

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

(i) Beechcraft Service Bulletin 78-4133, dated May 2015.

(ii) Reserved.

(3) For Beechcraft service information identified in this AD, contact Beechcraft Corporation, TMDC, P.O. Box 85, Wichita, KS 67201-0085; telephone: 316-676-8238; fax: 316-671-2540; email: tmdc@beechcraft.com; Internet: <http://pubs.beechcraft.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate,

1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

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

Issued in Renton, Washington, June 22, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-15622 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-2964; Directorate Identifier 2014-NM-206-AD; Amendment 39-18584; AD 2016-14-03]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A319, A320, and A321 series airplanes. This AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. This AD requires reinforcing the forward pressure bulkhead at a certain stringer on both the left-hand and right-hand sides, and doing related investigative and corrective actions if necessary. We are issuing this AD to prevent fatigue cracking of the forward pressure bulkhead, which could result in reduced structural integrity of the airplane.

DATES: This AD becomes effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 12, 2016.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—ELAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email

account.airworth-eas@airbus.com; Internet <http://www.airbus.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-2964.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-2964; 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 Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Model A319, A320, and A321 series airplanes. The NPRM published in the **Federal Register** on July 30, 2015 (80 FR 45457) (“the NPRM”). The NPRM was intended to complete certain mandated programs intended to support the airplane reaching its LOV of the engineering data that support the established structural maintenance program. The NPRM proposed to require reinforcing the forward pressure bulkhead at a certain stringer on both the left-hand and right-hand sides, and doing related investigative and corrective actions if necessary. We are issuing this AD to prevent fatigue cracking of the forward pressure bulkhead, which could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European

Union, has issued EASA Airworthiness Directive 2014-0209, dated September 19, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition on all Model A319, A320, and Model A321 series airplanes. The MCAI states:

During the A320 fatigue test campaign for Extended Service Goal (ESG), it was determined that fatigue damage could develop on the forward pressure bulkhead at Frame (FR) 35 on left hand (LH) side and right hand (RH) side.

This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.

To address this potential unsafe condition, a reinforcement modification was developed, which has been published through Airbus Service Bulletin (SB) A320-53-1268 for in-service application to allow aeroplanes to operate up to the new ESG limit.

For the reasons described above, this [EASA] AD requires reinforcement of the centre fuselage forward pressure bulkhead at FR35.

The forward pressure bulkhead reinforcement includes related investigative actions of measuring the diameters of certain fastener holes, and if they are not oversized, doing a rotating probe inspection for cracking of the fastener holes.

Required corrective actions include cold expanding crack-free holes or repairing oversize or cracked holes by using a method approved by the FAA, EASA, or Airbus’s EASA Design Organization Approval (DOA).

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-2964-0002.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request To Reference Revised Service Information

American Airlines requested that we reference Revision 03 of Airbus Service Bulletin A320-53-1268, dated May 7, 2015, as the appropriate source of service information.

We agree with American Airlines’ request. No additional work is specified by this revision for airplanes modified by any previous issue. We have revised paragraphs (g) and (h) of this AD to refer to Airbus Service Bulletin A320-53-1268, Revision 03, dated May 7, 2015; and revised paragraph (i) of this AD to also give credit for previous actions accomplished in accordance with

Airbus Service Bulletin A320-53-1268, Revision 02, dated July 15, 2014.

Request for Applicability Clarification

United Airlines (UAL) stated that the effectivity of Airbus Service Bulletin A320-53-1268, Revision 02, dated July 15, 2014, does not match the NPRM applicability. UAL also stated that the NPRM applicability does not mention pre-modification 153832 airplanes, and that Airbus Service Bulletin A320-53-1268, Revision 02, dated July 15, 2014, is classified as Airbus Modification 153832.

UAL stated that several alternative methods of compliance (AMOCs) may be needed because Airbus will add to the effectivity of Airbus Service Bulletin A320-53-1268, Revision 02, dated July 15, 2014, after operators purchase an extended design service goal from Airbus.

We agree to clarify the applicability. The requirements of this AD apply to all airplanes identified in the applicability of the AD. If there is any conflict between the AD applicability and the service information effectivity, then the AD takes precedence. The applicability of this AD also matches the applicability of the corresponding MCAI AD.

If operators are planning to operate the airplane beyond the LOV of engineering data approved for the original type design, the actions specified in this AD must be done in order to address the identified unsafe condition. We acknowledge that AMOCs may be needed to allow the use of future revisions of the service information. Therefore, we encourage operators to coordinate with Airbus for effective planning and compliance with the AD requirements if they intend to operate their fleet beyond its LOV. We have not changed this final rule in this regard.

Request for Terminating Action Clarification

UAL questioned why there is no terminating action in the proposed AD. UAL stated that the reinforcement specified in this proposed AD is intended to prevent fatigue cracking of the forward pressure bulkhead but there is no reference to related inspection tasks or termination of existing Airworthiness Limitation Items (ALIs). UAL noted that, for example, ALI 533186 is applicable for pre-Mod 153832 (Airbus Service Bulletin A320-53-1268) airplanes. UAL stated this will cause confusion as to whether or not ALI inspections are required if there is no terminating action paragraph.

In regard to UAL’s question on terminating action, ALI inspections

must be accomplished on an airplane to be in compliance with the approved type design independent of the forward pressure bulkhead reinforcement required by this AD. Accomplishing the reinforcement does not preclude the need for ALI inspections.

However, when the effectivity of an ALI inspection identifies pre-modification airplanes, then it is not applicable to airplanes in a post-modification configuration. Thus, ALI inspections that are identified as pre-Mod 153832 (Airbus Service Bulletin A320-53-1268) do not affect airplanes on which the reinforcement specified in Airbus Service Bulletin A320-53-1268 has been done. We have not changed this AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

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

Related Service Information Under 14 CFR Part 51

Airbus has issued Service Bulletin A320-53-1268, Revision 03, dated May 7, 2015. The service information describes procedures for reinforcing the forward pressure bulkhead at frame 35, stringer 30, on both the left-hand and right-hand sides; and for doing repairs. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this AD.

Costs of Compliance

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

We also estimate that it will take about 21 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$85,680, or \$1,785 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 the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016-14-03 Airbus: Amendment 39-18584. Docket No. FAA-2015-2964; Directorate Identifier 2014-NM-206-AD.

(a) Effective Date

This AD becomes effective August 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, all manufacturer serial numbers.

- (1) Airbus Model A319-111, -112, -113, -114, -115, -131, -132, and -133 airplanes.
- (2) Airbus Model A320-211, -212, -214, -231, -232, and -233 airplanes.
- (3) Airbus Model A321-111, -112, -131, -211, -212, -213, -231, and -232 airplanes.

(d) Subject

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

(e) Reason

This AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. We are issuing this AD to prevent fatigue cracking of the forward pressure bulkhead, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Reinforcement, Related Investigative Actions, and Corrective Actions

Before the accumulation of 48,000 total flight cycles or 96,000 total flight hours, whichever occurs first: Reinforce the forward pressure bulkhead at frame 35, stringer 30, on both the left-hand and right-hand sides; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1268, Revision 03, dated May 7, 2015, except as provided by paragraph (h) of this AD. Do all applicable related investigative and corrective actions before further flight.

(h) Exception to Service Information Specifications

Although Airbus Service Bulletin A320-53-1268, Revision 03, dated May 7, 2015, specifies to contact Airbus for repair

instructions, and specifies that action as "RC" (Required for Compliance), this AD requires repair before further flight using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using any of the Airbus service information specified in paragraphs (i)(1) through (i)(3) of this AD. This service information is not incorporated by reference in this AD.

(1) Airbus Service Bulletin A320-53-1268, dated January 8, 2013, which is not incorporated by reference in this AD.

(2) Airbus Service Bulletin A320-53-1268, Revision 01, dated July 23, 2013, which is not incorporated by reference in this AD.

(3) Airbus Service Bulletin A320-53-1268, Revision 02, dated July 15, 2014, which is not incorporated by reference in this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: Except as required by paragraph (h) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided

the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2014-0209, dated September 19, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-2964.

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

(l) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320-53-1268, Revision 03, dated May 7, 2015.

(ii) Reserved.

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

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

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

Issued in Renton, Washington, on June 23, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-15909 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-5808; Directorate Identifier 2015-NM-111-AD; Amendment 39-18585; AD 2016-14-04]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787-8 airplanes. This AD was prompted by reports of water leakage from the potable water system due to improperly installed waterline couplings, and water leaking into the electronics equipment (EE) bays from above the floor in the main cabin, resulting in water on the equipment in the EE bays. This AD requires replacing the potable waterline couplings above the forward and aft EE bays with new, improved couplings. This AD also requires sealing the main cabin floor areas above the aft EE bay, installing drip shields and foam blocks, and rerouting the wire bundles near the drip shields above the equipment in the aft EE bay. We are issuing this AD to prevent a water leak from an improperly installed potable water system coupling, or main cabin water source, which could cause the equipment in the EE bays to become wet, resulting in an electrical short and potential loss of system functions essential for safe flight.

DATES: This AD is effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 12, 2016.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5808.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-5808; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Susan L. Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6457; fax: 425-917-6590; email: susan.l.monroe@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 787-8 airplanes. The NPRM published in the **Federal Register** on November 19, 2015 (80 FR 72393), (“the NPRM”). The NPRM was prompted by reports of water leakage from the potable water system due to improperly installed waterline couplings, and water leaking into the EE bays from above the floor in the main cabin, resulting in water on the equipment in the EE bays. The NPRM proposed to require replacing the potable waterline couplings above the forward and aft EE bays with new, improved couplings. The NPRM also proposed to require sealing the main cabin floor areas above the aft EE bay, installing drip shields and foam blocks, and rerouting the wire bundles near the drip shields above the equipment in the aft EE bay. We are issuing this AD to prevent a water leak from an improperly installed potable water system coupling, or main cabin water source, which could cause the equipment in the EE bays to become wet, resulting in an electrical short and potential loss of system functions essential for safe flight.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments

received on the NPRM and the FAA’s response to each comment.

Support for the NPRM

The Airline Pilots Association International stated that it concurs with the contents of the NPRM.

United Airlines (UAL) stated that it supports the compliance time of 60 months to accomplish the actions proposed by the NPRM.

Requests To Revise Compliance Times

Mr. Geoffrey Barrance requested that we revise the compliance times specified in the NPRM to before further flight. Mr. Barrance stated that, in view of the effect of common mode faults to nullify the safety design of critical avionic systems housed in the avionics bay, this matter needs to be treated with the greatest urgency and that the correction of the problem should be required with far greater urgency than the timescales proposed in the NPRM. Mr. Barrance stated an example of the automatic landing function of the automatic flight control system that does not and cannot take into account common mode faults such as water ingress into multiple line replaceable units (LRUs), which are present to provide functional redundancy and fault tolerance. Mr. Barrance stated that no probability can be assessed for unwanted behavior resulting from water ingress into multiple redundant LRUs.

UAL requested that we extend the proposed compliance time from 24 months to 30 months for accomplishing the actions specified in Boeing Alert Service Bulletin B787-81205-SB380009-00, Issue 001, dated March 26, 2015. UAL stated that if maintenance requires an unforeseen disassembly of the airplane for access or to correct a test failure, a 30-month period is required to schedule the clamp inspection and replacement in a heavy check.

We do not agree to revise the compliance times required by this AD. In developing appropriate compliance times for this AD, we considered not only the safety implications, including evaluation of the hazards associated with water ingress into multiple redundant LRUs, but the manufacturer’s recommendations, the availability of required parts, and the practical aspect of accomplishing the required actions within an interval of time that corresponds to typical scheduled maintenance for affected operators. After considering all the available information, we have determined that the compliance times, as proposed, represent appropriate intervals of time in which the required actions can be

performed in a timely manner within the affected fleet, while still maintaining an adequate level of safety. Operators are always permitted to accomplish the requirements of an AD at a time earlier than the specified compliance time. Operators wanting additional time to comply with the requirements of an AD may request adjustments to the compliance time under the provisions of paragraph (k) of this AD. We will consider requests for an adjustment of the compliance time if data are submitted to substantiate that such an adjustment would provide an acceptable level of safety. We have not changed this AD in this regard.

Request To Use Alternative Moisture Barrier Tape

UAL requested that we approve the use of flame retardant (FR) moisture barrier tapes Nitto 11611-MB polyurethane tape or BMS8-346 Type II, Class 4 tape (3M 8657) as alternates to the BMS8-346 Type 1, Class 1 moisture barrier tape (Patco D9100) specified in Boeing Alert Service Bulletin B787 81205 SB530029-00, Issue 001, dated March 26, 2015. UAL stated that during a supplemental type certificate test for a Model 737 airplane, burn testing was performed on the Patco D9100 tape by Zodiac Northwest Aerospace Technologies, and it failed the 12-second vertical test. UAL stated that, therefore, the Patco D9100 tape could not be certified to meet the 14 CFR 25.853 flammability requirements.

We do not agree with UAL’s request. We have contacted Boeing who provided evidence that BMS8-346 Type 1, Class 1 moisture barrier tape (Patco D9100) material passed the 12-second vertical burn test. UAL did not submit specific evidence to substantiate that Nitto 11611-MB polyurethane tape or BMS8-346 Type II, Class 4 tape (3M 8657) is compliant and that BMS8-346 Type 1, Class 1 moisture barrier tape (Patco D9100) material is non-compliant. Under the provisions of paragraph (k) of this AD, we will consider requests for approval of an alternative method of compliance (AMOC) if sufficient data are submitted to substantiate that alternative tapes are compliant. We have not changed this AD in this regard.

Requests To Use Revised Service Information

Boeing and UAL requested that we revise the NPRM to refer to Boeing Alert Service Bulletin B787-81205-SB380009-00, Issue 002, dated December 9, 2015; Boeing Alert Service Bulletin B787-81205-SB530029-00, Issue 002, dated January 26, 2016; and

Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016.

We agree with the commenters' requests to use the most current service information. We have revised this AD as described below.

- Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015, adds notes, revises the waiting time in the leak test, and corrects typographical errors. We have revised paragraphs (c) and (g) of this AD to reference this service information.

- Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 002, dated January 26, 2016, extends the 24-month compliance time for sealing floor panels and seat tracks to 60 months; clarifies installation of components, revises tape requirements; revises sealant callouts; and corrects kit contents. We have revised paragraphs (c) and (h)(1) of this AD to reference this service information.

- Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016, extends the 24-month compliance time for installing drip shields and foam blocks to 60 months. This service information also revises the airplane groups into configurations to account for airplanes on which the drip shield between the floor beams at station (STA) 1233 and STA 1257 was not installed due to interference with wire bundles over the P100 panel. This service information also clarifies certain instructions, revises certain task hour estimates, and removes one airplane from the effectivity. This service information erroneously specifies "Group 6, Configuration 1" airplanes where it should specify "Group 7, Configuration 1" airplanes for Task 29 in multiple places. We have revised paragraphs (c) and (h)(2) of this AD to reference Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016. We have added new paragraph (i) to specify an exception for Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016.

We have also added new paragraph (j) of this AD to provide credit for actions done prior to the effective date of this AD using Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 001, dated March 26, 2015; Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 001, dated March 26, 2015; and Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 001, dated March 26, 2015; as applicable. We have redesignated subsequent paragraphs accordingly.

Request To Review Airplane Certification Procedures

Mr. Geoffrey Barrance requested that we conduct an internal review and a review with the manufacturer as to why the airplane equipment bay design was not reviewed and required to protect the avionics LRUs from water ingress at the time of certification. Mr. Barrance stated that this is not a new issue and must be a standard check item on design reviews and certification signoff. Mr. Barrance stated that this is a design and certification omission, not primarily a problem with the quality of work by the people doing the installation of the potable waterlines.

We partially agree with Mr. Barrance's request. We agree that this is a design issue that increased the likelihood of mis-installation, and not primarily a problem with the quality of work by personnel installing the potable waterlines. We asked the manufacturer to conduct a root-cause analysis to determine how it permitted design issues that created the unsafe condition. We are working with the manufacturer to determine if their company processes must be updated to better identify these hazards. The actions required by this AD address only the results of that analysis that directly relate to the identified design issues, and mandate changes to correct those issues.

We disagree that the EE bay design was not reviewed and required to protect the avionics LRUs from water ingress at the time of certification. A hazard analysis was completed for these systems, as part of the certification process, which required known hazards to be addressed. This event shows that despite the hazard analysis during the design and certification phase, further improvement is needed to remove the unsafe condition. Airplane manufacturers are responsible for the safety of their products and services, and must be in compliance with applicable safety requirements. As a component of our safety management system, we verify that the safety systems of the design approval holder meet applicable requirements. Working with approval holders during the design development process, we strive to avoid unsafe conditions in the first place. The design for this system was evaluated during the certification process and found at the time to be compliant. We also verify that the approval holders' processes, products, and services continue to maintain safety of their product during the operational phases of their service life. In this regard, we have evaluated the issues related to this system and acted on them.

We are continuously evaluating our certification system and procedures and improving them when problems are found. In addition, if the FAA is made aware of issues occurring on a certificated product, we conduct an investigation, evaluate the manufacturer's root-cause analysis, and make a determination whether or not an unsafe condition exists. We then take appropriate action to mitigate the unsafe condition. We have not changed this AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

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

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015.
- Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 002, dated January 26, 2016.
- Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016.

This service information describes procedures for replacing the potable waterline couplings above the forward and aft EE bays with new, improved couplings; sealing the floors, seat tracks, and lavatories above the aft EE bay; installing drip shields and foam blocks; and rerouting the wire bundles adjacent to the drip shields above the aft EE bay. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

We estimate that this AD affects 17 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace waterline couplings	Up to 24 work-hours × \$85 per hour = up to \$2,040	\$3,195	Up to \$5,235	Up to \$88,995
Seal floors and seat tracks	Up to 108 work-hours × \$85 per hour = up to \$9,180	137	Up to \$9,317	Up to \$158,389
Install drip shields and reroute wiring	Up to 42 work-hours × \$85 per hour = up to \$3,570	34,594	Up to \$38,164	Up to \$648,788

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

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

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

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

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–14–04 The Boeing Company:
Amendment 39–18585; Docket No. FAA–2015–5808; Directorate Identifier 2015–NM–111–AD.

(a) Effective Date

This AD is effective August 12, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 series airplanes, certificated in any category, as identified in the service information specified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.

(1) Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015.

(2) Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 002, dated January 26, 2016.

(3) Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 38, Water/Waste; and Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of water leakage from the potable water system due to

improperly installed waterline couplings, and water leaking into the electronics equipment (EE) bays from above the floor in the main cabin, resulting in water on the equipment in the EE bays. We are issuing this AD to prevent a water leak from an improperly installed potable water system coupling, or main cabin water source, which could cause the equipment in the EE bays to become wet, resulting in an electrical short and potential loss of system functions essential for safe flight.

(f) Compliance

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

(g) Replace Potable Waterline Couplings

Within 24 months after the effective date of this AD: Replace the existing potable waterline couplings located above the forward and aft EE bays with new, improved couplings, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015. Before further flight after doing the replacement, do a potable water system leak test and repair any leaks found before further flight, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015.

(h) Seal Floor Panels and Seat Tracks/Install Drip Shields and Reroute Wiring

Within 60 months after the effective date of this AD: Do the actions specified in paragraphs (h)(1) and (h)(2) of this AD.

(1) Apply sealant to the main cabin floor areas located above the aft EE bay, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 002, dated January 26, 2016.

(2) Install drip shields and foam blocks, and reroute the wire bundles above the equipment in the aft EE bay, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016, except as specified in paragraph (i) of this AD.

(i) Exception to Certain Service Information

Where Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016, specifies “Group 6, Configuration 1” airplanes in reference to Task 29, the correct airplane group identification is “Group 7, Configuration 1” airplanes.

(j) Credit for Previous Actions

This paragraph provides credit for the corresponding actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using the applicable service information specified in paragraphs (j)(1), (j)(2), and (j)(3) of this AD. This service information is not incorporated by reference in this AD.

(1) Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 001, dated March 26, 2015.

(2) Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 001, dated March 26, 2015.

(3) Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 001, dated March 26, 2015.

(k) Alternative Methods of Compliance (AMOCs)

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

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

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

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Susan L. Monroe, Aerospace Engineer, Cabin Safety and Environmental

Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6457; fax: 425–917–6590; email: susan.l.monroe@faa.gov.

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

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin B787–81205–SB380009–00, Issue 002, dated December 9, 2015.

(ii) Boeing Alert Service Bulletin B787–81205–SB530029–00, Issue 002, dated January 26, 2016.

(iii) Boeing Alert Service Bulletin B787–81205–SB530031–00, Issue 002, dated March 16, 2016.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet <https://www.myboeingfleet.com>.

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

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

Issued in Renton, Washington, on June 23, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15911 Filed 7–7–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2015–6541; Directorate Identifier 2015–NM–135–AD; Amendment 39–18581; AD 2016–13–16]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. This AD was prompted by reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. This AD requires an inspection or records check to determine if affected horizontal stabilizers are installed, related investigative actions, and for affected horizontal stabilizers, repetitive inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action if necessary. We are issuing this AD to detect and correct cracking of the rear spar upper chord, which can result in the failure of the upper chord and consequent departure of the horizontal stabilizer from the airplane, which can lead to loss of control of the airplane.

DATES: This AD is effective August 12, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 12, 2016.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–6541.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–6541; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket

Operations, M-30, West Building
Ground Floor, Room W12-140, 1200
New Jersey Avenue SE., Washington,
DC 20590.

FOR FURTHER INFORMATION CONTACT:

Gaetano Settineri, Aerospace Engineer,
Airframe Branch, ANM-120S, FAA,
Seattle Aircraft Certification Office
(ACO), 1601 Lind Avenue SW., Renton,
WA 98057-3356; phone: 425-917-6577;
fax: 425-917-6590; email:
gaetano.settineri@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes. The NPRM published in the *Federal Register* on November 30, 2015 (80 FR 74726) (“the NPRM”). The NPRM was prompted by reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. The NPRM proposed to require an inspection or records check to determine if affected horizontal stabilizers are installed, related investigative actions, and for affected horizontal stabilizers, repetitive inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action if necessary. We are issuing this AD to detect and correct cracking of the rear spar upper chord, which can result in the failure of the upper chord and consequent departure of the horizontal stabilizer from the airplane, which can lead to loss of control of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Support for the NPRM

Air Line Pilots Association International (ALPA) stated that it supports the NPRM. Boeing stated that it concurs with the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that installation of winglets per Supplemental Type Certificate (STC) ST00830SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184de9a71ec3fa5586257eae00707da6/$FILE/ST00830SE.pdf)

[184de9a71ec3fa5586257eae00707da6/\\$FILE/ST00830SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184de9a71ec3fa5586257eae00707da6/$FILE/ST00830SE.pdf)) does not affect the ability to accomplish the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) and added new paragraph (c)(2) to this AD to state that installation of STC ST00830SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184de9a71ec3fa5586257eae00707da6/$FILE/ST00830SE.pdf)

Request To Revise the Proposed Applicability

Airlines for America (A4A) requested that we revise the applicability of the proposed AD to state “This AD applies to all horizontal stabilizers with serial numbers identified in Boeing SB 737-55A1097.” A4A explained that the proposed AD is applicable to all Boeing Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes; however, Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, provides a list of affected horizontal stabilizers by serial number. A4A expressed that the physical plate inspections required by paragraph (g)(1)(ii) of the proposed AD are excessive and unneeded, as operators normally track serialized components without the need to physically inspect the airframe. A4A further reasoned that when paragraph (c) of the proposed AD is written against all Model 737 Next Generation airframes, the complexity of compliance reporting becomes more burdensome. The net result, stated A4A, is indefinite record keeping of AD compliance for airplanes that are not equipped with horizontal stabilizers affected by the manufacturing oversight.

We do not agree to revise the applicability of this AD as requested by the commenter. Paragraph (g)(1) of this AD gives operators the option of performing either a records check or an inspection. If the operator’s records are sufficient to determine the serial number of the horizontal stabilizers on the affected airplane, then a physical inspection is not required. Furthermore, the affected horizontal stabilizers are rotatable parts, so it is possible that an affected horizontal stabilizer could be installed on numerous airplanes during its service life, even on a new

production airplane once it enters service. As specified in paragraph 2.B.(2) of Chapter 6 of the AD Manual, FAA-IR-M-8040.1C ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/66ddd8e1d2e95db3862577270062aabd/\\$FILE/FAA-IR-M-8040_1C.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/66ddd8e1d2e95db3862577270062aabd/$FILE/FAA-IR-M-8040_1C.pdf)), when the unsafe condition results from the installation of the appliance or part on an aircraft, the AD action is issued against the aircraft, not the appliance or part. Therefore, we have determined that it is appropriate for this AD to apply to all airplanes of the specified model types. We have made no changes to the applicability of this AD.

Request To Allow Removal and Replacement of Affected Horizontal Stabilizers

A4A requested that we revise paragraph (h)(2) of the proposed AD to allow removal of an affected horizontal stabilizer, and replacement with an unaffected or an affected horizontal stabilizer that is within the parameters of paragraph 1.E. “Compliance,” of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015. A4A explained that paragraph (g)(2) of the proposed AD requires that the inspection specified in Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, be accomplished on any horizontal stabilizer found to be within the effectivity of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, and the compliance times found in paragraph 1.E., “Compliance.” A4A expressed that if cracking is found, operators must repair in accordance with paragraph (h)(2) of the proposed AD; paragraph (h)(2) of the proposed AD requires repair in accordance with paragraph (j) of the proposed AD before further flight.

We agree. We have determined that removing a damaged horizontal stabilizer and replacing it with a serviceable horizontal stabilizer, as provided in paragraph (i) of this AD, addresses the identified unsafe condition. We have revised paragraph (h)(2) of this AD accordingly.

Request for Review of Other Inspection Methods

A4A requested that the FAA and Boeing review other non-destructive test (NDT) inspection options such as an ultrasound process to satisfy the proposed inspection requirements. A4A pointed out that paragraph (g)(2) of the proposed AD specifies a high frequency eddy current (HFEC) method for inspection of the rear spar upper chord. A4A explained that the FAA should be aware that other methods, specifically

ultrasound inspection, may be better NDT diagnostic techniques, and that an ultrasound inspection, compared to the proposed HFEC process, may detect early crack development from the fitting holes versus cracking that has propagated up to and near the surface of the rear spar upper chord.

We partially agree. We agree with the commenter that other inspection methods may be better NDT diagnostic techniques and note that alternative methods of compliance (AMOCs) have been granted to ADs when updated service information containing improved procedures to address an unsafe condition becomes available.

We disagree to include other inspection options in this final rule, because the inspection technique required in this AD adequately addresses the unsafe condition and is accompanied by service information, which includes detectable crack lengths and inspection intervals. If additional service information that provides alternative NDT inspection methods becomes available, under the provisions of paragraph (j) of this AD, we will consider requests for approval of an AMOC if sufficient data are submitted to substantiate that the inspection method would provide an acceptable level of safety. We have made no changes to this AD in this regard.

Requests for Clarification of Parts Installation Requirements

A4A requested that we reword paragraphs (g) and (i) of the proposed AD to allow operators to maintain or install any affected horizontal stabilizer on any airplane, provided that the horizontal stabilizer is, or will be, inspected as specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015. A4A explained that paragraphs (i)(1) and (i)(2) of the proposed AD preclude installation of an affected horizontal stabilizer without accomplishing the required inspection. A4A explained further that other maintenance activity could cause a horizontal stabilizer to be removed and reinstalled prior to reaching the compliance times specified in Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015. With the potential interpretation of paragraph (g)(2) of the proposed AD being to inspect immediately, the initial inspection would be significantly accelerated, and the inspection schedule would be altered for the remaining life of the component.

All Nippon Airways (ANA) requested that we clarify the parts installation restrictions specified in paragraph (i) of

the proposed AD to reduce the burden for operators. ANA explained that parts installation is restricted based on its serial number, and that paragraph (i)(2)(i) of the proposed AD requires initial inspection specified in paragraph (g)(2) of the proposed AD before further flight. ANA expressed that this requirement is applicable if the flight cycles and/or the date of issuance the original certificate of airworthiness, or the original export certificate of airworthiness for the horizontal stabilizer are unknown or have already exceeded the proposed compliance time specified in paragraph (g)(2) of the proposed AD. ANA reasoned that, if the flight cycles and the date of issuance of the original certificate of airworthiness or the original export certificate of airworthiness of the horizontal stabilizer are known, and the flight cycles and years on the horizontal stabilizer are less than the compliance times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, operators may conduct the inspection specified in paragraph (g)(2) of this AD at the time specified in paragraph (g)(2) of this AD.

We agree to clarify. An affected horizontal stabilizer that has not reached the inspection threshold or the next repeat interval is still in compliance with this AD at the time it is installed on the airplane. We have revised paragraph (i)(2)(i) of this AD to read "Initial and repetitive HFEC inspections specified in paragraph (g)(2) of this AD are completed within the compliance times specified in paragraph (g)(2) of this AD." We also agree to clarify that the 10-year compliance time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, is measured using the airplane the affected horizontal stabilizer was delivered on.

Request for Specific Repair Instructions and Terminating Action

A4A requested that repair instructions be provided either in a revision to the service information, or via the structural repair manual (SRM). A4A also requested that the proposed AD be revised to include a preventive, terminating action including the option to remove and replace the subject bushings in the upper chord fitting during a heavy check schedule. A4A expressed that the NPRM and Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015, provide neither specific repair methods nor a means to terminate the inspections. A4A reasoned that the NPRM requires corrective action for any crack that is

discovered, and that such action is to be performed in accordance with paragraph (j) of the proposed AD, which is the AMOC section. A4A said that, although no known inspections have revealed cracking, we (the FAA) must believe that findings will occur, and that operators would benefit by having guidance from Boeing without the need for an AMOC request. Similarly, A4A expressed, without a repair plan, there should also be a means of terminating the inspections entirely. A4A pointed to a recent experience concerning seat track cracking that exposed the difficulties of embarking upon a required inspection plan without a defined recovery path. A4A referred to AD 2013-23-04, Amendment 39-17659 (78 FR 68693, November 15, 2013) ("AD 2013-23-04"), and stated that AD also directed operators to the AMOC process.

We do not agree. An AD is issued to address an identified unsafe condition, as required by 14 CFR part 39. The determination of the unsafe condition, mitigating action, and compliance times in this AD has all been coordinated with Boeing. This AD is being issued to address the lack of corrosion protection on a critical structural element. As a result, dissimilar metal corrosion may cause cracking of the horizontal stabilizer rear spar upper chord. With no service history of cracking yet reported, it is expected that any cracking will be limited and not result in a significant disruption to affected operators. The inspections required by this AD provide an acceptable level of safety for the affected airplanes. We have reviewed with Boeing the implementation issues associated with AD 2013-23-04 and expect that Boeing will provide us with approvable data for repair and terminating actions in a timely manner to address any cracking found.

For these reasons, we do not consider that delaying this action until after the possible release of revised service information is warranted, since sufficient technology and service information currently exist to accomplish the required actions within the compliance time. However, under the provisions of paragraph (j) of this AD, we will consider requests for approval of AMOCs for revised service information, repairs, or terminating actions if sufficient data are submitted to substantiate they would provide an acceptable level of safety. For these reasons, we have made no changes to this AD in this regard.

Request To Clarify Specific Parts of the Service Information

ANA stated that paragraph (g)(1)(i) of the proposed AD should refer to Part 1, and paragraph (g)(1)(ii) of the proposed AD should refer to Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015. ANA did not provide a reason for this request.

From these statements, we infer that ANA is requesting that we revise paragraphs (g)(1)(i) and (g)(1)(ii) of the proposed AD. We agree that the changes requested by ANA provide additional clarity. We have added ‘Part 1 of’ to paragraph (g)(1)(i) and ‘Part 2 of’ to paragraph (g)(1)(ii) of this AD.

Request for Assurance of Parts Availability

A4A also requested that, prior to release of the AD, we assure that Boeing has sections of the rear spar available for the horizontal stabilizer including a typical splice repair plan for each affected 737-NG fleet. A4A also requested that Boeing also provide or have available, horizontal stabilizers that are service ready prior to the release of the AD.

We do not agree. We do not consider that delaying this action until Boeing has assured that replacement parts will be available is warranted. This AD is issued to address an identified unsafe condition, as required by 14 CFR part 39. The determination of the unsafe

condition, mitigating action, and compliance times in this AD has all been coordinated with Boeing. This AD is being issued to address the lack of corrosion protection on a critical structural element. As a result, dissimilar metal corrosion may cause cracking of the horizontal stabilizer rear spar upper chord. With no service history of cracking yet reported, it is expected that any cracking will be limited and not be a significant disruption to affected operators. We understand that Boeing will make horizontal stabilizer parts and assemblies available as necessary for operators to address possible on-condition actions. However, since it is unknown how many repairs or replacements may be necessary and what parts would be necessary for each repair, we cannot estimate the type and number of parts needed. If parts availability becomes an issue, under the provisions of paragraph (j) of this AD, we may approve requests for adjustments to the compliance time for doing a repair or replacement if data are submitted to substantiate that such an adjustment would provide an acceptable level of safety. We have made no changes to this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD

with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

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

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015. The service information describes procedures for an inspection or records check to determine if affected horizontal stabilizers are installed, related investigative actions, HFEC inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

We estimate that this AD affects 1,397 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection or records check	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$118,745

We estimate the following costs to do any necessary inspections that would be required based on the results of the

inspection or records check. We have no way of determining the number of

aircraft that might need these inspections:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspections	4 work-hours × \$85 per hour = \$340	\$0	\$340

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.

We have received no definitive data that would enable us to provide cost

estimates for the on-condition repairs specified in this AD.

Authority for This Rulemaking

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

detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ‘‘General requirements.’’ Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–13–16 The Boeing Company:

Amendment 39–18581; Docket No. FAA–2015–6541; Directorate Identifier 2015–NM–135–AD.

(a) Effective Date

This AD is effective August 12, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and 900ER series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE ([http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184de9a71ec3fa5586257eae00707da6/\\$FILE/ST00830SE.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184de9a71ec3fa5586257eae00707da6/$FILE/ST00830SE.pdf)) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. We are issuing this AD to detect and correct cracking of the rear spar upper chord, which can result in the failure of the upper chord and consequent departure of the horizontal stabilizer from the airplane, which can lead to loss of control of the airplane.

(f) Compliance

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

(g) Serial Number Check or Inspection To Determine if Certain Horizontal Stabilizers Are Installed, Related Investigative Actions, Repetitive Inspections for Cracks, and Corrective Action

(1) Except as specified in paragraph (h)(1) of this AD, within the compliance time identified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, do the actions specified in paragraph (g)(1)(i) or (g)(1)(ii) of this AD.

(i) Do a records check to determine if an affected horizontal stabilizer is installed and if any horizontal stabilizer has been exchanged, and do all applicable related investigative actions, in accordance with Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015. Affected horizontal stabilizers are identified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015.

(ii) Do an inspection of the horizontal stabilizer identification plate to determine if any affected horizontal stabilizer is installed, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015. Affected horizontal stabilizers are identified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015.

(2) If, during any action required by paragraph (g)(1)(i) or (g)(1)(ii) of this AD, any affected horizontal stabilizer is found: Except as specified in paragraph (h)(1) of this AD, within the compliance time identified in

paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, do a high frequency eddy current (HFEC) inspection for any crack of the horizontal stabilizer rear spar upper chord and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, except as required by paragraph (h)(2) of this AD. Repeat the inspection thereafter at intervals identified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015.

(h) Exceptions to the Service Information Specifications

(1) Where Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, specifies a compliance time “after the original issue date of this service bulletin,” this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, specifies to contact Boeing for appropriate action: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD, or replace with a serviceable horizontal stabilizer as specified in paragraph (i) of this AD.

(i) Parts Installation Restrictions

As of the effective date of this AD, no person may install a horizontal stabilizer on any airplane, except as specified in paragraphs (i)(1) and (i)(2) of this AD.

(1) A horizontal stabilizer may be installed if the part is inspected in accordance with “Part 2: Horizontal Stabilizer Identification Plate Inspection” of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, and no affected serial number is found.

(2) A horizontal stabilizer may be installed if the part is inspected in accordance with “Part 2: Horizontal Stabilizer Identification Plate Inspection” of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015, and an affected serial number is found, provided that the actions specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD are done, as applicable.

(i) Initial and repetitive HFEC inspections specified in paragraph (g)(2) of this AD are completed within the compliance times specified in paragraph (g)(2) of this AD.

(ii) All applicable corrective actions are done before further flight as required by paragraph (h)(2) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k) of this AD. Information may be

emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

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

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

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

For more information about this AD, contact Gaetano Settineri, Aerospace Engineer, Airframe Branch, ANM 120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6577; fax: 425-917-6590; email: gaetano.settineri@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 737-55A1097, dated July 1, 2015.

(ii) Reserved.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://>

www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued in Renton, Washington, on June 23, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-15904 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9774]

RIN 1545-BM04

Method of Accounting for Gains and Losses on Shares in Money Market Funds; Broker Returns With Respect to Sales of Shares in Money Market Funds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide a simplified method of accounting for gains and losses on shares in money market funds (MMFs). The final regulations also provide guidance regarding information reporting requirements for shares in MMFs. The final regulations respond to Securities and Exchange Commission (SEC) rules that change the amount for which certain MMF shares are distributed, redeemed, and repurchased. The final regulations affect MMFs and their shareholders.

DATES: *Effective date:* These regulations are effective on July 8, 2016.

Applicability dates: For the dates of applicability, see §§ 1.446-7(e) and 1.6045-1(c)(3)(vi)(B).

FOR FURTHER INFORMATION CONTACT: Grace Cho at (202) 317-6895 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 (Income Tax Regulations) under sections 446 and 6045 of the Internal Revenue Code (Code). The regulations provide a method of accounting for gain or loss on shares in MMFs and are intended to simplify tax compliance for holders of shares in MMFs affected by SEC regulations that impose liquidity fees or change how certain MMF shares are priced. See Money Market Fund Reform; Amendments to Form PF, Securities Act

Release No. 33-9616, Investment Advisers Act Release No. IA-3879, Investment Company Act Release No. IC-31166, Financial Reporting Codification No. FR-84 (August 14, 2014) (SEC MMF Reform Rules). The regulations also provide guidance regarding information reporting requirements for shares in MMFs.

An MMF is a type of investment company registered under the Investment Company Act of 1940 (1940 Act) and regulated as an MMF under Rule 2a-7 under the 1940 Act (17 CFR 270.2a-7). MMFs have historically sought to keep stable the prices at which their shares are distributed, redeemed, and repurchased. The securities that Rule 2a-7 permits an MMF to hold generally result in no more than minimal fluctuations in the MMF's net asset value per share (NAV).¹

MMFs meeting the requirements of Rule 2a-7 have been permitted to value their assets based on the assets' cost, with certain adjustments (amortized cost method), and to price their shares by rounding the resulting NAV to the nearest 1 percent (penny rounding). These methods have enabled MMFs to maintain constant share prices in almost all circumstances. Because most MMFs target a \$1.00 share price, an MMF that fails to maintain a constant share price is said to "break the buck."

The SEC MMF Reform Rules generally bar the use of the amortized cost method and penny rounding for certain MMFs (floating-NAV MMFs) and require a floating-NAV MMF to value its assets using market factors and to round its price per share to the nearest basis point (the fourth decimal place, in the case of a fund with a \$1.0000 share price). Certain government-security-focused MMFs (government MMFs) and certain MMFs the beneficial owners of which are limited to natural persons (retail MMFs) may continue to use the amortized cost method and penny rounding. (A government MMF or retail MMF that continues to use the amortized cost method and penny rounding is called a stable-NAV MMF.)

The SEC MMF Reform Rules also establish circumstances under which an MMF is permitted or required to impose a liquidity fee or is permitted to impose a redemption gate. When an MMF has a liquidity fee in effect, the liquidity fee reduces the proceeds received by all redeeming shareholders. A redemption gate is the temporary suspension of redemptions of shares in the MMF. Liquidity fees and redemption gates

¹Note that the term "NAV" is used throughout this document to indicate the per-share amount that may be described elsewhere as "NAV per share."

may be imposed by both floating-NAV MMFs and stable-NAV MMFs. An MMF other than a government MMF is required to impose a liquidity fee in certain circumstances, unless the fund's board of directors determines that such a fee is not in the best interests of the fund.

The Treasury Department and the IRS published a notice of proposed rulemaking and notice of public hearing (REG-107012-14) in the **Federal Register** on July 28, 2014 (79 FR 43694). The proposed regulations described a simplified method of accounting for gain or loss on shares in a floating-NAV MMF (the net asset value method, or NAV method). Under the NAV method, a taxpayer's gain or loss on shares in an MMF is based on the change in the aggregate value of the taxpayer's shares during a computation period selected by the taxpayer and on the net amount of the purchases and redemptions during the computation period. The proposed regulations also provided guidance regarding information reporting requirements for shares in MMFs.

A request for a public hearing was received, and the hearing was held on November 19, 2014. The IRS received written comments responding to the proposed regulations regarding the method of accounting for gains and losses on shares in MMFs. The written comments are available for public inspection at <http://www.regulations.gov> or upon request. After considering the comments, the Treasury Department and the IRS adopt the proposed regulations regarding the method of accounting as final regulations with the modifications described in this Treasury decision. No comments were received on the portion of the proposed regulations that would revise § 1.6045-1(c)(3)(vi) to clarify that the exceptions under sections 6045, 6045A, and 6045B continue to apply to all MMFs, including floating-NAV MMFs. The Treasury Department and the IRS adopt the proposed regulations revising § 1.6045-1(c)(3)(vi) as final regulations without substantive change.

Summary of Comments and Explanation of Revisions

1. Application of the NAV Method to Stable-NAV MMFs

Under the proposed regulations, the NAV method would apply only to floating-NAV MMF shares. In the preamble to the proposed regulations, the Treasury Department and the IRS requested comments regarding whether the NAV method should be a permissible method of accounting for stable-NAV MMF shares.

Although stable-NAV MMFs seek to maintain constant share prices, there are circumstances in which shares in a stable-NAV MMF will give rise to gain or loss. On rare occasions, shares in a stable-NAV MMF may be redeemed at a price other than the target price, such as when the MMF breaks the buck. In addition, a stable-NAV MMF may impose liquidity fees, which will generally result in the realization of a loss by a redeeming shareholder. If the acquisition of other shares causes such a redemption to be a wash sale under section 1091, section 1091(d) will generally cause the basis of the acquired shares to exceed the cost of the shares. Because the price of a stable-NAV MMF share rarely changes, any disposition of those acquired, higher-basis shares will likely result in another loss, which also may be deferred by the wash sale rules. Therefore, even if a liquidity fee is in effect for only one redemption by a shareholder and the share price of the MMF remains constant, that fee may cause a difference between the basis and value of the shareholder's MMF shares that persists indefinitely. Determining gain or loss and basis on each transaction in a stable-NAV MMF, taking into account the wash sale rules, would impose significant burdens on shareholders under these circumstances. To eliminate those burdens, a shareholder might need to terminate the shareholder's entire interest in the affected MMF (and not initiate a new position until after the end of the period described in section 1091(a)).

Commenters recommended that the NAV method be applicable not only to shares in floating-NAV MMFs but also to shares in stable-NAV MMFs. The commenters added that many shareholders of stable-NAV MMFs may be retail shareholders (generally, individuals) who are likely to rely upon the cost basis reporting provided by funds or brokers for their other mutual funds. Those individuals are unlikely to have the systems necessary to record gains and losses and to track wash sales and the resulting basis adjustments.

The NAV method would reduce the complexity, and any tax-based motivation to terminate investments in MMFs, that would result from the imposition of a liquidity fee by a stable-NAV MMF. Under the NAV method, any loss that resulted from the imposition of a liquidity fee by an MMF would be determined for a shareholder's entire interest in the MMF (or in an account) for the appropriate taxable year (or computation period) rather than for a single transaction. Therefore, the wash sale rules would not defer the loss. The NAV method also requires fewer and

simpler computations than traditional accounting, even if there are no wash sales. For the years after an MMF breaks the buck or imposes a liquidity fee, the NAV method simplifies recordkeeping, because the gain or loss for each year is based on changes in the NAV during that year. Therefore, the final regulations permit taxpayers to apply the NAV method to shares in stable-NAV MMFs.

2. Consistency Requirement

The proposed regulations would provide that if a taxpayer applies the NAV method to shares in any MMF for a taxable year, the taxpayer must apply the NAV method to its shares in all MMFs for which that method is permissible.

Commenters requested that the final regulations permit taxpayers to apply different methods to shares in different MMFs or to shares in a single MMF held in different accounts. Commenters said that some taxpayers may receive sufficient information about their shares in certain MMFs to compute gain or loss realized on each transaction and that those taxpayers should be permitted to compute gain or loss realized on each transaction for those MMFs.

Commenters also noted that taxpayers may hold shares in a single MMF through different kinds of accounts (for example, an account with a broker and an account with the MMF itself) and may receive different information for the different accounts. The commenters recommended that, because of that possibility, taxpayers should be permitted to use different accounting methods for shares held in different accounts. Commenters also noted that many MMF shareholders will be large institutional investors, which might hold shares in the same MMF through separate accounts controlled by different divisions.

In response to these comments, the final regulations permit MMF shareholders to use different methods of accounting for shares in different MMFs or for shares in a single MMF held in different accounts.

3. Choosing NAV Method Computation Periods for RIC Excise Tax Purposes

Under the NAV method, computation periods are the periods that a taxpayer selects for computing gain and loss for an MMF. The proposed regulations would provide that computation periods may be the taxpayer's taxable year or a shorter period, provided that (i) computation periods are of approximately equal duration, (ii) every day during the taxable year falls within one, and only one, computation period,

and (iii) each computation period contains days from only one taxable year.

Most regulated investment companies (RICs) must pay an excise tax under section 4982 if they do not make the required distribution described in section 4982(b) for a calendar year. The required distribution is generally 98 percent of the RIC's ordinary income for the calendar year, plus 98.2 percent of the RIC's capital gain net income for the one-year period ending on October 31 of the calendar year. A commenter requested clarification that a RIC that holds MMF shares may use the NAV method for excise tax computations. That commenter also requested that the Treasury Department and the IRS confirm that a RIC that uses the NAV method is permitted to use the one-year period from November 1 to October 31 as its computation period for excise tax purposes. The commenter explained that RICs generally account for items that are marked to market using two different one-year periods for income tax and excise tax purposes. The commenter explained that, under section 4982(e)(2)(A), the term "capital gain net income" when used in section 4982 is determined by treating the one-year period ending on October 31 of any calendar year as the company's taxable year.

The Treasury Department and the IRS agree that the NAV method should be applicable for purposes of the computations required by section 4982 and that the taxable year for purposes of those computations should be the relevant period under section 4982(e). The final regulations adopt this change.

The final regulations, however, require a RIC to be consistent in applying the NAV method to MMF shares for income tax and excise tax purposes. For each MMF in each account, the final regulations generally require a RIC to use the NAV method either for both income tax and excise tax computations or for neither computation. The final regulations also clarify how a RIC may change to or from the NAV method.

The final regulations require a RIC to use the same computation periods for purposes of both excise tax and income tax computations. Therefore, under the final regulations, a RIC using the NAV method for its shares in an MMF generally treats the one-year period for which gain or loss from the MMF would be included in the amount determined under section 4982(e)(2) or (e)(6) (the section 4982 period) like a taxable year in applying the NAV method to determine the RIC's required

distribution under section 4982(b).² The RIC, however, may not use the section 4982 period as a computation period for excise tax purposes if the section 4982 period contains days from more than one income tax year.³ Instead, in this situation, the RIC must divide the section 4982 period into at least two computation periods so that each computation period contains days from only one income tax year. Similarly, the RIC may not use its full income tax year as a computation period for income tax purposes if the year contains days from more than one section 4982 period. These consistency requirements simplify and clarify the interaction of sections 852(b) and 4982.

The final regulations eliminate the requirement that computation periods be of approximately equal duration. The Treasury Department and the IRS do not believe that this requirement is essential to the operation of the NAV method, and eliminating the requirement will allow taxpayers more flexibility. In particular, permitting computation periods of unequal duration will reduce the burden on RICs of complying with the requirement of consistent computation periods for income and excise tax purposes. For example, a RIC that applies the NAV method to its shares in an MMF (held as a capital asset) and that has an income tax year ending on January 31 may meet the consistency requirements with two computation periods of unequal duration—one ending on January 31 and the other on October 31. The RIC also may use additional computation periods ending on other dates, such as December 31.

4. Clarification of Certain Amounts

A. Fair Market Value of MMF Shares

Under the proposed regulations, gain and loss under the NAV method would be determined by reference to the fair market value of MMF shares. Commenters requested that the Treasury Department and the IRS clarify that the fair market value of an MMF share for this purpose is the NAV reported by the MMF. One commenter suggested that the fair market value of a share in an MMF should be the published NAV as

² If a RIC has not made an election under section 4982(e)(4), the RIC's section 4982 period is the one-year period ending on October 31, because that is the period for determining capital gain net income under section 4982(e)(2) and (because the final regulations concerning the NAV method constitute a specified mark to market provision for purposes of section 4982(e)(6)(B)) ordinary income under 4982(e)(6)(A).

³ The section 4982 period will contain days from only one income tax year if (i) the RIC has in effect a valid election under section 4982(e)(4) or (ii) the RIC's income tax year ends on October 31.

of the end of the relevant day (or the next trading day, if the day in question is not a trading day). A second commenter suggested that, because MMFs may strike several NAVs throughout the day, the fair market value should be the next published NAV after a transaction.

In response to these comments, the final regulations clarify that the fair market value of a share in an MMF at the time of a transaction is presumed to be the published NAV (or other published amount for which the MMF would redeem the share, determined without regard to any liquidity fees (other redemption amount)). For purposes of computing the ending value for a computation period, the presumption applies to the last published NAV (or other redemption amount) in that computation period. For purposes of determining the fair market value of MMF shares surrendered or received in a redemption or exchange, the presumption generally applies to the NAV (or other redemption amount) used to determine the consideration received in the transaction, or if the consideration is not based on a published NAV (or other redemption amount), the first NAV (or other redemption amount) published for the MMF shares after the transaction. If no NAV (or other redemption amount) is published, or if facts and circumstances indicate that the NAV (or other redemption amount) does not represent the fair market value of a share in the MMF, the fair market value is determined on the basis of all the facts and circumstances.

B. Aggregate Amount Received

Under the proposed regulations, a taxpayer's net investment in an MMF for a computation period would equal the aggregate cost of shares in the MMF purchased during the computation period, minus the aggregate amount received during the computation period in redemption of shares in the MMF, subject to certain adjustments. A commenter suggested that the final regulations clarify that the aggregate amount received is based on: (i) If cash is received, the cash proceeds, (ii) if shares in another MMF are received, the published NAV of the shares received as of the end of the day on which the redemption or exchange occurs (or the next trading day, if the day in question is not a trading day), or (iii) if other non-cash property is received, the NAV of the redeemed or exchanged shares as of the end of the day on which the redemption or exchange occurs (or the next trading day if the day in question is not a trading day or, if the fund will

not publish a NAV on or after the end of the day on which the redemption or exchange occurs, the fund's last published NAV).

The final regulations include provisions for determining the amount received for purposes of computing a taxpayer's net investment in an MMF for a computation period. If the consideration received in exchange for an MMF share consists only of cash, other MMF shares, or both, the amount received is the amount of any cash plus the fair market value of any MMF shares received. If the consideration includes any property other than cash or MMF shares, the amount received is determined by reference to the fair market value of the surrendered MMF shares.

The same commenter recommended that a phrase in § 1.446-7(b)(5)(i)(B) of the proposed regulations, "if the transaction is one in which gain or loss would be recognized," be clarified to indicate that it refers to recognition of gain or loss other than pursuant to the NAV method. The final regulations make this clarification.

C. Substituted Basis

Under the proposed regulations, a taxpayer's net investment would increase if, during the computation period, the taxpayer acquired any shares in an MMF other than by purchase. In such cases, the net investment increases by the adjusted basis (for purposes of determining loss) of each such share immediately after its acquisition. The proposed regulations would also provide that if that adjusted basis would be determined by reference to the basis of one or more shares in an MMF that are being disposed of by the taxpayer in a transaction in which gain or loss is not recognized (exchanged basis), then the basis of each such disposed share is treated as being the fair market value of that share at the time of its disposition. A commenter noted that the proposed regulations do not address a situation in which the shareholder receives a transferred basis in MMF shares acquired from another person. The commenter suggested that, in that situation, if the person from whom the shareholder acquired the shares used the NAV method, then the adjusted basis of the acquired shares should be treated as the published NAV applicable to the acquisition date.

The final regulations clarify the effect on net investment of a share acquired from another person with a transferred basis. Similar to the commenter's suggestion, the final regulations provide that, if a shareholder receives a transferred basis in one or more

acquired MMF shares and the person from whom the shareholder acquired the shares used the NAV method, then the adjusted basis of the acquired shares will be their fair market value at the time of the acquisition, which value is presumed to be the next NAV (or other redemption amount) published by the MMF.

5. MMF Accounts With Shares of Mixed Character

The proposed regulations would provide that if a taxpayer uses the NAV method for shares in an MMF and each of those shares otherwise would give rise to capital gain or loss if sold or exchanged in a computation period, then the gain or loss from the shares in the MMF is treated as capital gain or loss under the NAV method. Likewise, if each of the shares otherwise would give rise to ordinary gain or loss if sold or exchanged in a computation period, then the gain or loss is treated as ordinary gain or loss. If, however, the sale of all of the shares in the MMF would give rise to a combination of ordinary gain or loss and capital gain or loss if sold or exchanged in a computation period, then all gain or loss from the shares in the MMF is treated as capital gain or loss.

A commenter noted that the proposed regulations do not explain why all gain or loss should be treated as capital in the case of an account containing MMF shares of mixed character. The commenter recommended that the character of gain or loss with respect to a mixed character account be bifurcated based on the portion of the shares that would generate gain or loss of each character.

The Treasury Department and the IRS believe that it is rare for a shareholder to hold shares of a single MMF the disposition of which would produce a mix of ordinary income and capital gain. Under that circumstance, a taxpayer may use different accounts to preserve the character of the shares that would produce ordinary income and capital gain. The purpose of the NAV method is to provide an alternative to traditional accounting for taxpayers seeking simplicity. The rationale for offering a method solely for MMFs is that the value of MMFs fluctuates so little that simplicity is more important than tracking each individual gain or loss. A rule that bifurcates gain or loss based on the value of the shares in a single account, when those values may change during a computation period, would make the NAV method more complex. That additional complexity is not warranted in light of the rarity of the circumstance the proposed bifurcation

would address and the ability of shareholders to prevent the treatment of all gain or loss as capital by using separate accounts. Therefore, the final regulations retain the simplifying rule for mixed-character accounts.

6. Other Requests and Comments

A. Wash Sale Rules Exemption for Stable-NAV MMFs

Concurrently with the release of the proposed regulations, the Treasury Department and the IRS released Rev. Proc. 2014-45 (2014-34 IRB 388), which provides that the wash sale rules in section 1091 will not be applied to redemptions of shares in floating-NAV MMFs. Commenters requested that the wash sale exemption, which is limited to floating-NAV MMFs, be extended to stable-NAV MMFs that impose liquidity fees.

The final regulations permit shareholders of stable-NAV MMFs to use the NAV method. A shareholder who uses the NAV method would not require an exemption from the wash sale rules because under the NAV method, net gain or loss is determined for each computation period, and no gain or loss is determined for any particular redemption of a taxpayer's shares in an MMF. Without a determination of loss for a particular redemption, that redemption does not implicate the wash sale rules. Because taxpayers may use the NAV method to prevent wash sales, the Treasury Department and IRS are not extending the exemption in Rev. Proc. 2014-45 to stable-NAV MMFs.

B. Other Requests

A commenter requested that the Treasury Department and the IRS issue guidance regarding the tax treatment of an MMF's receipt of financial support from an investment adviser to raise the NAV of the MMF (determined without the amortized cost method or penny rounding) to \$1.0000. In addition, the commenter requested guidance regarding the diversification requirements of section 817(h) for a segregated asset account that qualifies as, or invests in, a government MMF. On May 5, 2016, the Treasury Department and the IRS released guidance related to both of these requests. See Rev. Proc. 2016-31 (2016-21 IRB 988); Notice 2016-32 (2016-21 IRB 878).

The commenter also requested (and later withdrew its request) that the Treasury Department and the IRS issue guidance providing tax-free treatment for certain divisions of MMFs into retail and institutional MMFs. The Treasury Department and the IRS have

determined that this guidance does not appear essential to an orderly separation of different types of shareholders into different MMFs.

The commenter also requested that the Treasury Department and the IRS issue guidance setting forth the proper tax treatment by an MMF of liquidity fees that the MMF imposes. In addition, the commenter requested guidance providing that, if an MMF imposes liquidity fees and subsequently distributes to shareholders amounts that correspond to amounts that the MMF retained as liquidity fees, the MMF will be deemed to have sufficient earnings and profits to treat the distribution as a dividend. These requests do not relate directly to the NAV method or to the information reporting provision in the proposed regulations and so are not addressed in these final regulations. The Treasury Department and the IRS may consider guidance on these questions in the future.

7. Accounting Method Changes

As under the proposed regulations, a taxpayer may adopt the NAV method for shares in a floating-NAV MMF by use of the method in the Federal income tax return for the first taxable year in which both (1) the taxpayer holds shares in that MMF and (2) that MMF is a floating-NAV MMF.

The final regulations provide that a taxpayer seeking to change to or from the NAV method must secure the consent of the Commissioner in accordance with § 1.446-1(e). Simultaneously with the publication of these regulations, the Treasury Department and the IRS are issuing Rev. Proc. 2016-39 (2016-30 IRB), which provides the procedures by which a taxpayer may obtain automatic consent to change to or from the NAV method for shares in an MMF.

In certain circumstances, Rev. Proc. 2016-39 permits taxpayers to change to the NAV method on a federal tax return without filing a Form 3115, "Application for Change in Accounting Method." This simplified procedure applies to a taxpayer that holds shares in a stable-NAV MMF and wants to change to the NAV method for a taxable year if (1) the taxpayer has not used the NAV method for shares in the MMF for any taxable year prior to the year of change, and (2) prior to the beginning of the year of change, either (a) the taxpayer's basis in each share of the MMF has been at all times equal to the MMF's target share price, or (b) the taxpayer has not realized any gain or loss with respect to shares in the MMF.

For certain other changes, Rev. Proc. 2016-39 provides automatic consent

procedures that require a short Form 3115. For example, these automatic consent procedures apply to a taxpayer that (1) has adopted a realization method for shares in a floating-NAV MMF and wants to change to the NAV method for shares in that MMF, or (2) has adopted the NAV method for shares in a floating-NAV MMF and wants to change to a permissible realization method for shares in that MMF.

Effective/Applicability Dates

The final regulations concerning the NAV method apply to taxable years ending on or after July 8, 2016. For taxable years ending on or after July 28, 2014, and beginning before July 8, 2016, however, shareholders of MMFs may rely either on the rules concerning the NAV method in the proposed regulations or on the final regulations.

The final regulations concerning information reporting apply to sales of shares in calendar years beginning on or after July 8, 2016. Taxpayers and brokers (as defined in § 1.6045-1(a)(1)), however, may rely on the rules in the regulations concerning information reporting for sales of shares in calendar years beginning before July 8, 2016.

Statement of Availability for IRS Documents

IRS Revenue Procedures cited in this preamble are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at <http://www.irs.gov>.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses. No comments were received.

Drafting Information

The principal author of the final regulations is Grace Cho, IRS Office of

the Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *
Section 1.446-7 also issued under 26 U.S.C. 446.

■ **Par. 2.** Section 1.446-7 is added to read as follows:

§ 1.446-7 Net asset value method for certain money market fund shares.

(a) *In general.* This section provides a permissible method of accounting (the net asset value method, or NAV method) for gain or loss on shares in a money market fund (or MMF).

(b) *Definitions.* For purposes of this section—

(1) *Computation period.* Computation periods are the periods (of either equal or varying length) that a taxpayer selects for computing gain and loss under the NAV method for shares in an MMF. Computation periods must possess all of the following attributes:

(i) Every day during the taxable year falls within one, and only one, computation period;

(ii) Each computation period contains days from only one taxable year; and

(iii) If the taxpayer is a regulated investment company (RIC) that is not described in section 4982(f)—

(A) The same computation periods are used for purposes of both income tax accounting under chapter 1 and excise tax computations under section 4982; and

(B) The requirements in paragraphs (b)(1)(i) and (ii) of this section are also satisfied if applied by substituting the RIC's section 4982 period for the RIC's taxable year.

(2) *Ending value.* The ending value of a taxpayer's shares in an MMF for a computation period is the aggregate fair market value of the taxpayer's shares at the end of that computation period.

(3) *Fair market value.* The fair market value of a share in an MMF is determined as follows:

(j) *Presumption based on applicable published redemption amount.* For purposes of this section, the fair market value of a share in an MMF is presumed to be the applicable published redemption amount for the share.

(ii) *Published redemption amount.* The published redemption amount for a share in an MMF is the published amount for which the MMF would redeem the share (usually, the net asset value per share (NAV)), taking into account any corrections and not taking into account any liquidity fee described in Rule 2a-7(c)(2) under the Investment Company Act of 1940 (17 CFR 270.2a-7(c)(2)).

(iii) *Applicable published redemption amount.* The applicable published redemption amount is—

(A) For purposes of determining the ending value of a taxpayer's shares in an MMF for a computation period under paragraph (b)(2) of this section, the last published redemption amount on the last day of that computation period;

(B) For purposes of determining the value of MMF shares received in a redemption or exchange described in paragraph (b)(5)(ii)(A) of this section, the published redemption amount for such MMF shares used to determine the consideration received in the redemption or exchange, or if the consideration received is not based on a published redemption amount, the first published redemption amount for such MMF shares after the redemption or exchange;

(C) For purposes of determining the amount received in a redemption or exchange described in paragraph (b)(5)(ii)(B) of this section in which the consideration received is based on a published redemption amount for the redeemed shares, that published redemption amount; and

(D) For purposes of determining the amount received in an exchange described in paragraph (b)(5)(ii)(B) of this section that is not described in paragraph (b)(3)(iii)(C) of this section, or the amount of any adjustment resulting from a disposition transaction described in paragraph (b)(5)(iii) of this section, the first published redemption amount for the exchanged or disposed of MMF shares after the exchange or other transaction.

(iv) *Facts and circumstances determination.* If there is no applicable published redemption amount or if circumstances indicate that the amount does not represent the fair market value of a share in the MMF, the fair market value is determined on the basis of all of the facts and circumstances.

(4) *Money market fund (or MMF).* An MMF is a regulated investment

company that is permitted to hold itself out to investors as a money market fund under Rule 2a-7 under the Investment Company Act of 1940 (17 CFR 270.2a-7). See paragraph (c)(5) of this section for the treatment of shares in a single MMF held in more than one account.

(5) *Net investment*—(i) *In general.* The net investment in an MMF for a computation period may be a positive amount, a negative amount, or zero. Except as provided in paragraph (b)(5)(iii) of this section, the net investment is equal to—

(A) The aggregate cost of shares in the MMF purchased during the computation period (including purchases through reinvestment of dividends); minus

(B) The aggregate amount received during the computation period in redemption of (or otherwise in exchange for) shares in the MMF in transactions in which gain or loss would be recognized if the taxpayer did not apply the NAV method to the shares.

(ii) *Aggregate amount received.* For purposes of paragraph (b)(5)(i)(B) of this section, the amount received in a redemption or exchange of an MMF share is—

(A) If no property other than cash and shares in one or more other MMFs is received, the amount of any cash plus the fair market value of any MMF shares received; or

(B) If any property other than cash or shares in one or more other MMFs is received, the fair market value of the redeemed MMF share.

(iii) *Adjustments*—(A) *Dispositions in which gain or loss is not recognized.* If, during the computation period, any shares in an MMF are disposed of in transactions in which gain or loss would not be recognized if the taxpayer did not apply the NAV method to the shares, the net investment in the MMF for the computation period is decreased by the fair market value of each such share at the time of its disposition.

(B) *Acquisitions other than by purchase.* If, during the computation period, any shares in an MMF are acquired other than by purchase, the net investment in the MMF for the computation period is increased by the adjusted basis (for purposes of determining loss) of each such share immediately after its acquisition. If the adjusted basis of an acquired share would be determined by reference to the basis of a share or shares in an MMF that are being disposed of by the taxpayer in a transaction that is governed by paragraph (b)(5)(iii)(A) of this section, then the adjusted basis of each such disposed share is treated for purposes of this section as being the fair

market value of that share at the time of its disposition. If the adjusted basis of an acquired share would be determined by reference to the basis of that share in the hands of the person from whom the share is acquired and that person was applying the NAV method to the share at the time of the transaction, then the adjusted basis of the share in the hands of the person from whom the share is acquired is treated for purposes of this section as being the fair market value of that share at the time of the transaction.

(6) *Section 4982 period.* If a taxpayer using the NAV method is a RIC to which section 4982 applies, the section 4982 period is the one-year period with respect to which gain or loss is determined for purposes of section 4982(e)(2) and (e)(6). The preceding sentence is applied taking into account the application of section 4982(e)(4). See paragraph (c)(8) of this section regarding the application of section 4982(e)(6).

(7) *Starting basis.* The starting basis of a taxpayer's shares in an MMF for a computation period is—

(i) Except as provided in paragraph (b)(7)(ii) of this section, the ending value of the taxpayer's shares in the MMF for the immediately preceding computation period; or

(ii) For the first computation period in a taxable year, if the taxpayer did not use the NAV method for shares in the MMF for the immediately preceding taxable year, the aggregate adjusted basis of the taxpayer's shares in the MMF at the end of the immediately preceding taxable year.

(c) *NAV method*—(1) *Scope.* A taxpayer may use the NAV method described in this section to determine the gain or loss for a taxable year on the taxpayer's shares in an MMF. A taxpayer may have different methods of accounting, different computation periods, and gains or losses of differing character, for its shares in different MMFs. See paragraph (c)(5) of this section for the treatment of shares in a single MMF held in more than one account. See paragraph (c)(6) of this section for rules applicable to RICs to which section 4982 applies. See paragraph (c)(8) of this section for rules applicable to accounting method changes.

(2) *Net gain or loss for a taxable year*—(i) *Determination for each computation period.* Subject to any adjustment under paragraph (c)(2)(ii) of this section, the net gain or loss for each computation period with respect to the shares in an MMF to which the NAV method applies equals the ending value, minus the starting basis, minus the net investment in the MMF for the

computation period. If the computation produces a result that is greater than zero, the taxpayer has a gain for the computation period with respect to the shares in the MMF; if the computation produces a result that is less than zero, the taxpayer has a loss for the computation period with respect to the shares in the MMF; and if the computation produces a result that is equal to zero, the taxpayer has no gain or loss for the computation period with respect to the shares in the MMF.

(ii) *Adjustment of gain or loss to reflect any basis adjustments.* If, during a computation period, there is any downward (or upward) adjustment to the taxpayer's basis in the shares in the MMF under any provision of internal revenue law, then the net gain or loss for the computation period on shares in the MMF determined under paragraph (c)(2)(i) of this section is increased (or decreased) by the amount of the adjustment.

(iii) *Timing of gains and losses.* Gain or loss determined under the NAV method with respect to a taxpayer's shares in an MMF during a computation period is treated as arising on the last day of the computation period.

(iv) *Determination of net gain or loss for each taxable year.* The taxpayer's net gain or loss for a taxable year on shares in an MMF is the sum of the net gains or losses on shares in the MMF for the computation period (or computation periods) that comprise the taxable year.

(3) *Character*—(i) In the case of a taxpayer that applies the NAV method to shares in an MMF, the gain or loss with respect to those shares for a computation period is treated as gain or loss from a sale or exchange of a capital asset provided the sale or exchange of one or more of those shares during the computation period would give rise to capital gain or loss if the taxpayer did not apply the NAV method to the shares.

(ii) In the case of a taxpayer that applies the NAV method to shares in an MMF, the gain or loss with respect to those shares for a computation period is treated as ordinary gain or loss provided the sale or exchange of every one of those shares during the computation period would give rise to ordinary gain or loss if the taxpayer did not apply the NAV method to the shares.

(iii) See paragraph (c)(5) of this section for the treatment of shares in a single MMF held in more than one account.

(4) *Holding period.* Capital gains and losses determined under the NAV method are treated as short-term capital gains and losses.

(5) *More than one account.* If a taxpayer holds shares in an MMF through more than one account, the taxpayer must treat its holdings in each account as a separate MMF for purposes of this section. A taxpayer therefore may have different methods of accounting, different computation periods, and gains or losses of differing character, for its shares of a single MMF held in different accounts.

(6) *Consistency requirement for MMF shareholders that are RICs.* If the taxpayer is a RIC that is not described in section 4982(f) (and therefore is subject to the section 4982 excise tax), then, for each MMF, the taxpayer must use the NAV method for both income tax and excise tax computations or for neither computation. See paragraph (c)(5) of this section for the treatment of shares in a single MMF held in more than one account. See paragraph (c)(8)(ii) of this section for changes to or from the NAV method by a RIC.

(7) *Treatment of ordinary gains and losses under section 4982(e)(6).* Under section 4982(e)(6)(B), this section is a specified mark to market provision, and therefore any ordinary gains and losses determined under the NAV method are governed by section 4982(e)(6)(A).

(8) *Accounting method changes*—(i) *In general.* A change to or from the NAV method is a change in method of accounting to which the provisions of section 446 and the accompanying regulations apply. A taxpayer seeking to change to or from the NAV method must secure the consent of the Commissioner in accordance with § 1.446-1(e) and follow the administrative procedures issued under § 1.446-1(e)(3)(ii) for obtaining the Commissioner's consent to change the taxpayer's accounting method. Any such change will be made on a cut-off basis. Because there will be no duplication or omission of amounts as a result of such a change to or from the NAV method, no adjustment under section 481(a) will be required or permitted.

(ii) *RICs*—(A) *In general.* A RIC that is subject to the excise tax under section 4982 and that changes to or from the NAV method for its shares in an MMF for income tax purposes must apply the new method for excise tax purposes starting with the first day of the RIC's income tax year of change. If that first day is not the first day of the RIC's section 4982 period that ends in or with the RIC's income tax year, then solely for purposes of applying the NAV method to compute the RIC's required distribution for the calendar year that ends with or within the RIC's income tax year of change, the section 4982 period is bifurcated into two portions,

each of which is treated as a separate taxable year. The first portion begins on the first day of the section 4982 period and ends on the last day of the RIC's income tax year that precedes the year of change. The second portion begins on the first day of the income tax year of change and ends on the last day of the section 4982 period.

(B) *Example.* If a RIC that holds MMF shares as capital assets changes from a realization method to the NAV method for its income tax year ending January 31, 2019, the section 4982 period is bifurcated into two portions that are treated as separate taxable years solely for purposes of applying this section. For the portion starting on November 1, 2017, and ending on January 31, 2018, the RIC applies its realization method for excise tax purposes. For the portion starting on February 1, 2018, and ending on October 31, 2018, the RIC applies the NAV method for excise tax purposes, treating February 1, 2018, as the first day of the RIC's tax year for purposes of paragraphs (b)(1) and (6) of this section. The RIC's net gain or loss for this later portion is determined under paragraph (c)(2)(iii) of this section. This net gain or loss and any gains and losses for the earlier portion determined under the realization method are taken into account in determining the RIC's capital gain net income for the full one-year period described in section 4982(b)(1)(B).

(d) *Example.* The provisions of this section may be illustrated by the following example:

Example. (i) Fund is an MMF. Shareholder is a person whose taxable year is the calendar year. On January 1 of Year 1, Shareholder owns 5,000,000 shares in Fund with an adjusted basis of \$5,000,000.00. The price of Fund shares has not varied from \$1.00 from the date Shareholder acquired the shares through January 1 of Year 1. During that period, Shareholder has engaged in multiple purchases and redemptions of Fund shares, but Shareholder has reported no gains or losses with respect to the shares because Shareholder realized an amount in each redemption equal to Shareholder's basis in the redeemed shares. During Year 1, the price of Fund shares begins to float. During Year 1, Shareholder receives \$32,158.23 in taxable dividends from Fund and makes 120 purchases of additional shares in Fund (including purchases through the reinvestment of those dividends) totaling \$1,253,256.37 and 28 redemptions totaling \$1,124,591.71. The fair market value of Shareholder's shares in Fund at the end of Year 1 is \$5,129,750.00. All of Shareholder's shares in Fund are held in a single account and as capital assets. There is no adjustment to the basis in Shareholder's shares in Fund under any provision of internal revenue law during Year 1.

(ii) Prior to Year 1, Shareholder has had no gains or losses to report with respect to the

Fund shares under a realization method and no changes in fair market value that would have been reported under the NAV method. Therefore, Shareholder may use the NAV method for the shares in Fund for Year 1. Shareholder uses the NAV method for the shares with its taxable year as the computation period. Shareholder's net investment in Fund for Year 1 equals \$128,664.66 (the \$1,253,256.37 in purchases, minus the \$1,124,591.71 in redemptions). Shareholder's Year 1 gain therefore is \$1,085.34, which is the ending value of Shareholder's shares (\$5,129,750.00), minus the starting basis of Shareholder's shares (\$5,000,000.00), minus Shareholder's net investment in the fund for the taxable year (\$128,664.66). The gain of \$1,085.34 is treated as short-term capital gain. Shareholder's starting basis for Year 2 is \$5,129,750.00. Shareholder also must include the \$32,158.23 in dividends in its income for Year 1 in the same manner as if Shareholder did not use the NAV method.

(iii) If Shareholder had instead adopted the calendar month as its computation period, it would have used the NAV method for every month of Year 1, even though prices of Fund shares may have been fixed for some months.

(e) *Effective/applicability date.* Except as provided in the following sentence, this section applies to taxable years ending on or after July 8, 2016. For taxable years ending on or after July 28, 2014, and beginning before July 8, 2016, however, shareholders of MMFs may rely either on this section or on § 1.446-7 of the 2014 proposed regulations REG-107012-14 (79 FR 43694).

■ **Par. 3.** Section 1.6045-1 is amended by revising paragraph (c)(3)(vi) to read as follows:

§ 1.6045-1 Returns of information of brokers and barter exchanges.

* * * * *

(c) * * *

(3) * * *

(vi) *Money market funds*—(A) *In general.* No return of information is required with respect to a sale of shares in a regulated investment company that is permitted to hold itself out to investors as a money market fund under Rule 2a-7 under the Investment Company Act of 1940 (17 CFR 270.2a-7).

(B) *Effective/applicability date.* Paragraph (c)(3)(vi)(A) of this section applies to sales of shares in calendar years beginning on or after July 8, 2016. Taxpayers and brokers (as defined in § 1.6045-1(a)(1)), however, may rely on paragraph (c)(3)(vi)(A) of this section for

sales of shares in calendar years beginning before July 8, 2016.

* * * * *

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: June 15, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016-16149 Filed 7-7-16; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 94

[Docket No.: OJP (OVC) 1523]

RIN 1121-AA69

Victims of Crime Act Victim Assistance Program

AGENCY: Office for Victims of Crime, Justice.

ACTION: Final rule.

SUMMARY: The Office for Victims of Crime (“OVC”) of the U.S. Department of Justice’s Office of Justice Programs (“OJP”), publishes this final rule to implement the victim assistance formula grant program (“Victim Assistance Program”) authorized by the Victims of Crime Act of 1984 (“VOCA”). VOCA authorizes OVC to provide an annual grant from the Crime Victims Fund to each State and eligible territory for the financial support of services to crime victims by eligible crime victim assistance programs. The rule codifies and updates the existing VOCA Victim Assistance Program Guidelines (“Guidelines”) to reflect changes in OVC policy, needs of the crime victim services field, and VOCA itself.

DATES: *Effective Date:* This rule is effective August 8, 2016.

Compliance Date: See 28 CFR 94.101(d), as added by this final rule.

FOR FURTHER INFORMATION CONTACT: Toni Thomas, Office for Victims of Crime, at (202) 307-5983.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Regulatory Action

The Victims of Crime Act of 1984 (VOCA) authorizes the Office for Victims of Crime (OVC) to provide an annual formula grant from the Crime Victims Fund to each State and eligible territory for the purpose of providing assistance to victims of crime.¹ These

¹ Pursuant to 42 U.S.C. 10603(d)(1), and as used in this preamble and rule unless context indicates

annual Victim Assistance Program formula grants are used by the States to provide financial support to eligible crime victim assistance programs. See 42 U.S.C. 10603. OVC promulgates this rule pursuant to the rulemaking authority granted to the OVC Director by 42 U.S.C. 10604(a). This rule codifies and updates the existing Program Guidelines to reflect changes in OVC policy, the needs of the crime victim services field, and VOCA itself.

B. Summary of the Major Provisions of the Final Rule

Most provisions in this final rule are substantively the same as the corresponding provisions of the Guidelines. The final rule reorganizes the program rules into six major divisions: (1) *General Provisions*; (2) *State Administering Agency (“SAA”) Program Requirements*; (3) *SAA Use of Funds for Administration and Training*; (4) *Sub-Recipient Program Requirements*; (5) *Sub-Recipient Project Requirements*; and (6) *Sub-Recipient Allowable/Unallowable Costs*.

The rules in the *General Provisions* heading do not depart substantively from the Guidelines. OVC defines frequently-used terms, most of which are consistent with those in the Guidelines. OVC adds a new definition of the statutory term “victim of child abuse” to make clear OVC’s existing flexible approach of allowing States to address a broad variety of harm to children. Additional technical changes were made in response to comments, and are described below.

The *SAA Program Requirements* heading sets forth general considerations for SAA use of VOCA funding under the VOCA Assistance Program at the State level, and sets forth the rules SAAs must follow in meeting the statutory eligibility and certification requirements. OVC clarifies that pass-through funding is permissible, and sets parameters for such funding arrangements. OVC explains how States must allocate VOCA funding among various types of victim service programs, but does not change the allocation percentages set out in the Guidelines. OVC adds a requirement that States maintain a documented methodology for selecting all sub-recipients. Finally, OVC maintains the default monitoring requirements of the Guidelines, but now permits States to seek a waiver from the OVC Director to use alternatives.

otherwise, “the term ‘State’ includes the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, and any other territory or possession of the United States.”

The revised *State Administering Agency Use of Funds for Administration and Training* heading updates the Guideline provisions regarding SAA use of funds for administration and training to make those consistent with statutory changes that occurred after the Guidelines were issued in 1997. The rule lists allowable administrative and training costs at the SAA level, all of which are consistent with those set out in the Guidelines.

The *Sub-Recipient Program Requirements* heading sets out the eligibility and organizational requirements for sub-recipients. These provisions mostly track the Guidelines, except that OVC adds a provision addressing non-disclosure of confidential or private information.

The *Sub-Recipient Project Requirements* heading sets out rules that VOCA-funded victim service projects must follow. These provisions generally are consistent with the Guidelines. OVC maintains the existing project match rules, requiring that sub-recipients provide a 20% project match, but excepting U.S. territories (not including Puerto Rico). OVC adds an exception to match for projects undertaken by American Indian and Alaskan Native tribes, and projects that operate on tribal lands, as these projects, like those operating in U.S. territories, often have difficulties accessing matching resources.

The *Sub-Recipient Allowable/Unallowable Costs* heading lists activities that sub-recipients may undertake using VOCA funding. The majority of the listed costs are the same as those listed in the existing Guidelines; but OVC makes some substantive changes. OVC now allows the States to provide a broader array of legal support services (outside of the emergency context permitted by the Guidelines) to victims, should States choose to do so. OVC removes the prohibition on providing services to incarcerated victims (*e.g.*, victims of sexual assault in prison). Although VOCA funding may not support prison costs, such as prison guard salaries or administrative expenses, States are no longer prohibited from allowing VOCA-funded organizations to assist incarcerated victims. OVC also adds greater flexibility for States to support transitional housing and relocation expenses using VOCA funds. OVC adds greater flexibility for States to allow sub-recipients to use VOCA funds for coordination activities, which help leverage community resources to provide better and more cost-effective direct services. Finally, to better align the program rules with the government-

wide grant rules at 2 CFR part 200, OVC makes allowable indirect organizational costs at the sub-recipient level, by removing the provision in the Guidelines that prohibited sub-recipients from charging these to VOCA funds.

C. Cost and Benefits

As discussed in more detail under the Executive Orders 12866 and 13563 (in the Regulatory Review discussion below), the rule clarifies and updates existing Guidelines, but does not alter the existing program structure. Updating the existing Guidelines to clearly and accurately reflect the statutory parameters will facilitate State compliance with VOCA, and thus avoid potentially costly non-compliance findings. The rule makes only a few substantive changes to the existing Guidelines, and most of the changes expand State flexibility in the use of VOCA funding. Some changes, like allowing more flexibility to coordinate and leverage community resources, and adopt alternative monitoring strategies, impose no costs but allow States to use existing funding more efficiently. Other changes, which allow States to allocate funding to services not presently allowable under the Guidelines, could expand the types of victim service organizations funded with VOCA funds and the services provided by existing organizations. Such allocations of funding, however, are not mandated under the rule, and each State will continue to make the final decision about whether to change its funding allocations. This is not a change from the present discretion that States have to allocate funding according to their priorities. OVC anticipates that most States will continue to allocate the majority of VOCA funding to victim services for certain types of crimes (*i.e.*, intimate partner violence, sexual assault, child abuse) at consistent levels and that any potential reallocations would be relatively minor (even when taken in aggregate across States) in comparison to the overall range of allowable victim services, and thus unlikely to create new costs or significant fund transfers. In any event, the real benefits of additional allowable services for currently underserved and unserved victims are significant.

III. Background

A. Overview

This rule implements OVC's Victim Assistance Program, a formula grant program authorized by Section 1404 of the Victims of Crime Act of 1984, Public Law 98-473, codified at 42 U.S.C.

10603. This section of VOCA authorizes OVC to provide an annual grant from the Crime Victims Fund to each State for the financial support of services to victims of crime by eligible crime victim assistance programs. This rule supersedes the VOCA Guidelines (published at 62 FR 19607) that have been in effect since April 22, 1997, and reflects changes in OVC policy, the needs of the crime victim services' field, and VOCA itself, as well as the comments submitted in response to the Notice of Proposed Rulemaking.

OVC's Victim Assistance Program is funded from the Crime Victims Fund. The Fund receives Federal criminal fines, penalties, and assessments, as well as certain gifts and bequests, but does not receive any general tax revenue. The Crime Victims Fund is administered by OVC and amounts that may be obligated therefrom are allocated each year according to the VOCA formula at 42 U.S.C. 10601. The amount annually available for obligation through the VOCA formula allocations typically has been set by statute, through limits in the annual DOJ appropriation act, at less than the total amount available in the Fund. The VOCA formula specifies that (in most years) the first \$20M available in the Fund for that year will go toward child abuse prevention and treatment programs, with a certain amount to be set-aside for programs to address child abuse in Indian Country. After that, such sums as may be necessary are available to the Federal Bureau of Investigation and the U.S. Attorneys Offices to improve services to victims of Federal crime, and to operate a victim notification system. The remaining balance is allocated as follows: 47.5% for OVC's Victim Compensation Program, 47.5% for OVC's Victim Assistance Program, and 5% for the OVC Director to distribute in discretionary awards in certain statutorily defined categories. Generally, under the distribution rules for the Victim Compensation Program, if a portion of the 47.5% available for Compensation is not needed for that purpose, it is (per the statutory formula) made available to augment the Victim Assistance Program. The Victim Assistance Program distributes funds to States as mandated by VOCA, at 42 U.S.C. 10603. The VOCA statutory distribution formula provides each State with a base amount (presently \$500,000 for each State and the District of Columbia; \$200,000 for each eligible territory), and distributes the remainder proportionately, based on population.

B. History of This Rulemaking

OVC published the Final Program Guidelines, Victims of Crime Act, FY1997 Victim Assistance Program on April 22, 1997 (62 FR 19607). Those Guidelines were based on OVC experience with the Victim Assistance Program, legal opinions rendered since the inception of the program in 1986, and comments from the field on the Proposed Program Guidelines, which were published in the **Federal Register** on February 18, 1997 (62 FR 7256).

On September 3, 2002, OVC published a notice of Proposed Program Guide at 67 FR 56444, seeking comments to refine the administration of the Victim Assistance Program further; thereafter, however, OVC chose not to issue final guidance to supersede the 1997 Guidelines. After receiving comments on the 2002 Proposed Program Guide, OVC instead decided to pursue the publication of codified program regulations rather than merely revise the guideline document. Throughout 2010, OVC sought preliminary input from the victim services field regarding improving victim services and potential modifications to the Victim Assistance Program rules that would facilitate such improvement.

OVC incorporated this input into a Notice of Proposed Rulemaking, which it published at 78 FR 52877 (Aug. 27, 2013), and OVC received 108 public comments over a 60 day period. OVC considered all comments submitted during the comment period in drafting this final rule.

IV. Discussion of Comments and Changes Made by This Rule

The 1997 Guidelines have been outpaced by changes in VOCA, developments in the crime victim services field, technological advances, and new approaches to State administration of VOCA funding. This rule updates the program Guidelines to account for developments over the last decade and a half, and to reflect more accurately program parameters applicable to each participating entity. In so doing, OVC hopes to allow administering agencies and victim service providers fully to leverage the progress that the field has made over the last decade in knowledge of victim needs, victim service strategies, and efficient program administration, with the end goal of assisting crime victims more effectively. Many of the provisions in the existing Guidelines have been retained in substance, though the text has been reformatted in some cases. OVC describes below the main

substantive changes to the program Guidelines, and the comments received.

Structure and General Comments

The rule reorganizes the provisions of the Guidelines, primarily to accommodate the requirements for publication in the Code of Federal Regulations (CFR), but also to organize information more logically. The rule omits repetition of statutory language, except where needed for context and ease of use. OVC notes that the rule is drafted to be read *in conjunction* with VOCA (42 U.S.C. 10603). OVC also uses consistent terminology throughout the document.

Some commenters expressed concern that the proposed rule conflated provisions applicable to VOCA-funded projects in some cases with provisions relating to a VOCA-eligible program, and several endorsed the National Association of Victim Assistance Administrators' (NAVAA) suggestions for reorganizing it. In the final rule, OVC more clearly distinguishes between the two concepts, and adopts most of the NAVAA's helpful suggestions for reorganizing the rule.

In connection with reorganizing the provisions of the final rule for greater logical consistency and clarity, OVC has moved or renumbered many of the sections of the proposed rule. In order to assist readers, a derivation table is included listing the sections of the final rule and the corresponding section or sections of the proposed rule. The public comments on provisions of the proposed rule are discussed below according to where those provisions are codified in the final rule.

Final rule	NPRM
§ 94.101	§ 94.101
§ 94.102	§ 94.102
§ 94.103	§ 94.103; § 94.112(i)-(j);
§ 94.103(f),(g)	NEW
§ 94.104	§ 94.105; § 94.108(d)
§ 94.105(a),(b)	§ 94.106
§ 94.105(c)	New
§ 94.106	§ 94.107
§ 94.107(a)-(d)	§ 94.110
§ 94.107(e)	§ 94.118(f)
§ 94.108(a),(b)(1)	§ 94.111(b),(c)
§ 94.108(b)(2)	§ 94.103(b)(3)
§ 94.109(a),(b)(1-11)	§ 94.111(a); § 94.112
§ 94.109(b)(12)	New
§ 94.110	§ 94.113
§ 94.111	§ 94.104(a); § 94.106(c)
§ 94.112(a)	§ 94.104(b);
	§ 94.108(b)-(e)
§ 94.112(b)	§ 94.104(c)-(e)
§ 94.112(c)	§ 94.115(d)
§ 94.113	§ 94.104(g);
	§ 94.115(a)-(c)
§ 94.114	§ 94.104(h)
§ 94.115	NEW
§ 94.116	§ 94.114

Final rule	NPRM
§ 94.117	§ 94.115(e); § 94.109
§ 94.118	§ 94.104(f); § 94.116
§ 94.119	§ 94.117
§ 94.120(a)-(f)	§ 94.118
§ 94.120(g)	New
§ 94.121	§ 94.108(a); § 94.119
§ 94.122	§ 94.120

Many commenters expressed their desire that the Crime Victims Fund "cap" be raised substantially. As such a change requires legislative action, it is beyond the scope of OVC's authority to do so. However, we note that the Department of Justice Fiscal Years 2015 and 2016 Appropriation Acts did substantially increase—more than threefold—the cap for those years. *See* Department of Justice Appropriation Act, 2015, Public Law 113–235, Div. B, Title II, Sec. 510 (setting the obligation cap at \$2.361B compared to \$745M available to OVC in FY 2014); Department of Justice Appropriation Act, 2016, Public Law 114–113, Div. B, Title II, Sec. 510 (setting the cap at \$3.042B, of which approximately \$2.663B is available to OVC).

General Provisions

§ 94.101 Purpose and Scope; Future Guidance; Construction and Severability; Compliance Date

The general provisions of the final rule—including statement of purpose, future guidance, and construction and severability—are largely unchanged from the proposed rule. OVC added a paragraph describing the date on which SAAs must comply with the rule. The rule applies upon its effective date to all OVC grants made after that date, except for funding under such grants that was obligated before the effective date. Pre-award obligations are a standard practice of SAAs under the VOCA Assistance Program, as the annual appropriation cycle typically does not permit for awards to be made until late in the fiscal year. VOCA Assistance grants typically have an award period that extends retroactively to October 1st of the fiscal year of the award, thus there may be funds under grants made after the effective date that were obligated by the SAA prior to the effective date, and subsequently ratified by OVC's approval of the grant. The final rule does not apply retroactively, and thus it does not require that SAAs anticipate rules that are not in effect when making such obligations. However, OVC will permit SAAs to apply the provisions that expand SAA discretion in the use funds (*e.g.*, the final rule permits SAAs to fund a greater range of transitional housing services

than the Guidelines permit) to VOCA assistance funding under OVC grants made before the effective date of the rule that is obligated on or after the effective date. As most of the changes in this rule are of a permissive nature and expand SAA discretion, OVC does not anticipate that implementation of the rule will be burdensome, though some effort by SAAs to understand the changes and communicate these to applicants for sub-awards will be necessary.

§ 94.102 Definitions

The final rule contains several terms and definitions that are used throughout. These are set out in section 94.102 for ease of reference.

The definition of *crime victim* and *victim of crime* remains unchanged from the Guidelines, and is meant to be a broad definition, taking into account many kinds of harm resulting from criminal acts. States are encouraged to include those domiciled in their states who are victimized while working in their official capacities overseas as VOCA eligible victims.

Some commenters liked the proposed definition, but others wanted OVC to include more examples in the definition to illustrate coverage of a broader range of harms. OVC kept the more conceptual definition from the proposed rule, as it is substantively the same as the long-standing Guideline definition and because—as one commenter pointed out—this definition has been sufficiently broad to encompass the harm from various crimes on a wide and diverse range of individuals.

OVC has added a definition of the term *spousal abuse* that clarifies that the term includes domestic and intimate partner violence. Spousal abuse was the terminology used in the victim services field in the 1980s, and consequently in VOCA, but the term has since fallen out of use, as it is under-inclusive of the range of relationships in which this type of victimization frequently occurs. OVC retains the term in the final rule because it is a statutory term, but clarifies that OVC understands it to encompass domestic and intimate partner violence. This is consistent with longstanding OVC practice and the Guidelines, which use the term “domestic abuse” when describing the priority category of “spousal abuse.” Several commenters supported the proposed definition, but asked that OVC include the more commonly-used term “domestic violence” in the definition. OVC agrees, and has done this. OVC has also removed “dating violence,” as this concept is encompassed already by the more general concept of “intimate

partner violence.” Some commenters asked that OVC clarify how this definition (which affects the priority category of “spousal abuse”) would affect LGBTQ survivors of domestic or intimate partner violence. OVC notes that States may serve (and count those services toward the priority category) all victims of domestic and intimate partner violence—encompassing violence or abuse by one person against another in a domestic context or intimate-partner context—as the OVC definition does not require legal recognition of any particular relationship, nor does it implicate State or territorial laws concerning marriage rights.

A commenter noted that OVC did not propose to define “sub-recipient” or “VOCA project,” and asked that OVC define these terms so as to differentiate between a VOCA-funded project, and the organization that is eligible to receive VOCA funds to undertake the project. OVC agrees and adds these definitions, and has made conforming changes throughout the rule.

The final rule adds a definition of the statutory term *victim of child abuse*, in order to clarify that the term covers a broad variety of harm to children. Child abuse victims are a statutorily-mandated priority category, and the clarification makes plain that VOCA-funded State victim assistance programs may support a broad variety of victim assistance projects that address the abuse of children.

OVC received many comments on the proposed definition of child abuse. Many commenters supported the proposed definition. Other commenters supported the proposed definition, but recommended changes or expressed concerns about certain parts of it. One commenter worried that the inclusion of the concept of children exposed to violence may lead states to view a non-offending parent who cannot leave an abusive household as a co-offender. OVC notes that the definition of child abuse in this rule does not control (or affect) how a state views or treats potential offenders. Nonetheless, it is OVC’s express intent that the definition should not be misconstrued to mean that failure to leave an abusive relationship, in the absence of other action constituting abuse or neglect, is itself abuse or neglect. A commenter asked that the definition encompass sex and labor trafficking, and several others asked OVC to include slurs and family rejection as examples of the emotional abuse of children encompassed by the definition. OVC notes that the definition of child abuse is sufficiently broad to encompass these harms without listing

specific abusive activities, if States consider them to be child abuse. Some commenters worried that the inclusion of exposure to violence would dilute available resources, and confuse States operating victim assistance programs.

OVC acknowledges resource limitations facing many States, but keeps the expanded definition in the final rule to allow States to prioritize within the category based on local capacity and needs. The Department’s own Defending Childhood initiative demonstrated the importance of services for children exposed to violence, and the new definition will permit services addressing this. OVC, in response to several comments, has clarified in the definition that it encompasses harm to children, and is not meant to include adults who were victimized as children. This does not, however, preclude States from funding services to adults victimized as children; it merely means that States cannot count such services under the child-abuse priority category.

SAA Program Requirements

§ 94.103 Purpose of State-Level VOCA Funding; SAA Eligibility

Section 94.103(a) sets forth the purpose of OVC’s annual VOCA formula grants to the States. Several commenters asked that OVC re-draft the language to make it less confusing. OVC agrees and has done so. Commenters also asked that OVC add a statement about State discretion in determining sub-award recipients and amounts. OVC agrees and has added a sentence accordingly.

Section 94.103(b) sets forth the general rules for State eligibility certifications required by VOCA. OVC requires States to submit these certifications annually in their applications for funding. Reporting and technical requirements specific to a given fiscal year are set out in the annual program solicitation, or in supplemental OVC communications if time does not permit publication in the solicitation.

Section 94.103(c) clarifies that a SAA may award its VOCA funds to another organization to distribute—known as pass-through administration—and highlights SAA obligations with regard to use of administrative and training funds, monitoring, and reporting should this method be used. Several commenters supported pass-through administration, but advocated that pass-through entities should have specific expertise and experience related to the use of the funding (e.g., a pass through entity administering funds for sexual assault services would have experience/expertise related to sexual violence).

OVC does not disagree with the commenters' views, but believes that States are in the best position to choose which entity should administer pass-through funding, and thus maintains the rule as proposed. A commenter asked for clarification regarding the proposed requirement that SAAs not use a pass-through mechanism to bypass the statutory limitation on use of administrative funds. OVC has rewritten this statement to be clearer.

A commenter was concerned that the proposed rule eliminated language in the guidelines about things that States should consider in strategic planning and asked that OVC add it back to the final rule. OVC agrees that the language is desirable and has added a new paragraph (d) with this language. Finally, several commenters expressed concern that OVC did not highlight the need for States to consider sustainability of services in strategic planning. OVC agrees that sustainability is an important consideration, and has added this to paragraph (d).

Section 94.103(g) sets forth that SAAs shall, upon request, and consistent with 2 CFR 200.336, permit OVC access to all records related to the use of VOCA funding. Access to SAAs' records is subject to the provision of the government-wide grant rules at 2 CFR 200.336, which permits access to the true names of crime victims only in extraordinary and rare circumstances, not for routine monitoring, and requires protection of sensitive information by all agencies involved if access is granted.

§ 94.104 Allocation of Subawards

OVC moved the provisions of proposed section 94.104, *Eligible crime victim assistance programs*, to a new heading titled "Sub-recipient Program Requirements," which includes sections 94.111 through 94.115 of the final rule. Comments on the proposed section 94.104 are addressed below in the discussion of sections 94.111 through 94.114.

In the final rule, section 94.104, *Allocation of subawards* (which was proposed as section 94.105), sets forth—pursuant to 42 U.S.C. 10603(a)(2)(A) (priority category), and (B) (underserved category)—how SAAs must allocate their subawards. The allocation amounts in the final rule are the same as those in the Guidelines and proposed rule. Some commenters noted that victims of a priority category might also be underserved victims in some circumstances (e.g., child victims of sex trafficking might be underserved in a particular jurisdiction, however, sex trafficking of a minor would also be

child sexual abuse), and that this causes confusion in reporting allocation amounts to OVC. Moreover, some victims with certain demographics (e.g., LGBTQ, American Indian/Alaskan Native) may be underserved even in the priority categories (e.g., victims of sexual assault). In response, the final rule clarifies that SAAs may count funds allocated to such projects in either the priority or underserved category, but not both.

Section 94.104(c) sets out the criteria by which SAAs must identify (for allocation of funds, reporting, and compliance purposes) services that assist previously underserved populations of victims of violent crime. SAAs must identify such a service for underserved victims of violent crime by the type of crime they experience (e.g., victims of elder abuse) or the characteristics of the victim (e.g., LGBTQ victims), or both (e.g., victims of violent crime in high crime urban areas). Underserved victims may differ between jurisdictions, but some examples of victim populations often underserved at the time of this rulemaking may include, but are not limited to, DUI/DWI victims; survivors of homicide victims; American Indian/Alaskan Native victims in certain jurisdictions with insufficient victim service resources; victims of physical assault; adults molested as children; victims of elder abuse; victims of hate and bias crimes; victims of kidnapping; child victims and adult survivors of child pornography; child victims of sex trafficking; victims of violent crime in high crime areas; LGBTQ victims; victims of federal crimes, victims of robbery; and victims of gang violence. OVC has removed from the final rule the examples of possibly underserved victim populations, as such a list may change over time and is more appropriately set out in the preamble and supplementary OVC guidance, as necessary.

A commenter asked that OVC add economic crimes, such as identity theft, to the list of examples of underserved victims. OVC notes that, for the underserved victim category, VOCA requires funding be allocated to projects serving "previously underserved populations of victims of *violent crime*", and identity theft is not a violent crime. OVC, therefore, declines to make the change, but does note that States may still fund services for victims of such crimes, but cannot count those services toward meeting the required allocation for the underserved victim category.

A commenter asked that OVC increase the percentage of funding required to be allocated to underserved populations.

OVC has kept the mandated percentage at its present level, which balances the need for stability in state victim assistance funding with the need to ensure State victim assistance programs are responsive to emerging needs. The commenter also asked that OVC clarify that the exception allowing States to deviate from the underserved and priority percentages should be used sparingly. OVC notes that such requests are extremely rare (OVC has record of only one); thus, as a practical matter, an additional limitation of the exception is unnecessary. Other commenters asked OVC to require States to consult with sub-recipients prior to requesting approval to change allocations. As explained above, OVC anticipates such requests will be extremely rare, and declines to add such a requirement. The same commenter asked that OVC not tie exceptions for allocations for the sexual-assault priority category to overall crime rates, explaining that crime rates in a given time period are not necessarily reflective of victim service needs during the corresponding time period, as victims may not seek services immediately. OVC agrees, and the final rule allows other types of data to be used in supporting an exemption request.

A commenter asked that OVC require States to consult with rape crisis centers and sexual assault coalitions about the needs of sexual violence victims. OVC agrees that such consultation may be useful, but declines to include such a requirement in the rule, as OVC prefers to allow States to consult with a wide variety of stakeholders as appropriate.

Section 94.104(e) sets for the minimum requirements for SAAs sub-award process. It requires that SAAs have a documented methodology for selecting sub-recipients, follow DOJ grant rules regarding conflicts of interest, and encourages SAAs to fund eligible sub-recipients through a competitive process, which is described.

The proposed rule would have required competition of all sub-awards. Some commenters liked the proposed competition requirement, but others were opposed to it. Several commenters noted that requiring competition could increase administrative costs for SAAs, and could destabilize small victim assistance programs that would no longer be able to rely on consistent funding. Commenters noted that this may decrease the availability of services in rural areas where there are not many providers. A commenter from a SAA explained that it uses a conduit funding process in which it distributes funds to local victim witness units based on a formula, and these units then sub-award

the funding to local non-profit victim service organizations in accordance with State and county procurement rules. The commenter expressed concern that a competition requirement may undermine this process. Other commenters expressed concern that the requirement might cause problems with State contract cycles, and could undermine some prosecutor-based victim-witness assistance programs. Commenters also questioned whether there is evidence that competition creates innovation.

OVC appreciates the thoughtful comments submitted in response to this proposal, and recognizes the importance of allowing States discretion in determining which organizations receive funds and in what amounts. Due to the potential administrative burden of requiring competition (particularly in jurisdictions with a limited number of SAA staff), OVC has not included such a requirement, though OVC does encourage SAAs to use a competitive process where feasible.

Many commenters expressed their opinion that VOCA funding should not be used as seed money for new organizations. OVC notes that any organization funded with VOCA Assistance funding—even through a competitive process—must meet the statutory program eligibility criteria, which requires either a record of effective victim services and financial support from non-VOCA funding, or substantial support from non-VOCA funding. One commenter asked that OVC require States to have a strategic state plan for allocating funding. The final rule encourages States to develop a funding strategy, and requires States to have a documented method of making funding decisions.

§ 94.105 Reporting Requirements

OVC renumbered this section from 94.106 in the proposed rule to 94.105 in the final rule. This section sets out SAA reporting requirements. The two key reports—subgrant award reports and performance reports—are the same reports required by the Guidelines, and the proposed rule. The rule does not specify time or manner in which these reports are to be submitted. The Government Performance and Results Modernization Act of 2010, Public Law 111–352 (Jan. 4, 2011), shifted many federal performance reporting requirements to a quarterly default, and OVC has changed the default performance reporting period in the rule accordingly. OVC will communicate the technical details of each year's reporting requirements to grantees via annual

program solicitations and supplemental guidance.

A commenter noted that multiple budget revisions may occur during the grant period, and that the proposed requirement that SAAs update the subgrant award report within 30 days of such revisions would be burdensome. The commenter requested that OVC retain its current practice of allowing SAAs to submit a revised subgrant award report before project closeout. In response, OVC notes that the subgrant award report contains only minimal budget information, and the importance of having accurate and timely information on subawards outweighs the minimal additional burden of updating this report within the specified timeframe. Recent upgrades to OVC's performance reporting systems should reduce the burden on SAAs as subrecipients now have the ability to enter SAR data directly. The final rule keeps the thirty-day reporting requirement.

Another commenter suggested that OVC should require additional reporting, specifically on unmet needs of victims and the estimated costs of providing such services. OVC declines to add such a requirement to the rule. One commenter suggested that the final rule should allow flexibility for OVC to change the reporting period for the performance report; OVC agrees and has added this but keeps the Federal fiscal year as the default reporting period.

§ 94.106 Monitoring Requirements

OVC renumbered this section from 94.107 in the proposed rule to 94.106 in the final. This section sets out the SAA's obligation to monitor its sub-awards. Many commenters complained that the proposed two-year on-site monitoring timeframe would be too burdensome and would be difficult for large jurisdictions to implement, and may lead to unintended consequences, such as SAAs' making fewer awards but of larger dollar amounts. Commenters pointed out that many states use risk assessment tools to determine priority for on-site monitoring, and some requested that OVC make the default rule three years instead of two years. Another commenter asked that OVC clarify that SAAs may request alternative monitoring plans as well as alternative monitoring frequency.

The final rule requires SAAs to develop and implement monitoring plans based on a default of regular desk monitoring, and biennial on-site monitoring, of all sub-awards. OVC also adds a requirement that such monitoring plans contain a risk assessment plan. The rule, consistent

with 2 CFR 200.331(b), (d) and (e), continues to permit SAAs to develop and implement alternative monitoring plans (e.g., quarterly reports and desk audits instead or in addition to site visits), and further clarifies that SAAs may also implement alternative monitoring timeframes as well. OVC believes that biennial on-site monitoring is a reasonable timeframe that balances resource demands with effective oversight, but SAAs may propose alternative plans. OVC recognizes that certain sub-recipients may have a long established history of appropriately administering a sub-award and may therefore require less intensive scrutiny than a relatively new sub-recipient or an established sub-recipient providing new services.

SAA Use of VOCA Funds for Administration and Training

§ 94.107 Administration and Training

OVC renumbered this section from 94.110 in the proposed rule to 94.107 in the final rule. This section is substantively unchanged from the proposed rule, except that OVC clarifies that SAAs must certify, pursuant to VOCA, at 42 U.S.C. 10604(h), in the notification of use of training/administrative funds, that they will not use VOCA funds to supplant State or local government funding. (The substantive rules regarding supplantation are set out in the next section, section 94.108.)

Overall, this section makes the program rules match the statutory provisions, which had changed after issuance of the Guidelines. VOCA limits administrative and training costs to five percent total for the combined costs of administration and training at the SAA level.

§ 94.108 Prohibited Supplantation of Funding for Administrative Costs

OVC renumbered this section from 94.111 in the proposed rule, to 94.108 in the final rule, and re-titled it to more accurately reflect what the section addresses. (Proposed section 94.108(a) is moved to section 94.121 in the final rule. Proposed section 94.108(b) through (e) is moved to section 94.112 in the final rule.) Section 94.108 sets out the rules for SAA use of VOCA funds for administrative costs and prohibits supplantation of State and local government funding with VOCA funding.

One commenter asked whether the baseline is to be established and documented on a one-time basis or each year of the grant. OVC currently requires SAAs to document a baseline each fiscal

year, based on its expenditures for administrative costs during that fiscal year and the previous fiscal year. A commenter pointed out that OJP has a definition of supplanting in its Financial Guide that differs from that in the proposed rule, and suggested that OVC simply adopt the DOJ Grants Financial Guide definition of the term instead of setting forth a separate definition. OVC agrees and has revised this paragraph to reference the Financial Guide definition. OVC requires SAAs to certify that they are not supplanting State administrative support for the State crime victim assistance program with VOCA funding.

§ 94.109 Allowable Administrative Costs

OVC renumbered this section from 94.112 in the proposed rule, to 94.109 in the final rule. (Proposed section 94.109 is moved to section 94.117 in the final rule.) Section 94.109 sets out allowable administrative costs.

Several commenters asked OVC to add a category for “activities that impact the delivery and quality of services to crime victims throughout the state,” including training managers of victim service agencies, State-wide victim notification systems, and support for victims’ rights compliance programs. OVC has added these activities. (OVC notes that direct service funding also may be used to support victim notification systems as well.) Direct service provider manager training is allowed, but categorized as a training expense under section 94.110. Several commenters expressed concern that allowing program evaluation would divert funding from direct services. OVC notes that the provision does not require evaluation, but merely allows it; furthermore, the total amount of funding for administrative costs is already capped by VOCA.

§ 94.110 Allowable Training Costs

OVC renumbered this section from 94.113 in the proposed rule, to 94.110 in the final rule. (Proposed section 94.110 is moved to section 94.107 in the final rule.) This section sets out allowable uses of training funds.

A commenter asked OVC to clarify that the allowable training costs are not limited by the two listed examples. In response, OVC edited the text to clearly state that such costs “generally include, but are not limited to” the two listed examples; these are merely examples and not limitations. Commenters also asked OVC to clarify that SAAs may use training funds to train managers and board members of victim service agencies, as is permitted under the

current Guidelines. OVC has added this to the final rule. Several commenters asked OVC to raise the percentage limits on administrative and training costs; as these are statutory requirements, however, OVC has no authority to do so.

Sub-Recipient Program Requirements

Sections 94.111 through 94.115 of the final rule set out the requirements that an entity must meet to be an “eligible crime victim assistance program.” (Sections 94.111 through 94.114 of the proposed rule are moved to section 94.108, 94.109, 94.110, and 94.116, respectively, of the final rule. Section 94.115(a) through (d) of the proposed rule is moved to section 94.112 of the final rule; and 94.115(e) of the proposed rule is moved to section 94.117 of the final rule. The responses to comments addressing those provisions of the proposed rule are found in the discussions of the corresponding sections as set forth in the final rule.)

Several commenters suggested that OVC reorganize the rule such that the requirements for eligibility as a sub-recipient entity versus the requirements for operating a sub-recipient project, are clearly delineated. OVC agrees, and has created a new heading “Sub-Recipient Program Requirements” and moved the requirements in the proposed rule section 94.104 *Eligible crime victim assistance programs*, to sections 94.111 through 94.115 of the final rule, under this heading. OVC also moved proposed 94.108(b) through (e) to section 94.112 of the final rule. Thus, sections 94.111 through 94.115 of this rule consolidate the eligibility requirements for the sub-recipient *organization* (i.e., program).

§ 94.111 Eligible Crime Victim Assistance Programs

VOCA establishes the criteria for an “eligible crime victim assistance program,” and the final rule merely provides clarifying interpretation needed for practical implementation. Section 94.111 of the final rule sets out the basic principle that the SAA may fund only eligible programs, and contains a provision requiring compliance with additional SAA criteria and reporting requirements. Several commenters asked that OVC strengthen language (in proposed section 94.115(d)) requiring sub-recipients to follow reporting requirements of the SAA. OVC has done so in section 94.111.

§ 94.112 Types of Eligible Organizations and Organizational Capacity

This section sets out the general types of eligible entities, and special

considerations for specific types of entities (moved from proposed section 94.108), as well as criteria for determining the organizational capacity of the entity’s program.

In section 94.112(a)(3) of the final rule, OVC modifies the proposed provision (proposed section 94.108(e)) on victim assistance organizations located in an adjacent state to eliminate unnecessarily bureaucratic requirements in the Guidelines, while keeping the requirement to provide notice to the SAA where the organization is located, and encouraging co-ordination on various award oversight matters. Several commenters asked for clarification of the rules for SAA programs operating direct services projects with VOCA funds (proposed section 94.108(d)). In response, OVC has modified section 94.112(a)(4) of the final rule to clarify these points by eliminating confusing and redundant text that reiterated the statutory requirement that SAAs use no more than five percent of VOCA funds for administrative and training costs.

With regard to determining the organizational capacity of a sub-recipient, under section 94.112(b) of the final rule, the SAA determines what constitutes “a record of effective services to victims of crime,” and this may vary depending on the State, and community served, and the entity providing services. Though this provision is reworded slightly for clarity, OVC leaves unchanged in the final rule the non-exclusive list of considerations that SAAs may take into account when making this determination. The SAA should be able to articulate the basis for its determination, should OVC request it. SAAs may also consider additional factors, such as the type of victim the entity’s services address, the type of services provided, best practices within that service field, and the characteristics of the entity (e.g. small, specialized service provider; larger, comprehensive service provider).

§ 94.113 Use of Volunteers, Community Efforts, Compensation Assistance

Commenters urged OVC to make it clear that the mandated use-of-volunteers provision, at section 94.115(a) of the proposed rule, applies as an eligibility requirement for sub-recipient organizations (programs), not as a requirement for individual projects. OVC agrees with the commenters that the use-of-volunteers provision applies to programs, not individual projects, and has thus placed the final rule provision addressing waiver of this

statutory requirement in section 94.113(a) of the final rule.

Commenters asked that OVC clarify proposed section 94.115(c), to state that a sub-recipient may comply with the VOCA requirement to assist victims in applying for compensation by providing referrals. OVC agrees and has made this clarification in section 94.113(d) of the final rule.

A commenter asked that OVC add additional requirements to the VOCA mandate that sub-recipients assist victims in applying for victim compensation by requiring that sub-recipients also assist victims in understanding their State and federal rights, how to assert those rights, and what to do if their rights are not considered or denied. OVC has not added such a mandate, as these are not eligibility criteria mandated by VOCA, but OVC does encourage all victim assistance organizations to assist victims in understanding their rights, or providing referrals to organizations that can do so, where appropriate. A commenter asked that OVC clarify that victim assistance programs should also assist victims of federal crime in applying for compensation. OVC agrees, and has added language accordingly.

§ 94.114 Prohibited Discrimination

OVC received several comments on proposed section 94.104(h) (now section 94.114 of the final rule), which stated “The VOCA non-discrimination provisions specified at 42 U.S.C. 10604(e) shall be implemented in accordance with 28 CFR part 42, and guidance from the Office for Civil Rights within the Office of Justice Programs.” Several commenters advocated that OVC add explicit regulatory language prohibiting discrimination based on sexual orientation and gender identity to the final rule and offered several reasons why such a provision would benefit victims. OVC acknowledges that people who identify as lesbian, gay, bisexual, transgender, or questioning/queer (“LGBTQ”) suffer disproportionately from violence and its effects, and often do not have access to informed services to help them recover in the aftermath of a crime. However, because OVC did not include in the proposed rule a definition that discrimination based on sex includes discrimination based on sexual orientation, and because OVC anticipates that the law will continue to evolve on this issue, OVC declines to include such language at this time. OVC will continue to monitor legal developments in this area. With respect to gender identity, the Department of Justice has concluded that statutory

prohibitions on discrimination on the basis of sex encompass discrimination based on gender identity in other contexts. See, e.g., Memorandum from Eric H. Holder, Attorney General, Re: Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014). OVC is aware of no reason why the statutory phrase “on the ground of . . . sex” in 42 U.S.C. 10604(e) should receive a different construction.

§ 94.115 Non-Disclosure of Confidential or Private Information

Several commenters noted that OVC had not included a provision regarding confidentiality in the proposed rule, and suggested that OVC add such a provision. The commenters noted that the 2013 reauthorization of the Violence Against Women Act contained a provision, 42 U.S.C. 13935(b)(2), that many VOCA-funded organizations would have to comply with as a condition of their VAWA funding, and suggested that OVC model its provision on that. OVC agrees and has done this in section 94.115 of the final rule.

Sub-Recipient Project Requirements

§ 94.116 Purpose of VOCA-Funded Projects.

OVC renumbered section 94.114 of the proposed rule as section 94.116 of the final rule, under the heading “Sub-Recipient Project Requirements” instead of “Sub-Recipient Program Requirements.” (Section 94.116 of the proposed rule is moved to section 94.118 of the final rule.) This section sets forth a brief statement of the purpose of VOCA sub-awards. The proposed provision was confusing, and OVC has attempted to draft the statement more clearly in the final rule.

Additionally, the requirement in the Guidelines (sec. IV.B.11) that sub-recipients must provide services to victims of federal crimes on the same basis as to victims of crimes under State or local law is added to the final rule, as it was inadvertently omitted from the proposed rule but is a long-standing principle applicable to federal victim assistance funding. The final rule also sets forth OVC’s policy clarification that victim eligibility for direct services under the VOCA Assistance Program is not dependent on the victim’s immigration status. This principle derives from the nature of services provided by most VOCA-funded victim service providers in light of the Personal Responsibility Work Opportunity Reconciliation Act of 1996, and was communicated to all VOCA Assistance

(and Compensation) SAAs in a June 28, 2010, OVC Director Memorandum.

§ 94.117 Cost of Services; Sub-Recipient Program Income

This section sets forth the rules for VOCA-funded projects that will charge for victim services. (Section 94.117 of the proposed rule is moved to section 94.119 of the final rule.) OVC has long held that VOCA-funded victim services should be free of charge for victims where possible, although it recognizes that in some situations a service provider may be justified in charging for services or otherwise generating program income.

The provisions in section 94.117 of the final rule are adapted from sections 94.115(e) and 94.109 of the proposed rule. A commenter suggested that this section be moved to a new division setting out VOCA project requirements; OVC has done this. Commenters also suggested that OVC re-word the provision to be more direct. OVC has done this, as well. OVC also simplified the provision to state that program income must be used consistently with Federal grant rules and the DOJ Grants Financial Guide (available on the Office of Justice Programs’ Web site, at www.ojp.gov), instead of reiterating those requirements here. This aligns the program income rules for this program with the recently issued government-wide grant rules, and this simplification will reduce the burden of compliance on SAAs and sub-recipients.

A commenter requested that OVC add a requirement that sub-recipients provide proof or certification of compliance with the program income requirements when seeking reimbursement from State compensation programs. OVC declines to add such a requirement to this rule, as this type of requirement is more appropriately created in the application requirements and collateral source verification procedures for victim compensation programs, or as an arrangement among State agencies.

§ 94.118 Project Match Requirements

This section is renumbered from 94.116 in the proposed rule to 94.118 in the final rule, and moved under the “Sub-recipient Project Requirements” heading, as commenters correctly pointed out that match is applicable to the VOCA project, not the program. (Section 94.118 of the proposed rule is moved to section 94.120 of the final rule.)

Some commenters suggested eliminating match all together, while others suggested various different levels for match. OVC has kept a match

requirement, as it serves several purposes, including leveraging federal funding, indicating organizational capacity, and encouraging local investment and engagement in VOCA-funded projects.

Some commenters recommended that OVC consider allowing match at the State level, rather than on a sub-recipient by sub-recipient basis, as this would bring VOCA grant rules into harmony with match requirements under other programs (e.g., those in Family Violence Prevention and Services Act and Violence Against Women Act). OVC has declined to make this change, as it would be a major departure from the Guidelines, and as match required on the project level ensures that sub-recipients have a stake in, and are invested and engaged in, the VOCA-funded project. OVC does note, however, that an SAA is authorized to contribute to match using non-federal funds for any (or all) sub-recipient projects, which authorization, as a practical matter, permits SAAs to provide match at the State level.

A commenter asked that OVC modify the proposed requirement that match be used for the same uses and timing as the project's VOCA funding. OVC declines to do so, as this rule is long-standing and consistent with similar rules that apply to other OVC and federal awards. OVC does note, however, that non-cash contributions—for example, professional services—may be counted as match.

Commenters also questioned why Native American and Alaskan Native sub-recipients and projects on tribal lands, as well as projects in U.S. territories and possessions (excluding Puerto Rico), are not required to provide match. Some commenters asked OVC to keep the 5% match for tribes, while other commenters asked that OVC keep the rule as proposed. OVC has found that these communities often lack victim services, have great victim service needs, and are more often likely to have difficulty meeting match requirements. Match serves the purpose of encouraging collaboration among service providers, and creating a local stake in project outcomes, but it also can present a barrier to applying for VOCA assistance funding in tribal and territorial communities that have relatively few victim service organizations, and have not traditionally been supported by resources available to organizations operating in states. Not requiring match as a default for such communities is designed to streamline application requirements in these areas where, in OVC's experience, the benefits of a match requirement are outweighed

by its burdens. OVC agrees that other areas of the country may face similar circumstances, and, therefore, the final rule provides that OVC will consider exceptions to match upon SAA request, and sets forth generally how OVC will evaluate such requests.

Sub-Recipient Allowable/Unallowable Costs

§ 94.119 Allowable Direct Service Costs

This section is renumbered from 94.117 in the proposed rule to 94.119 in the final rule. (Section 94.119 of the proposed rule is moved to section 94.121 of the final rule.) This section sets forth allowable direct service costs for VOCA projects. Most of these allowable costs (and the parameters under which the direct services may be provided) are essentially the same as those in the existing Guidelines and in the proposed rule, but there are some differences, which are discussed below.

General comments. Some general comments asked OVC to clarify that it is not encouraging States to significantly shift funding by allowing new activities. Nowhere in the proposed or this final rule does OVC state that it is encouraging States to significantly shift funding by allowing new activities. Rather, the changes to costs allowed under this program, described below, are important, but marginal, changes that should give States more flexibility when compared to the Guidelines to best serve victims in their communities, but does not require a significant reallocation of resources. Thus, no change is being made in section 94.119 of the final rule to address this comment.

The commenter also asked that OVC clarify that all services provided by VOCA-funded projects are voluntary and should not be contingent upon the client participating in certain support services. OVC is unclear what support services the commenter refers to and so declines to make a change to the rule based on this comment but notes that there are existing rules in place (see 28 CFR part 42) prohibiting services being contingent upon participation in religious activity.

Emergency medical/health care. A commenter expressed concern that proposed section 94.117(a)(1)(ix), which allowed for certain emergency costs for medical and health care, would have limited the amount of time that such services could be provided to 48 hours. OVC believes that the commenter misunderstood the proposed provision, which does not limit such costs, but merely requires that the service provider

reasonably believe that an alternative source of payment will not be available within 48 hours. OVC has clarified, in final section 94.119(a)(9), that service providers may pay these costs when other resources are not expected to be available in time to meet emergency victim needs.

Facilitation of participation in criminal justice and other proceedings.

A commenter suggested that OVC expand the proposed section 94.117(a)(5) to allow service providers to facilitate victim participation in any public proceeding (e.g., juvenile justice hearings; probation, parole, pardon proceedings; grievance procedures, and sexual predator civil commitment proceedings), not merely criminal justice proceedings. OVC agrees that victims often have an interest in participating as a victim in various fora, and has modified the provisions of section 94.119(e) of the final rule accordingly, to allow the facilitation of such participation.

Legal assistance. The final rule, section 94.119(a)(10), is substantively equivalent to the corresponding section of the proposed rule (which was substantively the same as the Guidelines) regarding use of VOCA funds for emergency legal assistance. In the proposed rule, section 94.117(a)(6) would have expanded allowable legal assistance for victims beyond the emergency context. OVC received many comments on this proposed paragraph, which is renumbered as section 94.119(f) in the final rule.

Many of the comments opined that the proposed provision on allowable legal assistance was either too broad or too narrow in what it allowed. One commenter asked that OVC state expressly that legal services for divorce, child support, criminal defense, and tort lawsuits are not appropriate uses of VOCA funding. Other commenters asked that OVC clarify that criminal defense services may be appropriate where it is directly related to intimate partner violence.

OVC has clarified the rule to state expressly which costs are unallowable—those for criminal defense and tort lawsuits. This clarification makes the program consistent with the OVW Legal Assistance for Victims program (many organizations receive both OVC and OVW funding), which also does not fund criminal defense or tort lawsuits, and also creates a bright-line rule that is more easily administered. OVC notes that some jurisdictions allow victims to file a motion to vacate and/or expunge certain convictions based on their status of being victims. OVC has clarified that such services are allowable with VOCA

funds. The OVW program does support legal assistance with victim-related family law matters, and OVC has drafted the language of paragraph (f)(3) to be broad enough to include these and other non-tort legal services in a civil context that are reasonably necessary as a direct result of the victimization as allowable costs. Such non-tort, civil legal services include, but are not limited to, assistance in divorce, and child custody and support proceedings.

Many commenters wanted OVC to expand its examples of allowable legal assistance costs in the proposed rule to include specific examples relevant to the organization commenting. On the other hand, some commenters expressed concern that some organizations may misinterpret the examples in the proposed rule as limits. OVC has carefully considered these comments and, in the final rule, has opted to move most of the examples into the preamble of the rule. OVC will issue supplementary guidance as may be needed to further clarify the applicability of the rule in specific factual scenarios.

The following are examples (which are merely illustrative, and not meant to be a comprehensive listing) of some circumstances where civil legal services may be appropriate: Proceedings for protective/restraining orders or campus administrative protection/stay-away orders; family, custody, contract, housing, and dependency matters, particularly for victims of intimate partner violence, child abuse, sexual assault, elder abuse, and human trafficking; immigration assistance for victims of human trafficking, sexual assault, and domestic violence; intervention with creditors, law enforcement (e.g., to obtain police reports), and other entities on behalf of victims of identity theft and financial fraud; intervention with administrative agencies, schools/colleges, tribal entities, and other circumstances where legal advice or intervention would assist in addressing the consequences of a person's victimization. OVC recognizes that the available resources in each State differ, and, therefore, States retain broad discretion to set limits on the type and scope of legal services that it allows its sub-recipients to provide with VOCA funding.

Forensic medical evidence collection examinations. OVC received several generally supportive comments regarding proposed section 94.117(a)(7), which allowed forensic medical evidence collection examinations to the extent that other funding sources are insufficient, the examination meets State standards, and appropriate crisis

counseling and/or other victim services are offered in conjunction with the examination. The final rule, renumbered as section 94.119(g), is unchanged from the proposed rule, except that the final rule does not require examinations to meet State standards, but rather encourages sub-recipients to use specially trained examiners such as Sexual Assault Nurse Examiners to perform these exams. The final rule, similarly, encourages, rather than mandates, that crisis counseling or other services be offered in conjunction with the examination, in order to allow sub-recipients to provide such services as may be appropriate in any given situation.

Forensic interviews. OVC received several comments on proposed section 94.117(a)(8), which allowed forensic interviews, and which is renumbered as section 94.119(h) in the final rule. Some commenters supported allowing VOCA funding for forensic interviews, while others expressed the opinion that VOCA funds should not fund investigative costs. Allowing States to support the costs of victim-centered forensic interviews, particularly those conducted in a multi-disciplinary setting, will help victims by reducing traumatization.

The final rule does not include the provision in proposed section 94.117(a)(8)(iv), which would have disallowed VOCA funding used to supplant other funding available for forensic interviews, including criminal justice funding. OVC believes that providing States additional flexibility to meet this important victim need (which, if unsupported, may lead to re-traumatization of the victim) outweighs potential concerns that victim service funding will supplant law enforcement funding for this activity.

A commenter cautioned that forensic interviews should be conducted by child advocacy center forensic interviewers who have training and adhere to the National Child Advocacy Center guidelines. OVC believes this comment is well intentioned, but notes that not all victims needing specialized forensic interviews are children—for example, some victims are adults with disabilities. Moreover, the Federal Bureau of Investigation and some States use alternative standards. Therefore, OVC defers to SAAs to determine what organizations appropriately may provide this service.

Services to incarcerated individuals. The existing Guidelines do not allow OVC Victim Assistance Program funds to be used for rehabilitative services or support services to incarcerated individuals (see Guidelines, section IV.E.3.b). OVC, in proposed section

94.120(b) would have modified the prohibition on perpetrator rehabilitation and counseling, to allow services to incarcerated victims in certain circumstances, and, in proposed section 94.117(a)(11), set out proposed rules describing such circumstances.

In this final rule, OVC simply removes the prohibition on perpetrator rehabilitation and counseling, as the prohibition unnecessarily prevents States and communities from fully leveraging all available resources to provide services to these victims, who have been shown to have a great need for such services. States and VOCA-funded sub-recipients may set eligibility criteria for their victim service projects, and thereby determine, in accordance with VOCA and this rule, whether and how such victims might be served by VOCA-funded projects. Correspondingly, OVC does not include any provision under allowable costs addressing services to incarcerated victims, as the costs permitted for direct services to incarcerated victims are the same as those permitted for such services to any crime victim.

OVC received a wide range of comments on this provision. Many were supportive of the removal of the prohibition on providing services to incarcerated victims. Some commenters wanted OVC to affirmatively encourage States to permit sub-grantees to use VOCA funding for such services. Some commenters expressed the sentiment that the prison system should be responsible for addressing victim services for incarcerated persons, in the same way that it provides medical care and other services. OVC agrees that the government agencies that oversee detention/correctional facilities have responsibilities for the care of victims within their custody, but believes that prohibiting VOCA-funded organizations from providing services to incarcerated victims deprives such victims of, and communities of, experienced victim service resources. Indeed, such organizations are often the only organizations able to provide such services in some communities.

A commenter noted that the restriction causes agencies routinely to deny services to incarcerated victims but provides the exact same services for the exact same crime to those assaulted just outside the facility. OVC recognizes that victim service resources are finite, but believes that States are best positioned to make resource allocation decisions. Removing the prohibition on serving incarcerated victims will allow States to serve all victims better and more efficiently leverage the expertise of victim service organizations.

Several commenters expressed concern that the proposed rule may trigger the Prison Rape Elimination Act (PREA) provision requiring a reduction or reallocation of federal funding available to a State for “prison purposes” if the State fails to certify compliance with the Department’s National Standards to Prevent, Detect, and Respond to Prison Rape. See 42 U.S.C. 15607(e); 28 CFR part 115. The commenters suggested various ways to re-draft the proposed rule to make it clear that VOCA funds are not available for “prison purposes” and mandated reduction or reallocation under PREA. Some commenters expressed support for the proposed rule, but only if the Department clarified that the change would not bring VOCA funding under the PREA penalty. In response, OVC notes that VOCA funds are not available for “prison purposes,” but rather, are—by statute—specifically allocated for victim services.

The final rule, in response to these concerns, does not require that services to incarcerated victims must be provided, or how such services should be provided, but merely removes the express prohibition on such services that existed in the Guidelines. As noted in section 94.103 of the final rule, SAAs have sole discretion to determine what organizations will receive funds, and in what amounts, subject to the minimum requirements of this final rule and VOCA. Nothing in VOCA, or this final rule, allows VOCA funding to be diverted to “prison purposes;” rather, VOCA funding is expressly limited by statute to victim services and associated activities. A letter issued to State governors by OVC and OVW on February 11, 2014, did not list any VOCA programs as being available for prison purposes. See http://www.prearesourcecenter.org/sites/default/files/content/feb_11_2014_prea_letter_with_certification_and_assurance_forms.pdf. VOCA funding, therefore, is not subject to mandated reduction or reallocation for non-compliance under PREA.

Transitional housing. The final rule, at section 94.119(k), includes one noteworthy change from section 94.117(a)(12) of the proposed rule, in which OVC proposed to allow States more flexibility to allow VOCA-funded projects to support transitional housing. Specifically, the final rule provides examples of expenses typically associated with transitional housing to help illustrate allowable uses of this funding. OVC views transitional housing as a necessary victim expense for some victims. This is particularly true for victims of human trafficking,

victims with disabilities abused by caretakers, domestic violence victims and their dependents, and sexual assault victims. Under the proposed rule, States may use VOCA funds for housing and shelter purposes to the extent that such is necessary as a consequence of the victimization and for the well-being of the victim.

For example, shelters for victims of domestic violence or human trafficking would be allowable uses of VOCA funds. Similarly, it would be allowable in the case of sexual assault, where a victim needs to move. To the extent SAAs choose to permit VOCA funds to be used for transitional housing purposes, OVC anticipates that these agencies would focus on those victims with the most need.

Some commenters liked the proposed rules on transitional housing and relocation, while others opposed them. A commenter noted that VOCA-funded programs may not have the experience or resources to monitor housing programs. OVC recognizes that some SAAs will not have such experience, but the rule merely *allows* States to fund this activity; it does not require it. OVC expects that States will exercise their discretion to fund only projects that they believe will be able to undertake the allowed activities successfully.

One commenter wanted OVC to clarify that state limits on types of victims eligible for transitional housing assistance must not violate VOCA non-discrimination provisions. OVC agrees that States may not violate the non-discrimination provision when prescribing limits on allowable costs for transitional housing. The commenter also requested that OVC define “dependent child” to include dependents of all LGBTQ survivors. OVC strongly agrees that dependents of LGBTQ victims should be eligible for such assistance to the same extent as dependents of non-LGBTQ victims, if such assistance is provided. The VOCA rule establishes the basic rules for State administration of VOCA funds, however, and prescribing detailed rules for eligibility for particular types of assistance projects, as the commenter suggests, is beyond the scope of the rule.

A commenter suggested that OVC add language setting out factors that States should consider when setting limits on transitional housing expenses. OVC declines to include these in the rule, but notes that States may choose to consider the factors mentioned, which include the availability of affordable alternative and rental housing; other sources of support and housing for the victim, such as Section 8 housing vouchers in the immediate locale of the victim; and

waiting lists for Section 8 housing in the area.

A commenter suggested that OVC use OVW’s transitional housing program as a model. OVC is not setting detailed parameters for transitional housing costs in this rule. To the extent they find the OVW model is useful, the final rule allows States to follow that model.

A commenter requested that OVC advise States to use their VOCA Compensation funds to meet transitional housing needs, before accessing VOCA Assistance funding for this purpose. OVC notes that it does not anticipate States using VOCA Assistance funding to create new programs for transitional housing, though this would be permissible. Instead, OVC anticipates that States may allow VOCA-funded service providers to expand the range of services offered to victims, and supported by the VOCA subaward, to include transitional housing. OVC further notes that each State Compensation program determines coverage of crimes and expenses for its jurisdiction. Therefore, some State Compensation programs may not cover transitional housing needs. OVC wishes to allow States the flexibility to access either VOCA Assistance or Compensation funding for transitional housing related needs, as would best serve victims and is permissible in their jurisdictions, and therefore declines to recommend that States access VOCA Compensation funds prior to accessing VOCA Assistance funds.

Relocation expenses. The final rule, at 94.119(l), generally remains substantially unchanged from the proposed rule, 94.117(a)(13), although the language in this paragraph is reorganized from the proposed rule. The final rule removes the emphasis on particular victims (*i.e.*, domestic violence victims, victims of sexual assault, and victims of human trafficking) who may be in need of relocation assistance. This language is removed so as not to limit inadvertently those victims who are eligible for relocation expenses.

Additionally, the final rule omits the reference in the proposed rule to providing “mortgage assistance”, due to the complicated nature of administering such assistance. Thus, under the final rule, while relocation expenses are allowable, mortgage expenses are not allowable.

§ 94.120 Allowable Costs for Activities Supporting Direct Services

OVC renumbered this section from 94.118 in the proposed rule to 94.120 in the final rule, setting forth allowable activities that support direct services.

(Section 94.120 of the proposed rule is moved to section 94.122 of the final rule.)

One commenter asked (with regard to co-ordination activities, automated systems and technology, and volunteer trainings) whether these are allowable as stand-alone projects that may be funded by a State, or whether they must be part of a direct service project. OVC intends that these may be funded by a State in either manner. If they are funded as stand-alone activities, however, they should be activities that leverage resources for direct victim services (e.g., a stand-alone project to train volunteers may make more volunteers available to provide direct services).

Coordination of activities. The final rule gives SAAs the latitude to allow sub-recipients to use VOCA funds for activities coordinating victim services. Many commenters supported this provision in the proposed rule. A few opposed, as they were concerned this would divert VOCA resources away from other activities. OVC notes that the final rule provides States with additional flexibility, but does not mandate that States reallocate any funding. Moreover, in the last decade it has become apparent that co-ordination and oversight activities are desirable and may in many cases improve the provision of direct victim services.

A commenter requested that OVC add coalitions to support and assist victims to the list of allowable activities, and OVC has done this.

Contracts for professional services. OVC proposed to allow sub-recipients to contract for professional services not available within the sub-recipient organization (in contrast to the Guidelines, which does not allow this). OVC has maintained this section as proposed, in section 94.120(d) of the final rule, but made the examples more concise and conceptual to improve readability. Some commenters suggested that the rule needed to reflect better how contract service providers charge overhead costs, suggesting that the rule be made consistent with that for volunteered services; i.e., the contract rate must be a reasonable market rate for the services provided. OVC agrees and has done this.

Automated systems and technology. The proposed rule at section 94.118(e) would have allowed the use of funds for automated systems and technology that support delivery of direct services to victims, and provided examples of such systems and technology, and provided that procurement of personnel, hardware, and other items, were allowable if permitted by the SAA. The

final rule, at section 94.120(e), reorganizes the proposed paragraph to fit with the revised structure of the overall section. It also adds a provision indicating that the allowability of such systems and technology is subject to the DOJ Financial Guide and government-wide grant rules, which provide detailed rules relating to the acquisition, use, and disposition of technology equipment and supplies. See 2 CFR part 200. Certain criteria for SAAs to consider when permitting sub-recipients to use funding for automated systems and technology were set out in the Guidelines, but were omitted from the proposed rule. These are added back into the final rule as factors that may be useful for SAAs to consider when determining whether to permit funding to be used for this purpose.

Volunteer trainings. The proposed rule, at section 94.118(f) allowed the use of direct service funding in certain circumstances to train volunteer direct service providers, and OVC has kept this provision largely unchanged, at 94.120(6). The proposed rule focused on Court Appointed Special Advocate (CASA) volunteers, but commenters suggested that the final rule should be more general, so as not to limit such funding to the CASA context. OVC agrees and has made this edit. The use of direct service funds to support training and co-ordination of volunteer services in such circumstances is appropriate, as it typically allows funded organizations to cost-effectively leverage the available funds and volunteer efforts to provide more direct services for victims.

Restorative justice. The proposed rule inadvertently omitted reference to restorative justice efforts, which are permitted in the current Guidelines. OVC has added this back into this final rule at section 94.120(g). The final rule is substantially similar to the Guidelines, except that the paragraph is reorganized to fit stylistically within the final rule, and to provide examples of restorative justice efforts (e.g., tribal community-led meetings and peace-keeping activities). Also, where the Guidelines required such efforts to have “possible” beneficial or therapeutic value, the final rule requires that such efforts must have “reasonably anticipated” beneficial or therapeutic value. OVC believes that such a standard is better suited to meet victim needs.

The final rule provides that a victim’s opportunity to withdraw must be inherent in any restorative justice effort supported by program funds, whereas the Guidelines had merely included this as one of several criteria that SAAs

should consider when deciding whether to fund such efforts. Lastly, the Guidelines included as another criteria the benefit or therapeutic value to the victim, while the final rule requires that SAAs also consider the costs in relation to the benefit or therapeutic value to the victim, as restorative justice efforts can be expensive and those costs may not be justified under certain circumstances.

§ 94.121 Allowable Sub-Recipient Administrative Costs

Section 94.121 of the final rule sets out allowable sub-recipient administrative costs. These are substantively the same as those in the existing Guidelines, and as in proposed section 94.119.

A commenter noted that there was a discrepancy in the proposed rule, in that training costs were allowed for non-VOCA-funded service providers, but travel costs to attend trainings were *not* allowed for such providers. OVC agrees that training and training-related travel for non-VOCA-funded service provider staff should be allowable, and has changed the final rule accordingly, at section 94.121(c). The commenter also asked that OVC include certain additional items (e.g., costs of Web sites, social media, mobile devices) in the examples of allowable administrative costs, and OVC has done this in section 94.121(f).

Several commenters suggested that evaluation costs in section 94.121(j) should be capped at a percentage of the grant. OVC believes that evaluation is an important part of improving victim services by developing data-driven improvements to programs and does not cap evaluation costs in the rule. OVC does note that the rule does not prevent SAAs from capping such costs (on a State-wide or project-by-project basis, as appropriate), or limiting such costs to amounts that are reasonable given State goals and funding constraints.

§ 94.122 Expressly Unallowable Sub-Recipient Costs

OVC has renumbered proposed 94.120 as section 94.122 of the final rule, setting forth expressly unallowable project costs. Most of these provisions are the same as those in the existing Guidelines, and the proposed rule, with the following exceptions:

Perpetrator rehabilitation and counseling. The rule prohibiting use of VOCA funds for perpetrator rehabilitation and counseling has been removed to allow VOCA-funded service providers to provide victim assistance services to victims who are incarcerated. This is more fully discussed above in

the discussion of comments under section 94.115 of the final rule.

Victim attendance at conferences. OVC has removed this odd provision from the list of unallowable costs, but expects that sub-recipients will not use funds for this purpose.

Purchasing vehicles. Some commenters favored allowing the purchase of vehicles with VOCA funds, but others opposed it. OVC agrees with comments that pointed out that in some jurisdictions purchasing a vehicle may be more cost effective than leasing a vehicle for victim service work and has removed purchasing vehicles from the list of unallowable costs. States now have the discretion to allow sub-recipients to lease or purchase vehicles.

Indirect organizational costs. The government-wide grant requirements in 2 CFR part 200, as implemented in December 2014 by the Department of Justice at 2 CFR part 2800 (79 FR 76081, Dec. 19, 2014), state a policy that federal awards should bear their fair share of costs, including reasonable, allocable, and allowable direct and indirect costs. This contrasts with the VOCA Guidelines, which prohibit indirect organizational costs. Given the policy in the recently issued government-wide requirements, OVC has removed the provision that prohibited sub-recipients from using VOCA funds for certain organizational costs. Removing the prohibition should simplify administration of VOCA sub-awards, by aligning the requirements for VOCA-funded projects, with the government-wide grant requirements and cost principles, which allow federal funding to support sub-recipient indirect costs (*see* 2 CFR 200.331 and 200.414).

In the Guidelines, and the proposed rule at 94.120(f), liability insurance on buildings, and body guards (which OVC understands to mean security guards, as it is listed as a capital expense), were not allowable. OVC removes these from the list of unallowable costs in the final rule, as these costs may be allowable under the revised government-wide grant rules in 2 CFR part 200, if appropriately allocated to an award either directly or indirectly.

IV. Regulatory Certifications

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Office for Victims of Crime has reviewed this regulation and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. The OVC Victim Assistance Program distributes funding to States pursuant to

the VOCA formula, a statutory provision, which is not affected by this regulation. The VOCA formula sets out the allocation of grant funds among States, and designates the States that will receive grant funds—the regulation alters neither the allocation of Federal funding, nor the designation of which States will receive annual funding pursuant to that allocation. Moreover, VOCA affords substantial latitude to the States in determining where to allocate the formula funding within each jurisdiction. This rule, to the extent that it creates certain set asides and permissible areas of emphasis for State victim assistance programs, only applies to federally provided funding. As a rule governing a Federal grant program to States and major U.S. territories, the only economic impact on small entities is that of potential financial assistance, as the rule would not apply to any entity that was not a recipient of VOCA funding under this program. This regulation, therefore, will not have a significant economic impact on a substantial number of small entities.

Executive Orders 12866 and 13563—Regulatory Review

This rule has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review” section 1(b), Principles of Regulation, and in accordance with Executive Order 13563 “Improving Regulation and Regulatory Review” section 1(b), General Principles of Regulation.

The Office of Justice Programs has determined that this rule is a “significant regulatory action” under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits and costs are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitative values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The rule merely clarifies and updates the existing Guidelines, but does not

alter the existing program structure at all. Updating the existing Guidelines to clearly and accurately reflect the statutory parameters will facilitate State compliance with VOCA requirements, and thus avoid potentially costly non-compliance findings. The rule makes some substantive changes to the existing Guidelines, but most of these would be of a permissive, not restrictive or mandatory, nature. Some changes, like allowing more flexibility to co-ordinate and leverage community resources, and adopt alternative monitoring strategies, would impose no costs but will potentially allow States to use existing funding more efficiently. Other changes that allow States to allocate funding to services not presently allowable could change the allocation of VOCA funding among victim services provided by sub-recipient organizations, and among victim service organizations. Such reallocations of funding, however, are not mandated and each State would make the ultimate decision with regard to whether to change its current funding allocations, if it chooses to do so at all. This is not a change from the present discretion that States have to allocate funding according to State priorities. Any potential reallocations would be relatively minor (even when taken in aggregate across States) in comparison to the overall mix of allowable victim services, and thus they are unlikely to create new costs or significant fund transfers. In any event, the benefits of additional services for underserved and un-served victims are significant.

The provision allowing alternative risk-based monitoring procedures imposes no new costs on States that choose to retain their existing procedures, but will allow States that wish to implement more cost effective alternatives to do so.

The elimination of match for American Indian and Alaskan Native tribes and projects on tribal lands will permit victim service organizations in these communities, many of which do not have the resources to provide matching funds, the ability to more easily seek VOCA funding for victim services. This will benefit victims in these communities, many of whom are underserved. This change is unlikely to impose new costs on States, as there is no requirement that the administering agencies fund American Indian or Alaskan Native tribes or organizations at a particular level, and the amount of funding allocated to these organizations historically is a very small percentage of overall VOCA funding.

All of the changes to the provisions governing allowable and unallowable costs are in the nature of granting States

additional flexibility to fund certain activities. None of the changes would require States to expend additional funding in any area, or change funding allocations. Moreover, the changes, while important, are relatively minor when compared to the entire scope of costs allowable with VOCA funding. Consequently, to the extent that States choose to fund the newly allowable victim services (e.g., increased time allowed in transitional housing), the reallocation of funding will not result in a significant reallocation of overall funding, given the small number of newly allowable services when compared to the overall mix of allowable victim services. In addition, it is not certain which States will permit what additional services if given the flexibility to do so, and to what extent, as these decisions typically are often made through State legislative or administrative processes and address considerations unique to each State. The important benefit of such potential minor reallocations of resources, whether within organizations that presently receive VOCA funding and will provide augmented services, or (in the less common case) to new organizations, would be that previously underserved or un-served victims would receive needed assistance.

Executive Order 13132—Federalism

This rule 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, as the rule only affects the eligibility for, and use of, federal funding under this program. The rule will not impose substantial direct compliance costs on State and local governments, or preempt any State laws. Therefore, in accordance with Executive Order No. 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) & (b)(2) of Executive Order No. 12988. Pursuant to section 3(b)(1)(I) of the Executive Order, nothing in this or any previous rule (or in any administrative policy, directive, ruling, notice, guideline, guidance, or writing) directly relating to the Program that is the subject of this rule is intended to create any legal or procedural rights enforceable against the United States, except as the same may be contained

within subpart B of part 94 of title 28 of the Code of Federal Regulations.

Unfunded Mandates Reform Act of 1995

This rule 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. The VOCA Victim Assistance Program is a formula grant program that provides funds to States to provide financial support to eligible crime victim assistance programs. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule 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.

Paperwork Reduction Act

This rule does not propose any new, or changes to existing, “collection[s] of information” as defined by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) and its implementing regulations at 5 CFR part 1320.

OVC sets forth a requirement, in section 94.105 of the final rule that SAAs update their subgrant award report information within 30 days of a change in such information. This requirement does not change the overall burden of the subgrant award report, which is estimated to take approximately three minutes to complete. It merely provides a reasonable timeframe for updating information that changes during a grant period. As the report contains only high level summary data, not detailed budget data, OVC estimates that the burden of requiring updates of this report throughout the grant period will be minimal.

List of Subjects in 28 CFR Part 94

Administrative practice and procedure, Formula grant program, Victim assistance.

Accordingly, for the reasons set forth in the preamble, Title 28, part 94, of the

Code of Federal Regulations is amended as follows:

PART 94—CRIME VICTIM SERVICES

■ 1. The authority citation for part 94 is revised to read as follows:

Authority: 42 U.S.C. 10603, 10603c, 10604(a), 10605.

■ 2. Add subpart B to read as follows:

Subpart B—VOCA Victim Assistance Program

General Provisions

Sec.

94.101 Purpose and scope; future guidance; construction and severability; compliance date.

94.102 Definitions.

SAA Program Requirements

94.103 General.

94.104 Allocation of sub-awards.

94.105 Reporting requirements.

94.106 Monitoring requirements.

SAA Use of Funds for Administration and Training

94.107 Administration and training.

94.108 Prohibited supplantation of funding for administrative costs.

94.109 Allowable administrative costs.

94.110 Allowable training costs.

Sub-Recipient Program Requirements

94.111 Eligible crime victim assistance programs.

94.112 Types of eligible organizations and organizational capacity.

94.113 Use of volunteers, community efforts, compensation assistance.

94.114 Prohibited discrimination.

94.115 Non-disclosure of confidential or private information.

Sub-Recipient Project Requirements

94.116 Purpose of VOCA projects.

94.117 Costs of services; sub-recipient program income.

94.118 Project match requirements.

Sub-Recipient Allowable/Unallowable Costs

94.119 Allowable direct service costs.

94.120 Allowable costs for activities supporting direct services.

94.121 Allowable sub-recipient administrative costs.

94.122 Expressly unallowable sub-recipient costs.

Subpart B—VOCA Victim Assistance Program

General Provisions

§ 94.101 Purpose and scope; future guidance; construction and severability; compliance date.

(a) *Purpose and scope.* This subpart implements the provisions of VOCA, at 42 U.S.C. 10603, which, as of July 8, 2016, authorize the Director to make an annual grant to the chief executive of each State for the financial support of

eligible crime victim assistance programs. VOCA sets out the statutory requirements governing these grants, and this subpart should be read in conjunction with it. Grants under this program also are subject to the government-wide grant rules in 2 CFR part 200, as implemented by the Department of Justice at 2 CFR part 2800, and the DOJ Grants Financial Guide.

(b) *Future guidance.* The Director may, pursuant to 42 U.S.C. 10604(a), prescribe guidance for grant recipients and sub-recipients under this program on the application of this subpart.

(c) *Construction and severability.* Any provision of this subpart held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable from this part and shall not affect the remainder thereof or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

(d) *Compliance date.* This subpart applies to all grants under this program made by OVC after August 8, 2016, except for funds that the SAA obligated before August 8, 2016 (*i.e.* pre-award funds under grants made in 2016). SAAs may permit the use of funds that are unobligated as of August 8, 2016 for activities permitted by this subpart, but not by the Guidelines.

§ 94.102 Definitions.

As used in this subpart:

Crime victim or victim of crime means a person who has suffered physical, sexual, financial, or emotional harm as a result of the commission of a crime.

Director means the Director of OVC.

Direct services or services to victims of crime means those services described in 42 U.S.C. 10603(d)(2), and efforts that—

- (1) Respond to the emotional, psychological, or physical needs of crime victims;
- (2) Assist victims to stabilize their lives after victimization;
- (3) Assist victims to understand and participate in the criminal justice system; or
- (4) Restore a measure of security and safety for the victim.

OVC means the Office for Victims of Crime, within the United States Department of Justice's Office of Justice Programs.

Project means the direct services project funded by a grant under this program, unless context indicates otherwise.

Spousal abuse includes domestic and intimate partner violence.

State Administering Agency or SAA is the governmental unit designated by the chief executive of a State to administer grant funds under this program.

Sub-recipient means an entity that is eligible to receive grant funds under this program from a State under this subpart.

Victim of child abuse means a victim of crime, where such crime involved an act or omission considered to be child abuse under the law of the relevant SAA jurisdiction. In addition, for purposes of this program, victims of child abuse may include, but are not limited to, child victims of: Physical, sexual, or emotional abuse; child pornography-related offenses; neglect; commercial sexual exploitation; bullying; and/or exposure to violence.

Victim of federal crime means a victim of an offense in violation of a federal criminal statute or regulation, including, but not limited to, offenses that occur in an area where the federal government has jurisdiction, whether in the United States or abroad, such as Indian reservations, national parks, federal buildings, and military installations.

VOCA means the Victims of Crime Act of 1984, Public Law 98–473 (Oct. 12, 1984), as amended.

VOCA funds or VOCA funding means grant funds (or grant funding) under this program.

VOCA grant means the annual grant from OVC to a State under this program.

SAA Program Requirements

§ 94.103 General.

(a) *Direct services.* SAAs may use VOCA funds to provide direct services through sub-recipients or in their own projects, and to cover administrative and training costs of the SAA. SAAs have sole discretion to determine which organizations will receive funds, and in what amounts, subject to the minimum requirements set forth in VOCA and this subpart. SAAs must ensure that projects provide services to victims of federal crimes on the same basis as to victims of crimes under State or local law. SAAs may fund direct services regardless of a victim's participation in the criminal justice process. Victim eligibility under this program for direct services is not dependent on the victim's immigration status.

(b) *SAA eligibility certification.* Each SAA must certify that it will meet the criteria set forth in VOCA, at 42 U.S.C. 10603(a)(2), and in this subpart. This certification shall be submitted by the chief executive of the State (or a designee) annually in such form and

manner as OVC specifies from time to time. As of July 8, 2016, VOCA requires the chief executive to certify that—

(1) Priority will be given to programs providing assistance to victims of sexual assault, spousal abuse, or child abuse;

(2) Funds will be made available to programs serving underserved victims;

(3) VOCA funds awarded to the State, and by the State to eligible crime victim assistance programs, will not be used to supplant State and local government funds otherwise available for crime victim assistance.

(c) *Pass-through administration.* SAAs have broad latitude in structuring their administration of VOCA funding. VOCA funding may be administered by the SAA itself, or by other means, including the use of pass-through entities (such as coalitions of victim service providers) to make determinations regarding award distribution and to administer funding. SAAs that opt to use a pass-through entity shall ensure that the total sum of VOCA funding for administrative and training costs for the SAA and pass-through entity is within the VOCA limit, the reporting of activities at the direct-service level is equivalent to what would be provided if the SAA were directly overseeing sub-awards, and an effective system of monitoring sub-awards is used. SAAs shall report on the pass-through entity in such form and manner as OVC may specify from time to time.

(d) *Strategic planning.* SAAs are encouraged to develop a funding strategy, which should consider the following: The range of direct services throughout the State and within communities; the sustainability of such services; the unmet needs of crime victims; the demographic profile of crime victims; the coordinated, cooperative response of community organizations in organizing direct services; the availability of direct services throughout the criminal justice process, as well as to victims who are not participating in criminal justice proceedings; and the extent to which other sources of funding are available for direct services.

(e) *Coordination.* SAAs are encouraged to coordinate their activities with their jurisdiction's VOCA compensation programs, STOP Violence Against Women Formula Grant Program administrator, victim assistance coalitions, federal agencies, and other relevant organizations.

(f) *Compliance with other rules and requirements.* SAAs shall comply (and ensure sub-recipient compliance) with all applicable provisions of VOCA, this subpart, and any guidance issued by

OVC, as well as all applicable provisions of the DOJ Grants Financial Guide and government-wide grant rules.

(g) *Access to records.* SAAs shall, upon request, and consistent with 2 CFR 200.336, permit OVC access to all records related to the use of VOCA funding.

§ 94.104 Allocation of sub-awards.

(a) *Directed allocation of forty percent overall.* Except as provided in paragraph (d) of this section, each SAA shall allocate each year's VOCA grant as specified below in paragraphs (b) and (c) of this section. Where victims of priority category crimes are determined to be underserved as well, an SAA may count funds allocated to projects serving such victims in either the priority category or the underserved category, but not both.

(b) *Priority categories of crime victims (thirty percent total).* SAAs shall allocate a minimum of ten percent of each year's VOCA grant to each of the three priority categories of victims specified in the certification requirement in VOCA, at 42 U.S.C. 10603(a)(2)(A), which, as of July 8, 2016, includes victims of—

- (1) Sexual assault,
- (2) Spousal abuse and
- (3) Child abuse.

(c) *Previously underserved category (ten percent total).* SAAs shall allocate a minimum of ten percent of each year's VOCA grant to underserved victims of violent crime, as specified in VOCA, at 42 U.S.C. 10603(a)(2)(B). To meet this requirement, SAAs shall identify which type of crime victim a service project assists by the type of crime they have experienced or the demographic characteristics of the crime victim, or both.

(d) *Exceptions to required allocations.* The Director may approve an allocation different from that specified in paragraphs (b) and (c) of this section, pursuant to a written request from the SAA that demonstrates (to the satisfaction of the Director) that there is good cause therefor.

(e) *Sub-award process: Documentation, conflicts of interest, and competition of funding to sub-recipients.* (1) SAAs have sole discretion to determine which organizations will receive funds, and in what amounts, subject to the requirements of VOCA, this subpart, and the provisions in the DOJ Grants Financial Guide relating to conflicts of interest. SAAs must maintain a documented methodology for selecting all competitive and non-competitive sub-recipients.

(2) SAAs are encouraged to award funds through a competitive process,

when feasible. Typically, such a process entails an open solicitation of applications and a documented determination, based on objective criteria set in advance by the SAA (or pass-through entity, as applicable).

(f) *Direct-service projects run by SAAs.* An SAA may use no more than ten percent of its annual VOCA grant to fund its own direct service projects, unless the Director grants a waiver.

§ 94.105 Reporting requirements.

(a) *Subgrant award reports.* SAAs shall submit, at such times and in such form and manner as OVC may specify from time to time, subgrant award reports to OVC for each project that receives VOCA funds. If an SAA awards funds to a pass-through entity, the SAA also shall submit a report on the pass-through entity, at such times and in such form and manner as OVC may specify from time to time.

(b) *Performance report.* SAAs shall submit, in such form and manner as OVC may specify from time to time, performance reports to OVC on a quarterly basis.

(c) *Obligation to report fraud, waste, abuse, and similar misconduct.* SAAs shall—

(1) Promptly notify OVC of any formal allegation or finding of fraud, waste, abuse, or similar misconduct involving VOCA funds;

(2) Promptly refer any credible evidence of such misconduct to the Department of Justice Office of the Inspector General; and

(3) Apprise OVC, in timely fashion, of the status of any on-going investigations

§ 94.106 Monitoring requirements.

(a) *Monitoring plan.* Unless the Director grants a waiver, SAAs shall develop and implement a monitoring plan in accordance with the requirements of this section and 2 CFR 200.331. The monitoring plan must include a risk assessment plan.

(b) *Monitoring frequency.* SAAs shall conduct regular desk monitoring of all sub-recipients. In addition, SAAs shall conduct on-site monitoring of all sub-recipients at least once every two years during the award period, unless a different frequency based on risk assessment is set out in the monitoring plan.

(c) *Recordkeeping.* SAAs shall maintain a copy of site visit results and other documents related to compliance.

SAA Use of Funds for Administration and Training

§ 94.107 Administration and training.

(a) *Amount.* No SAA may use more than the amount prescribed by VOCA, at

42 U.S.C. 10603(b)(3), for training and administration. As of July 8, 2016, the amount is five percent of a State's annual VOCA grant.

(b) *Notification.* An SAA shall notify OVC of its decision to use VOCA funds for training or administration, either at the time of application for the VOCA grant or within thirty days of such decision. Such notification shall indicate what portion of the amount will be allocated for training and what portion for administration. If VOCA funding will be used for administration, the SAA shall follow the rules and submit the certification required in § 94.108 regarding supplantation.

(c) *Availability.* SAAs shall ensure that each training and administrative activity funded by the VOCA grant occurs within the award period.

(d) *Documentation.* SAAs shall maintain sufficient records to substantiate the expenditure of VOCA funds for training or administration.

(e) *Volunteer training.* SAAs may allow sub-recipients to use VOCA funds to train volunteers in how to provide direct services when such services will be provided primarily by volunteers. Such use of VOCA funds will not count against the limit described in paragraph (a) of this section.

§ 94.108 Prohibited supplantation of funding for administrative costs.

(a) *Non-supplantation requirement.* SAAs may not use VOCA funding to supplant State administrative support for the State crime victim assistance program. Consistent with the DOJ Grants Financial Guide, such supplantation is the deliberate reduction of State funds because of the availability of VOCA funds. Where a State decreases its administrative support for the State crime victim assistance program, the SAA must submit, upon request from OVC, an explanation for the decrease.

(b) *Baseline for administrative costs.* In each year in which an SAA uses VOCA funds for administration, it shall—

(1) Establish and document a baseline level of non-VOCA funding required to administer the State victim assistance program, based on SAA expenditures for administrative costs during that fiscal year and the previous fiscal year, prior to expending VOCA funds for administration; and

(2) Submit the certification required by 42 U.S.C. 10604(h), which, as of July 8, 2016, requires an SAA to certify here that VOCA funds will not be used to supplant State funds, but will be used to increase the amount of such funds that would, in the absence of VOCA

funds, be made available for administrative purposes.

§ 94.109 Allowable administrative costs.

(a) Funds for administration may be used only for costs directly associated with administering a State's victim assistance program. Where allowable administrative costs are allocable to both the crime victim assistance program and another State program, the VOCA grant may be charged no more than its proportionate share of such costs. SAAs may charge a federally-approved indirect cost rate to the VOCA grant, provided that the total amount charged does not exceed the amount prescribed by VOCA for training and administration.

(b) Costs directly associated with administering a State victim assistance program generally include the following:

(1) *Salaries and benefits* of SAA staff and consultants to administer and manage the program;

(2) *Training* of SAA staff, including, but not limited to, travel, registration fees, and other expenses associated with SAA staff attendance at technical assistance meetings and conferences relevant to the program;

(3) *Monitoring compliance* of VOCA sub-recipients with federal and State requirements, support for victims' rights compliance programs, provision of technical assistance, and evaluation and assessment of program activities, including, but not limited to, travel, mileage, and other associated expenses;

(4) *Reporting* and related activities necessary to meet federal and State requirements;

(5) *Program evaluation*, including, but not limited to, surveys or studies that measure the effect or outcome of victim services;

(6) *Program audit costs* and related activities necessary to meet federal audit requirements for the VOCA grant;

(7) *Technology-related costs*, generally including for grant management systems, electronic communications systems and platforms (e.g., Web pages and social media), geographic information systems, victim notification systems, and other automated systems, related equipment (e.g., computers, software, fax and copying machines, and TTY/TDDs) and related technology support services necessary for administration of the program;

(8) *Memberships* in crime victims' organizations and organizations that support the management and administration of victim assistance programs, and publications and materials such as curricula, literature,

and protocols relevant to the management and administration of the program;

(9) *Strategic planning*, including, but not limited to, the development of strategic plans, both service and financial, including conducting surveys and needs assessments;

(10) *Coordination and collaboration efforts* among relevant federal, State, and local agencies and organizations to improve victim services;

(11) *Publications*, including, but not limited to, developing, purchasing, printing, distributing training materials, victim services directories, brochures, and other relevant publications; and

(12) *General program improvements*—Enhancing overall SAA operations relating to the program and improving the delivery and quality of program services to crime victims throughout the State.

§ 94.110 Allowable training costs.

VOCA funds may be used only for training activities that occur within the award period, and all funds for training must be obligated prior to the end of such period. Allowable training costs generally include, but are not limited to, the following:

(a) Statewide/regional training of personnel providing direct assistance and allied professionals, including VOCA funded and non-VOCA funded personnel, as well as managers and Board members of victim service agencies; and

(b) Training academies for victim assistance.

Sub-Recipient Program Requirements

§ 94.111 Eligible crime victim assistance programs.

SAAs may award VOCA funds only to crime victim assistance programs that meet the requirements of VOCA, at 42 U.S.C. 10603(b)(1), and this subpart. Each such program shall abide by any additional criteria or reporting requirements established by the SAA.

§ 94.112 Types of eligible organizations and organizational capacity.

(a) *Eligible programs.* Eligible programs are not limited to entities whose sole purpose is to provide direct services. There are special considerations for certain types of entities, as described below:

(1) *Faith-based and neighborhood programs.* SAAs may award VOCA funds to otherwise eligible faith-based and neighborhood programs, but in making such awards, SAAs shall ensure that such programs comply with all applicable federal law, including, but not limited to, part 38 of this chapter.

(2) *Crime victim compensation programs.* SAAs may provide VOCA victim assistance funding to compensation programs only for the purpose of providing direct services that extend beyond the essential duties of the staff administering the compensation program, which services may include, but are not limited to, crisis intervention; counseling; and providing information, referrals, and follow-up for crime victims.

(3) *Victim service organizations located in an adjacent State.* SAAs may award VOCA funds to otherwise eligible programs that are physically located in an adjacent State, but in making such awards, the SAA shall provide notice of such award to the SAA of the adjacent State, and coordinate, as appropriate, to ensure effective provision of services, monitoring, auditing of federal funds, compliance, and reporting.

(4) *Direct service programs run by the SAA.* SAAs may fund their own direct services programs, but, under § 94.104(f), may allocate no more than ten percent of the VOCA grant to such programs, and each such program shall adhere to the allowable/unallowable cost rules for sub-recipient projects set out in this subpart at §§ 94.119 through 94.122.

(b) *Organizational capacity of the program.* For purposes of VOCA, at 42 U.S.C. 10603(b)(1)(B), the following shall apply:

(1) *Record of effective services to victims of crime and support from sources other than the Crime Victims Fund.* A program has demonstrated a record of effective direct services and support from sources other than the Crime Victims Fund when, for example, it demonstrates the support and approval of its direct services by the community, its history of providing direct services in a cost-effective manner, and the breadth or depth of its financial support from sources other than the Crime Victims Fund.

(2) *Substantial financial support from sources other than the Crime Victims Fund.* A program has substantial financial support from sources other than the Crime Victims Fund when at least twenty-five percent of the program's funding in the year of, or the year preceding the award comes from such sources, which may include other federal funding programs. If the funding is non-federal (or meets the DOJ Grants Financial Guide exceptions for using federal funding for match), then a program may count the used funding to demonstrate non-VOCA substantial financial support toward its project match requirement.

§ 94.113 Use of volunteers, community efforts, compensation assistance.

(a) *Mandated use of volunteers; waiver.* Programs shall use volunteers, to the extent required by the SAA, in order to be eligible for VOCA funds. The chief executive of the State, who may act through the SAA, may waive this requirement, provided that the program submits written documentation of its efforts to recruit and maintain volunteers, or otherwise demonstrate why circumstances prohibit the use of volunteers, to the satisfaction of the chief executive.

(b) *Waiver of use of volunteers.* SAAs shall maintain documentation supporting any waiver granted under VOCA, at 42 U.S.C. 10603(b)(1)(C), relating to the use of volunteers by programs.

(c) *Promotion of community efforts to aid crime victims.* Community served coordinated public and private efforts to aid crime victims may include, but are not limited to, serving on federal, State, local, or tribal work groups to oversee and recommend improvements to community responses to crime victims, and developing written agreements and protocols for such responses.

(d) *Assistance to victims in applying for compensation.* Assistance to potential recipients of crime victim compensation benefits (including potential recipients who are victims of federal crime) in applying for such benefits may include, but are not limited to, referring such potential recipients to an organization that can so assist, identifying crime victims and advising them of the availability of such benefits, assisting such potential recipients with application forms and procedures, obtaining necessary documentation, monitoring claim status, and intervening on behalf of such potential recipients with the crime victims' compensation program.

§ 94.114 Prohibited discrimination.

(a) The VOCA non-discrimination provisions specified at 42 U.S.C. 10604(e) shall be implemented in accordance with 28 CFR part 42.

(b) In complying with VOCA, at 42 U.S.C. 10604(e), as implemented by 28 CFR part 42, SAAs and sub-recipients shall comply with such guidance as may be issued from time to time by the Office for Civil Rights within the Office of Justice Programs.

§ 94.115 Non-disclosure of confidential or private information.

(a) *Confidentiality.* SAAs and sub-recipients of VOCA funds shall, to the extent permitted by law, reasonably protect the confidentiality and privacy

of persons receiving services under this program and shall not disclose, reveal, or release, except pursuant to paragraphs (b) and (c) of this section—

(1) Any personally identifying information or individual information collected in connection with VOCA-funded services requested, utilized, or denied, regardless of whether such information has been encoded, encrypted, hashed, or otherwise protected; or

(2) Individual client information, without the informed, written, reasonably time-limited consent of the person about whom information is sought, except that consent for release may not be given by the abuser of a minor, incapacitated person, or the abuser of the other parent of the minor. If a minor or a person with a legally appointed guardian is permitted by law to receive services without a parent's (or the guardian's) consent, the minor or person with a guardian may consent to release of information without additional consent from the parent or guardian.

(b) *Release.* If release of information described in paragraph (a)(2) of this section is compelled by statutory or court mandate, SAAs or sub-recipients of VOCA funds shall make reasonable attempts to provide notice to victims affected by the disclosure of the information, and take reasonable steps necessary to protect the privacy and safety of the persons affected by the release of the information.

(c) *Information sharing.* SAAs and sub-recipients may share—

(1) Non-personally identifying data in the aggregate regarding services to their clients and non-personally identifying demographic information in order to comply with reporting, evaluation, or data collection requirements;

(2) Court-generated information and law-enforcement-generated information contained in secure governmental registries for protection order enforcement purposes; and

(3) Law enforcement- and prosecution-generated information necessary for law enforcement and prosecution purposes.

(d) *Personally identifying information.* In no circumstances may—

(1) A crime victim be required to provide a consent to release personally identifying information as a condition of eligibility for VOCA-funded services;

(2) Any personally identifying information be shared in order to comply with reporting, evaluation, or data-collection requirements of any program;

(e) *Mandatory reporting.* Nothing in this section prohibits compliance with

legally mandated reporting of abuse or neglect.

Sub-Recipient Project Requirements**§ 94.116 Purpose of VOCA-funded projects.**

VOCA funds shall be available to sub-recipients only to provide direct services and supporting and administrative activities as set out in this subpart. SAAs shall ensure that VOCA sub-recipients obligate and expend funds in accordance with VOCA and this subpart. Sub-recipients must provide services to victims of federal crimes on the same basis as to victims of crimes under State or local law. Sub-recipients may provide direct services regardless of a victim's participation in the criminal justice process. Victim eligibility under this program for direct services is not dependent on the victim's immigration status.

§ 94.117 Cost of services; sub-recipient program income.

(a) *Cost of services.* Sub-recipients shall provide VOCA-funded direct services at no charge, unless the SAA grants a waiver allowing the sub-recipient to generate program income by charging for services. Program income, where allowed, shall be subject to federal grant rules and the requirements of the DOJ Grants Financial Guide, which, as of July 8, 2016, require in most cases that any program income be restricted to the same uses as the sub-award funds and expended during the grant period in which it is generated.

(b) *Considerations for waiver.* In determining whether to grant a waiver under this section, the SAA should consider whether charging victims for services is consistent with the project's victim assistance objectives and whether the sub-recipient is capable of effectively tracking program income in accordance with financial accounting requirements.

§ 94.118 Project match requirements.

(a) *Project match amount.* Sub-recipients shall contribute (*i.e.*, match) not less than twenty percent (cash or in-kind) of the total cost of each project, except as provided in paragraph (b) of this section.

(b) *Exceptions to project match requirement.* The following are not subject to the requirement set forth in paragraph (a) of this section:

(1) Sub-recipients that are federally-recognized American Indian or Alaska Native tribes, or projects that operate on tribal lands;

(2) Sub-recipients that are territories or possessions of the United States (except for the Commonwealth of Puerto

Rico), or projects that operate therein; and

(3) Sub-recipients other than those described in paragraphs (b)(1) and (2) of this section, that have applied (through their SAAs) for, and been granted, a full or partial waiver from the Director. Waiver requests must be supported by the SAA and justified in writing. Waivers are entirely at the Director's discretion, but the Director typically considers factors such as local resources, annual budget changes, past ability to provide match, and whether the funding is for new or additional activities requiring additional match versus continuing activities where match is already provided.

(c) *Sources of project match.*

Contributions under paragraph (a) of this section shall be derived from non-federal sources, except as may be provided in the DOJ Grants Financial Guide, and may include, but are not limited to, the following:

(1) *Cash*; *i.e.*, the value of direct funding for the project;

(2) *Volunteered professional or personal services*, the value placed on which shall be consistent with the rate of compensation (which may include fringe benefits) paid for similar work in the program, but if the similar work is not performed in the program, the rate of compensation shall be consistent with the rate found in the labor market in which the program competes;

(3) *Materials/Equipment*, but the value placed on lent or donated equipment shall not exceed its fair market value;

(4) *Space and facilities*, the value placed on which shall not exceed the fair rental value of comparable space and facilities as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality; and

(5) *Non-VOCA funded victim assistance activities*, including but not limited to, performing direct service, coordinating, or supervising those services, training victim assistance providers, or advocating for victims.

(d) *Discounts.* Any reduction or discount provided to the sub-recipient shall be valued as the difference between what the sub-recipient paid and what the provider's nominal or fair market value is for the good or service.

(e) *Use of project match.*

Contributions under paragraph (a) of this section are restricted to the same uses, and timing deadlines for obligation and expenditure, as the project's VOCA funding.

(f) *Recordkeeping for project match.*

Each sub-recipient shall maintain records that clearly show the source and

amount of the contributions under paragraph (a) of this section, and period of time for which such contributions were allocated. The basis for determining the value of personal services, materials, equipment, and space and facilities shall be documented. Volunteer services shall be substantiated by the same methods used by the sub-recipient for its paid employees (generally, this should include timesheets substantiating time worked on the project).

Sub-Recipient Allowable/Unallowable Costs

§ 94.119 Allowable direct service costs.

Direct services for which VOCA funds may be used include, but are not limited to, the following:

(a) *Immediate emotional, psychological, and physical health and safety*—Services that respond to immediate needs (other than medical care, except as allowed under paragraph (a)(9) of this section) of crime victims, including, but not limited to:

- (1) Crisis intervention services;
- (2) Accompanying victims to hospitals for medical examinations;
- (3) Hotline counseling;
- (4) Safety planning;
- (5) Emergency food, shelter, clothing, and transportation;
- (6) Short-term (up to 45 days) in-home care and supervision services for children and adults who remain in their own homes when the offender/caregiver is removed;

(7) Short-term (up to 45 days) nursing-home, adult foster care, or group-home placement for adults for whom no other safe, short-term residence is available;

(8) Window, door, or lock replacement or repair, and other repairs necessary to ensure a victim's safety;

(9) Costs of the following, on an emergency basis (*i.e.*, when the State's compensation program, the victim's (or in the case of a minor child, the victim's parent's or guardian's) health insurance plan, Medicaid, or other health care funding source, is not reasonably expected to be available quickly enough to meet the emergency needs of a victim (typically within 48 hours of the crime): Non-prescription and prescription medicine, prophylactic or other treatment to prevent HIV/AIDS infection or other infectious disease, durable medical equipment (such as wheelchairs, crutches, hearing aids, eyeglasses), and other healthcare items are allowed; and

(10) Emergency legal assistance, such as for filing for restraining or protective orders, and obtaining emergency custody orders and visitation rights;

(b) *Personal advocacy and emotional support*—Personal advocacy and emotional support, including, but not limited to:

- (1) Working with a victim to assess the impact of the crime;
- (2) Identification of victim's needs;
- (3) Case management;
- (4) Management of practical problems created by the victimization;
- (5) Identification of resources available to the victim;
- (6) Provision of information, referrals, advocacy, and follow-up contact for continued services, as needed; and
- (7) Traditional, cultural, and/or alternative therapy/healing (*e.g.*, art therapy, yoga);

(c) *Mental health counseling and care*—Mental health counseling and care, including, but not limited to, outpatient therapy/counseling (including, but not limited to, substance-abuse treatment so long as the treatment is directly related to the victimization) provided by a person who meets professional standards to provide these services in the jurisdiction in which the care is administered;

(d) *Peer-support*—Peer-support, including, but not limited to, activities that provide opportunities for victims to meet other victims, share experiences, and provide self-help, information, and emotional support;

(e) *Facilitation of participation in criminal justice and other public proceedings arising from the crime*—The provision of services and payment of costs that help victims participate in the criminal justice system and in other public proceedings arising from the crime (*e.g.*, juvenile justice hearings, civil commitment proceedings), including, but not limited to:—

- (1) Advocacy on behalf of a victim;
- (2) Accompanying a victim to offices and court;
- (3) Transportation, meals, and lodging to allow a victim who is not a witness to participate in a proceeding;
- (4) Interpreting for a non-witness victim who is deaf or hard of hearing, or with limited English proficiency;
- (5) Providing child care and respite care to enable a victim who is a caregiver to attend activities related to the proceeding;
- (6) Notification to victims regarding key proceeding dates (*e.g.*, trial dates, case disposition, incarceration, and parole hearings);
- (7) Assistance with Victim Impact Statements;

(8) Assistance in recovering property that was retained as evidence; and

(9) Assistance with restitution advocacy on behalf of crime victims.

(f) *Legal assistance*—Legal assistance services (including, but not limited to,

those provided on an emergency basis), where reasonable and where the need for such services arises as a direct result of the victimization. Such services include, but are not limited to:

(1) Those (other than criminal defense) that help victims assert their rights as victims in a criminal proceeding directly related to the victimization, or otherwise protect their safety, privacy, or other interests as victims in such a proceeding;

(2) Motions to vacate or expunge a conviction, or similar actions, where the jurisdiction permits such a legal action based on a person's being a crime victim; and

(3) Those actions (other than tort actions) that, in the civil context, are reasonably necessary as a direct result of the victimization;

(g) *Forensic medical evidence collection examinations*—Forensic medical evidence collection examinations for victims to the extent that other funding sources such as State appropriations are insufficient. Forensic medical evidence collection examiners are encouraged to follow relevant guidelines or protocols issued by the State or local jurisdiction. Sub-recipients are encouraged to provide appropriate crisis counseling and/or other types of victim services that are offered to the victim in conjunction with the examination. Sub-recipients are also encouraged to use specially trained examiners such as Sexual Assault Nurse Examiners;

(h) *Forensic interviews*—Forensic interviews, with the following parameters:

(1) Results of the interview will be used not only for law enforcement and prosecution purposes, but also for identification of needs such as social services, personal advocacy, case management, substance abuse treatment, and mental health services;

(2) Interviews are conducted in the context of a multi-disciplinary investigation and diagnostic team, or in a specialized setting such as a child advocacy center; and

(3) The interviewer is trained to conduct forensic interviews appropriate to the developmental age and abilities of children, or the developmental, cognitive, and physical or communication disabilities presented by adults.

(i) *Transportation*—Transportation of victims to receive services and to participate in criminal justice proceedings;

(j) *Public awareness*—Public awareness and education presentations (including, but not limited to, the development of presentation materials,

brochures, newspaper notices, and public service announcements) in schools, community centers, and other public forums that are designed to inform crime victims of specific rights and services and provide them with (or refer them to) services and assistance.

(k) *Transitional housing*—Subject to any restrictions on amount, length of time, and eligible crimes, set by the SAA, transitional housing for victims (generally, those who have a particular need for such housing, and who cannot safely return to their previous housing, due to the circumstances of their victimization), including, but not limited to, travel, rental assistance, security deposits, utilities, and other costs incidental to the relocation to such housing, as well as voluntary support services such as childcare and counseling; and

(l) *Relocation*—Subject to any restrictions on amount, length of time, and eligible crimes, set by the SAA, relocation of victims (generally, where necessary for the safety and well-being of a victim), including, but not limited to, reasonable moving expenses, security deposits on housing, rental expenses, and utility startup costs.

§ 94.120 Allowable costs for activities supporting direct services.

Supporting activities for which VOCA funds may be used include, but are not limited to, the following:

(a) *Coordination of activities*—Coordination activities that facilitate the provision of direct services, include, but are not limited to, State-wide coordination of victim notification systems, crisis response teams, multi-disciplinary teams, coalitions to support and assist victims, and other such programs, and salaries and expenses of such coordinators;

(b) *Supervision of direct service providers*—Payment of salaries and expenses of supervisory staff in a project, when the SAA determines that such staff are necessary and effectively facilitate the provision of direct services;

(c) *Multi-system, interagency, multi-disciplinary response to crime victim needs*—Activities that support a coordinated and comprehensive response to crime victims needs by direct service providers, including, but not limited to, payment of salaries and expenses of direct service staff serving on child and adult abuse multi-disciplinary investigation and treatment teams, coordination with federal agencies to provide services to victims of federal crimes and/or participation on Statewide or other task forces, work groups, and committees to develop

protocols, interagency, and other working agreements;

(d) *Contracts for professional services*—Contracting for specialized professional services (e.g., psychological/psychiatric consultation, legal services, interpreters), at a rate not to exceed a reasonable market rate, that are not available within the organization;

(e) *Automated systems and technology*—Subject to the provisions of the DOJ Grants Financial Guide and government-wide grant rules relating to acquisition, use and disposition of property purchased with federal funds, procuring automated systems and technology that support delivery of direct services to victims (e.g., automated information and referral systems, email systems that allow communications among victim service providers, automated case-tracking and management systems, smartphones, computer equipment, and victim notification systems), including, but not limited to, procurement of personnel, hardware, and other items, as determined by the SAA after considering—

(1) Whether such procurement will enhance direct services;

(2) How any acquisition will be integrated into and/or enhance the program's current system;

(3) The cost of installation;

(4) The cost of training staff to use the automated systems and technology;

(5) The ongoing operational costs, such as maintenance agreements, supplies; and

(6) How additional costs relating to any acquisition will be supported;

(f) *Volunteer trainings*—Activities in support of training volunteers on how to provide direct services when such services will be provided primarily by volunteers; and

(g) *Restorative justice*—Activities in support of opportunities for crime victims to meet with perpetrators, including, but not limited to, tribal community-led meetings and peace-keeping activities, if such meetings are requested or voluntarily agreed to by the victim (who may, at any point, withdraw) and have reasonably anticipated beneficial or therapeutic value to crime victims. SAAs that plan to fund this type of service should closely review the criteria for conducting these meetings, and are encouraged to discuss proposals with OVC prior to awarding VOCA funds for this type of activity. At a minimum, the following should be considered:—

(1) The safety and security of the victim;

(2) The cost versus the benefit or therapeutic value to the victim;

(3) The procedures for ensuring that participation of the victim and offenders are voluntary and that the nature of the meeting is clear;

(4) The provision of appropriate support and accompaniment for the victim;

(5) Appropriate debriefing opportunities for the victim after the meeting; and

(6) The credentials of the facilitators.

§ 94.121 Allowable sub-recipient administrative costs.

Administrative costs for which VOCA funds may be used by sub-recipients include, but are not limited to, the following:

(a) *Personnel costs*—Personnel costs that are directly related to providing direct services and supporting activities, such as staff and coordinator salaries expenses (including fringe benefits), and a prorated share of liability insurance;

(b) *Skills training for staff*—Training exclusively for developing the skills of direct service providers, including paid staff and volunteers (both VOCA-funded and not), so that they are better able to offer quality direct services, including, but not limited to, manuals, books, videoconferencing, electronic training resources, and other materials and resources relating to such training.

(c) *Training-related travel*—Training-related costs such as travel (in-State, regional, and national), meals, lodging, and registration fees for paid direct-service staff (both VOCA-funded and not);

(d) *Organizational Expenses*—Organizational expenses that are necessary and essential to providing direct services and other allowable victim services, including, but not limited to, the prorated costs of rent; utilities; local travel expenses for service providers; and required minor building adaptations necessary to meet the Department of Justice standards implementing the Americans with Disabilities Act and/or modifications that would improve the program's ability to provide services to victims;

(e) *Equipment and furniture*—Expenses of procuring furniture and equipment that facilitate the delivery of direct services (e.g., mobile communication devices, telephones, braille and TTY/TDD equipment, computers and printers, beepers, video cameras and recorders for documenting and reviewing interviews with children, two-way mirrors, colposcopes, digital cameras, and equipment and furniture for shelters, work spaces, victim waiting rooms, and children's play areas),

except that the VOCA grant may be charged only the prorated share of an item that is not used exclusively for victim-related activities;

(f) *Operating costs*—Operating costs include but are not limited to—

(1) Supplies;

(2) Equipment use fees;

(3) Property insurance;

(4) Printing, photocopying, and postage;

(5) Courier service;

(6) Brochures that describe available services;

(7) Books and other victim-related materials;

(8) Computer backup files/tapes and storage;

(9) Security systems;

(10) Design and maintenance of Web sites and social media; and

(11) Essential communication services, such as web hosts and mobile device services.

(g) *VOCA administrative time*—Costs of administrative time spent performing the following:

(1) Completing VOCA-required time and attendance sheets and programmatic documentation, reports, and statistics;

(2) Collecting and maintaining crime victims' records;

(3) Conducting victim satisfaction surveys and needs assessments to improve victim services delivery in the project; and

(4) Funding the prorated share of audit costs.

(h) *Leasing or purchasing vehicles*—Costs of leasing or purchasing vehicles, as determined by the SAA after considering, at a minimum, if the vehicle is essential to the provision of direct services;

(i) *Maintenance, repair, or replacement of essential items*—Costs of maintenance, repair, and replacement of items that contribute to maintenance of a healthy or safe environment for crime victims (such as a furnace in a shelter; and routine maintenance, repair costs, and automobile insurance for leased vehicles), as determined by the SAA after considering, at a minimum, if other sources of funding are available; and

(j) *Project evaluation*—Costs of evaluations of specific projects (in order to determine their effectiveness), within the limits set by SAAs.

§ 94.122 Expressly unallowable sub-recipient costs.

Notwithstanding any other provision of this subpart, no VOCA funds may be used to fund or support the following:

(a) *Lobbying*—Lobbying or advocacy activities with respect to legislation or to administrative changes to regulations

or administrative policy (cf. 18 U.S.C. 1913), whether conducted directly or indirectly;

(b) *Research and studies*—Research and studies, except for project evaluation under § 94.121(j);

(c) *Active investigation and prosecution of criminal activities*—The active investigation and prosecution of criminal activity, except for the provision of victim assistance services (e.g., emotional support, advocacy, and legal services) to crime victims, under § 94.119, during such investigation and prosecution;

(d) *Fundraising*—Any activities related to fundraising, except for fee-based, or similar, program income authorized by the SAA under this subpart.

(e) *Capital expenses*—Capital improvements; property losses and expenses; real estate purchases; mortgage payments; and construction (except as specifically allowed elsewhere in this subpart).

(f) *Compensation for victims of crime*—Reimbursement of crime victims for expenses incurred as a result of a crime, except as otherwise allowed by other provisions of this subpart;

(g) *Medical care*—Medical care, except as otherwise allowed by other provisions of this subpart; and

(h) *Salaries and expenses of management*—Salaries, benefits, fees, furniture, equipment, and other expenses of executive directors, board members, and other administrators (except as specifically allowed elsewhere in this subpart).

Dated: June 30, 2016.

Karol V. Mason,

Assistant Attorney General, Office of Justice Programs.

[FR Doc. 2016–16085 Filed 7–7–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 723, 724, 845, and 846

RIN 1029–AC72

[Docket ID: OSM–2016–0008; S1D1S SS08011000 SX066A0067F 167S180110; S2D2D SS08011000 SX066A00 33F 16XS501520]

Civil Penalties Inflation Adjustments

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Interim final rule.

SUMMARY: Pursuant to the Federal Civil Penalties Inflation Adjustment Act

Improvements Act of 2015 and Office of Management and Budget (OMB) guidance, this rule adjusts the level of civil monetary penalties assessed under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

DATES: This rule is effective on August 1, 2016. Comments will be accepted until September 6, 2016.

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

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Search for Docket No. OSM-2016-0008 and follow the online instructions for submitting comments.

- *Mail, Hand Delivery, or Courier:* Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 252 SIB, 1951 Constitution Avenue NW., Washington, DC 20240. Please include the Docket ID: OSM-2016-0008.

FOR FURTHER INFORMATION CONTACT: Adrienne Alsop, Office of Surface Mining Reclamation and Enforcement, South Interior Building MS-203, 1951 Constitution Avenue NW., Washington, DC 20240; Telephone (202) 208-2818.

SUPPLEMENTARY INFORMATION:

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I. Background

A. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

Section 518 of SMCRA, 30 U.S.C. 1268, authorizes the Secretary of the Interior to assess civil monetary

penalties (CMPs) for violations of SMCRA. The Office of Surface Mining Reclamation and Enforcement (OSMRE) regulations implementing the CMP provisions of section 518 are located in 30 CFR parts 723, 724, 845, and 846. We are adjusting CMPs in four sections—30 CFR 723.14, 724.14, 845.14, and 846.14.

On November 2, 2015, the President signed the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Public Law 114-74) (“the Act”) into law. The Act requires that Federal agencies promulgate rules to adjust the level of civil monetary penalties (“CMPs”) to account for inflation. The Act requires agencies to enact an initial “catch-up” adjustment by August 1, 2016. The Act also authorizes agencies to make subsequent annual adjustments to civil monetary penalties to account for inflation. These adjustments are aimed at maintaining the deterrent effect of civil penalties and furthering the policy goals of the statutes which authorize them.

Pursuant to SMCRA, this rule adjusts the following civil penalties:

CFR Citation	Points	Current penalty (\$)	Adjusted penalty (\$)
30 CFR 723.14	1	32	63
	2	74	127
	3	96	190
	3	108	253
	5	210	316
	6	232	380
	7	254	443
	8	276	506
	9	298	569
	10	320	633
	11	342	696
	12	364	759
	13	486	822
	14	508	886
	15	530	949
	16	552	1,012
	17	574	1,075
	18	596	1,139
	19	718	1,202
	20	740	1,265
	21	762	1,328
	22	784	1,392
	23	806	1,455
	24	828	1,518
	25	850	1,581
	26	960	1,898
	27	1,070	2,214
	28	1,080	2,530
	29	1,090	2,725
	30	2,100	3,163
	31	2,210	3,479
	32	2,320	3,795
	33	2,430	4,112
	34	2,540	4,428
	35	2,650	4,744

CFR Citation	Points	Current penalty (\$)	Adjusted penalty (\$)
	36	2,760	5,060
	37	2,870	5,377
	38	2,980	5,693
	39	3,090	6,009
	40	3,200	6,325
	41	3,310	6,642
	42	3,420	6,958
	43	3,530	7,274
	44	3,640	7,591
	45	4,750	7,907
	46	4,860	8,223
	47	4,970	8,539
	48	5,080	8,856
	49	5,190	9,172
	50	5,300	9,488
	51	5,410	9,804
	52	5,520	10,121
	53	5,630	10,437
	54	5,740	10,753
	55	5,850	11,070
	56	5,960	11,386
	57	7,070	11,702
	58	7,180	12,018
	59	7,290	12,335
	60	7,400	12,651
	61	7,510	12,967
	62	7,620	13,284
	63	7,730	13,600
	64	7,840	13,916
	65	7,950	14,232
	66	8,060	14,549
	67	8,170	14,865
	68	8,280	15,181
	69	8,390	15,497
	70	8,500	15,814
30 CFR 723.15(b) (Assessment of separate violations for each day)	Maximum	1,025	2,372
30 CFR 724.14(b) (Individual)	Maximum	8,500	17,395
30 CFR 845.14	1	32	63
	2	74	127
	3	96	190
	3	108	253
	5	210	316
	6	232	380
	7	254	443
	8	276	506
	9	298	569
	10	320	633
	11	342	696
	12	364	759
	13	486	822
	14	508	886
	15	530	949
	16	552	1,012
	17	574	1,075
	18	596	1,139
	19	718	1,202
	20	740	1,265
	21	762	1,328
	22	784	1,392
	23	806	1,455
	24	828	1,518
	25	850	1,581
	26	960	1,898
	27	1,070	2,214
	28	1,080	2,530
	29	1,090	2,725
	30	2,100	3,163
	31	2,210	3,479
	32	2,320	3,795
	33	2,430	4,112
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	40	3,200	6,325
	41	3,310	6,642
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	58	7,180	12,018
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	61	7,510	12,967
	62	7,620	13,284
	63	7,730	13,600
	64	7,840	13,916
	65	7,950	14,232
	66	8,060	14,549
	67	8,170	14,865
	68	8,280	15,181
	69	8,390	15,497
	70	8,500	15,814
30 CFR 845.15(b) (Assessment of separate violations for each day)	Maximum	1,025	2,372
30 CFR 846.14(b) (Individual)	Maximum	8,500	17,395

B. Calculation of Adjustments

The Office of Management and Budget (OMB) issued guidance on calculating the catch-up adjustment. See February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*.

The OMB guidance defines “civil monetary penalty” as “any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding.” It further instructs that a civil monetary penalty “does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory reviews.” The guidance also specifies that agencies should calculate the catch-up adjustment by determining the percent change between the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October in the

calendar year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI-U. OSMRE used this guidance to identify applicable civil monetary penalties and calculate the required catch-up adjustments.

Generally, OSMRE assigns points to a violation as described in 30 CFR 723.13 and 845.13. The CMP owed is based on the number of points received, ranging from one point to seventy points. For 2016, the Act requires that OSMRE adjust the civil penalty amounts for violations of SMCRA and provides the adjustment timing. The Act instructs OSMRE to use the maximum civil penalty amount as last adjusted by a provision of law other than the Federal Civil Penalties Inflation Adjustment Act of 1990 (Public Law 104-410) (FCPIA of 1990) when calculating the 2016 civil penalty adjustment. The maximum civil penalty amounts for violations of SMCRA have not been adjusted by a provision of law other than the FCPIA of 1990 since the penalties were established in SMCRA in 1977. Because

the penalties were first published in the **Federal Register** in 1979, in computing the new civil penalty amounts for violations of SMCRA, OSMRE used the adjustment factor for 1979 provided in OMB’s guidance. This resulted in a multiplying factor of 3.16274. The statutory maximum civil penalty amount (e.g., \$5,000) was multiplied by the multiplying factor (e.g., \$5,000 × 3.16274 = \$15,813.70). The Act requires that the maximum civil penalty amount be rounded to the nearest \$1.00 at the end of the calculation process (e.g., \$15,814). OSMRE’s calculated increases do not exceed 150 percent of the maximum civil penalty amount as of November 2, 2015, and thus, they comply with the Act. Also, pursuant to the Act, these increases apply to civil penalties assessed after the date they take effect, even if the associated violation predates such increase.

C. Effect of Rule in Federal Program States and on Indian Lands

OSMRE directly regulates surface coal mining and reclamation activities within a State or on tribal lands if the

State or tribe does not adopt its own program pursuant to section 503 of SMCRA. The increase in civil monetary penalties contained in this rule will apply to the following Federal program states: Arizona, California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for those States appear at 30 CFR parts 903, 905, 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. The increase in civil monetary penalties also applies to Indian lands under the Federal program for Indian lands, which appears in 30 CFR 750.18.

D. Effect of the Rule on Approved State Programs

State regulatory programs are not required to mirror all of the penalty provisions of our regulations. *In re Permanent Surface Mining Regulation Litigation*, No. 79–1144, Mem. Op. (D.D.C. May 16, 1980), 19 Env't Rep. Cas. (BNA) 1477. Thus, this rule has no effect on CMPs in states with SMCRA primacy.

II. Procedural Matters and Required Determinations

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements, to the extent permitted by statute.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (FRA) requires an agency to prepare a

regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to adjust civil penalties with an initial "catch-up" adjustment through an interim final rule. An interim final rule does not include first publishing a proposed rule. Thus, the RFA does not apply to this rulemaking.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (For further information see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on Energy Supply, Distribution, and Use (E.O. 13211)

This rule is not a significant energy action under the definition in Executive

Order 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by Executive Orders 12866 (section 1 (b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use common, everyday words and clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you believe that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

M. Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

N. Administrative Procedure Act

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to publish interim final rules by July 1, 2016, with an effective date for the adjusted penalties no later than August 1, 2016. To comply with the Act, we are issuing these regulations as an interim final rule and are requesting comments post-promulgation. Section 553(b) of the Administrative Procedure Act (APA) 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 prior public comment. 5 U.S.C. 553(b).

OSMRE finds that there is good cause to promulgate this rule without first providing for public comment. It would not be practicable to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Also, OSMRE is promulgating this final rule to implement the statutory directive in the

Act, which requires agencies to publish an interim final rule and to update the civil penalty amounts by applying a specified formula. OSMRE has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for pre-promulgation public comment on this rule. Thus, OSMRE finds pre-promulgation notice and public comment to be impracticable and unnecessary.

Also, OSMRE finds that there is good cause for publishing this rule less than thirty days before its effective date, since the Act requires agencies to publish interim final rules with an effective date no later than August 1, 2016. 5 U.S.C. 553(d). OSMRE has no discretion to provide for an effective date that is later than August 1, 2016.

List of Subjects

30 CFR Part 723

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

30 CFR Part 724

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

30 CFR Part 845

Administrative practice and procedure, Law enforcement, Penalties, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 846

Administrative practice and procedure, Penalties, Surface mining, Underground mining.

Dated: June 29, 2016.

Janice M. Schneider,

Assistant Secretary, Land and Minerals Management.

For the reasons given in the preamble, the Department of the Interior amends 30 CFR parts 723, 724, 845, and 846 as set forth below.

PART 723—CIVIL PENALTIES

■ 1. The authority citation for Part 723 is amended to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.*, and 31 U.S.C. 3701.

■ 2. Section 723.14 is amended by revising the table to read as follows:

§ 723.14 Determination of amount of penalty.

* * * * *

	Points	Dollars
1	63
2	127
3	190
4	253
5	316
6	380
7	443
8	506
9	569
10	633
11	696
12	759
13	822
14	886
15	949
16	1,012
17	1,075
18	1,139
19	1,202
20	1,265
21	1,328
22	1,392
23	1,455
24	1,518
25	1,581
26	1,898
27	2,214
28	2,530
29	2,725
30	3,163
31	3,479
32	3,795
33	4,112
34	4,428
35	4,744
36	5,060
37	5,377
38	5,693
39	6,009
40	6,325
41	6,642
42	6,958
43	7,274
44	7,591
45	7,907
46	8,223
47	8,539
48	8,856
49	9,172
50	9,488
51	9,804
52	10,121
53	10,437
54	10,753
55	11,070
56	11,386
57	11,702
58	12,018
59	12,335
60	12,651
61	12,967
62	13,284
63	13,600
64	13,916
65	14,232
66	14,549
67	14,865
68	15,181
69	15,497
70	15,814

■ 3. Section 723.15 is amended by revising paragraph (b) introductory text to read as follows:

§ 723.15 Assessment of separate violations for each day.
* * * *

(b) In addition to the civil penalty provided for in paragraph (a) of this section, whenever a violation contained in a notice of violation or cessation order has not been abated within the abatement period set in the notice or order or as subsequently extended pursuant to section 521(a) of the Act, 30 U.S.C. 1271(a), a civil penalty of not less than \$2,372 will be assessed for each day during which such failure to abate continues, except that:

PART 724—INDIVIDUAL CIVIL PENALTIES

■ 4. The authority citation for part 724 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.*, and 31 U.S.C. 3701.

■ 5. Section 724.14 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 724.14 Amount of individual civil penalty.
* * * *

(b) The penalty will not exceed \$17,395 for each violation. * * *

PART 845—CIVIL PENALTIES

■ 6. The authority citation for part 845 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.*, 31 U.S.C. 3701, Pub. L. 100–202, and Pub. L. 100–446.

■ 7. Section 845.14 is amended by revising the table to read as follows:

§ 845.14 Determination of amount of penalty.
* * * *

Points	Dollars
1	63
2	127
3	190
4	253
5	316
6	380
7	443
8	506
9	569
10	633
11	696
12	759
13	822
14	886
15	949
16	1,012
17	1,075
18	1,139
19	1,202
20	1,265
21	1,328
22	1,392

Points	Dollars
23	1,455
24	1,518
25	1,581
26	1,898
27	2,214
28	2,530
29	2,725
30	3,163
31	3,479
32	3,795
33	4,112
34	4,428
35	4,744
36	5,060
37	5,377
38	5,693
39	6,009
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41	6,642
42	6,958
43	7,274
44	7,591
45	7,907
46	8,223
47	8,539
48	8,856
49	9,172
50	9,488
51	9,804
52	10,121
53	10,437
54	10,753
55	11,070
56	11,386
57	11,702
58	12,018
59	12,335
60	12,651
61	12,967
62	13,284
63	13,600
64	13,916
65	14,232
66	14,549
67	14,865
68	15,181
69	15,497
70	15,814

■ 8. Section 845.15 is amended by revising paragraph (b) introductory text to read as follows:

§ 845.15 Assessment of separate violations for each day.
* * * *

(b) In addition to the civil penalty provided for in paragraph (a) of this section, whenever a violation contained in a notice of violation or cessation order has not been abated within the abatement period set in the notice or order or as subsequently extended pursuant to section 521(a) of the Act, a civil penalty of not less than \$2,372 will be assessed for each day during which such failure to abate continues, except that:

* * * *

PART 846—CIVIL PENALTIES

■ 9. The authority citation for part 846 continues to read as follows:

Authority: 28 U.S.C. 2461, 30 U.S.C. 1201 *et seq.*, and 31 U.S.C. 3701.

■ 10. Section 846.14 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 846.14 Amount of individual civil penalty.
* * * *

(b) The penalty will not exceed \$17,395 for each violation. * * *

[FR Doc. 2016–16190 Filed 7–7–16; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0633]

Drawbridge Operation Regulation; Housatonic River, Stratford, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Metro-North Devon Bridge across the Housatonic River, mile 3.9, at Stratford, Connecticut. This deviation is necessary to allow the bridge owner to perform timber ties replacement and steel repairs at the bridge.

DATES: This deviation is effective from 8 a.m. on September 6, 2016 to 8 a.m. on September 19, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0633] is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH”. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email judy.k.leung-ye@uscg.mil.

SUPPLEMENTARY INFORMATION: The Metro-North Devon Bridge, mile 3.9, across the Housatonic River, has a vertical clearance in the closed position of 19 feet at mean high water and 25 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.207(b).

The waterway is transited by seasonal recreational vessels.

The bridge owner, Connecticut Department of Transportation, requested a temporary deviation from the normal operating schedule to perform timber ties replacement and steel repairs at the bridge.

Under this temporary deviation, the Metro-North Devon Bridge will operate according to the schedule below:

a. From 8 a.m. on September 6, 2016 through 4 a.m. on September 9, 2016, the bridge will not open to marine traffic.

b. From 4 a.m. on September 9, 2016 through 8 a.m. on September 12, 2016, the bridge will open fully on signal upon 24 hr advance notice.

c. From 8 a.m. on September 12, 2016 through 4 a.m. on September 16, 2016, the bridge will not open to marine traffic.

d. From 4 a.m. on September 16, 2016 through 8 a.m. on September 19, 2016, the bridge will open fully on signal upon 24 hr advance notice.

Vessels able to pass under the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: July 5, 2016.

C.J. Bisignano,

*Supervisory Bridge Management Specialist,
First Coast Guard District.*

[FR Doc. 2016-16187 Filed 7-7-16; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2012-0950; FRL-9948-58-Region 1]

Air Plan Approval; New Hampshire; Infrastructure Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of State Implementation Plan (SIP) submissions from New Hampshire regarding the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2010 sulfur dioxide National Ambient Air Quality Standards (NAAQS). EPA is also updating the classification for two of New Hampshire's air quality control regions for sulfur dioxide based on recent air quality monitoring data collected by the state. Last, we are conditionally approving certain elements of New Hampshire's submittal relating to prevention of significant deterioration requirements.

The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

DATES: This final rule is effective on August 8, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R01-OAR-2012-0950. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.*, confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <http://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square, Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact 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 a.m. to 4:30 p.m., excluding legal holidays. **FOR FURTHER INFORMATION CONTACT:** Donald Dahl, (617) 918-1657, or by email at dahl.donald@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

- I. Summary of SIP Revision
- II. Public Comments

A. Sierra Club General Comments on Emission Limitations

1. The Plain Language of the CAA
2. The Legislative History of the CAA
3. Case Law
4. EPA Regulations, Such as 40 CFR 51.112(a)
5. EPA Interpretations in Other Rulemakings

B. Sierra Club Comments on New Hampshire SIP SO₂ Emission Limits

III. Final Action

IV. Statutory and Executive Order Reviews

I. Summary of SIP Revision

On June 22, 2010 (75 FR 35520), EPA promulgated a revised NAAQS for the 1-hour primary SO₂ at a level of 75 parts per billion (ppb), based on a 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe.

On September 13, 2013, the New Hampshire Department of Environmental Services (NH DES) submitted a SIP revision addressing infrastructure elements specified in section 110(a)(2) of the CAA to implement, maintain, and enforce the 2010 sulfur dioxide NAAQS. On July 17, 2015 (80 FR 42446), EPA published a notice of proposed rulemaking (NPR) for the State of New Hampshire proposing approval of New Hampshire's submittal. In the NPR, EPA proposed approval of the following infrastructure elements: Section 110(a)(2)(A), (B), (C) (enforcement and minor new source review), (D)(i)(II) (Visibility Protection), (D)(ii) (International Pollution Abatement), (E)(i) and (ii), (F), (G), (H), (J) (consultation, public notification, and visibility protection), (K), (L), and (M), or portions thereof. EPA also proposed to approve the PSD program relating to infrastructure elements (C)(ii), D(i)(II), D(ii), and (J)(iii), except to conditionally approve the aspect of the PSD program relating to notification to neighboring states. Within the same NPR, EPA also proposed taking similar action on New Hampshire's infrastructure SIP submittals for the 2008 lead, 2008 ozone, and the 2010 nitrogen dioxide standards. EPA has already finalized its action on the infrastructure SIPs for the 2008 lead, 2008 ozone, and the 2010 nitrogen dioxide standards (80 FR 78139, December 16, 2015).

In New Hampshire's September 13, 2013 infrastructure SIP for the SO₂ NAAQS, the state did not submit section 110(a)(2)(I) which pertains to the

nonattainment requirements of part D, Title I of the CAA, since this element is not required to be submitted by the 3-year submission deadline of section 110(a)(1), and will be addressed in a separate process. This rulemaking action also does not include action on section 110(a)(2)(D)(i)(I) of the CAA, because New Hampshire's September 13, 2013 infrastructure SIP submittal did not include provisions for this element. EPA will take later, separate action on section 110(a)(2)(D)(i)(I) for the 2010 SO₂ NAAQS for New Hampshire.

The rationale supporting EPA's proposed rulemaking action, including the scope of infrastructure SIPs in general, is explained in the published NPR. The NPR is available in the docket for this rulemaking at www.regulations.gov, Docket ID Number EPA-R01-OAR-2012-0950.

II. Public Comments and EPA's Responses

EPA received comments from the Sierra Club on the August 17, 2015 proposed rulemaking action on New Hampshire's 2010 SO₂ infrastructure SIP. A full set of these comments is provided in the docket for this final rulemaking action.

A. Sierra Club General Comments on Emission Limitations

1. The Plain Language of the CAA

Comment 1: Sierra Club (hereafter referred to as Commenter) contends that the plain language of section 110(a)(2)(A) of the CAA, legislative history of the CAA, case law, EPA regulations such as 40 CFR 51.112(a), and EPA interpretations in prior rulemakings require that infrastructure SIPs include enforceable emission limits that ensure attainment and maintenance of the NAAQS. Accordingly, Commenter contends that any infrastructure SIP where emission limits are inadequate to prevent exceedances of the NAAQS must be disapproved.

The Commenter states the main objective of the infrastructure SIP process "is to ensure that all areas of the country meet the NAAQS" and states that nonattainment areas are addressed through "nonattainment SIPs." The Commenter asserts the NAAQS "are the foundation upon which air emissions limitations and standards for the entire country are set," including specific emission limitations for most large stationary sources, such as coal-fired power plants. The Commenter discusses the CAA's framework whereby states have primary responsibility to assure air quality within the state, which the states

carry out through SIPs such as infrastructure SIPs required by section 110(a)(2). The Commenter also states that on its face the CAA requires infrastructure SIPs "to prevent exceedances of the NAAQS." In support, the Commenter quotes the language in section 110(a)(1), which requires states to adopt a plan for implementation, maintenance, and enforcement of the NAAQS, and the language in section 110(a)(2)(A), which requires SIPs to include enforceable emissions limitations as may be necessary to meet the requirements of the CAA, which the Commenter claims includes attainment and maintenance of the NAAQS. The Commenter also notes the use of the word "attain" in section 110(a)(2)(H)(ii) and suggests this is further evidence that the emission limits provided for in section 110(a)(2)(A) must ensure attainment of the NAAQS.

Response 1: EPA disagrees that section 110 is clear on its face and must be interpreted in the manner suggested by the Commenter. As we have previously explained in response to the Commenter's similar comments on EPA's actions approving other states' infrastructure SIPs, section 110 is only one provision that is part of the complicated structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and it must be interpreted in the context of not only that structure, but also of the historical evolution of that structure.¹

EPA interprets infrastructure SIPs as more general planning SIPs, consistent with the CAA as understood in light of its history and structure. When Congress enacted the CAA in 1970, it did not include provisions requiring states and the EPA to label areas as attainment or nonattainment. Rather, states were required to include all areas of the state in "air quality control regions" (AQCRs) and section 110 set forth the core substantive planning provisions for these AQCRs. At that time, Congress anticipated that states would be able to address air pollution quickly pursuant to the very general planning provisions in section 110 and could bring all areas into compliance with a new NAAQS within five years. Moreover, at that time, section 110(a)(2)(A)(i) specified that the section 110 plan provide for

¹ See 80 FR 46494 (Aug. 5, 2015) (approving Pennsylvania SO₂ and ozone infrastructure SIP); 80 FR 11557 (Mar. 4, 2015) (approving Virginia SO₂ infrastructure SIP); 79 FR 62022 (Oct. 16, 2014) (approving West Virginia SO₂ infrastructure SIP); 79 FR 19001 (Apr. 7, 2014) (approving West Virginia ozone infrastructure SIP); 79 FR 17043 (Mar. 27, 2014) (approving Virginia ozone infrastructure SIP); and 80 FR 63436 (Oct. 20, 2015) (approving Minnesota ozone, NO₂, SO₂, and PM_{2.5} infrastructure SIP).

"attainment" of the NAAQS and section 110(a)(2)(B) specified that the plan must include "emission limitations, schedules, and timetables for compliance with such limitations, and such other measures as may be necessary to insure attainment and maintenance [of the NAAQS]."

In 1977, Congress recognized that the existing structure was not sufficient and many areas were still violating the NAAQS. At that time, Congress for the first time added provisions requiring states and EPA to identify whether areas of a state were violating the NAAQS (*i.e.*, were nonattainment) or were meeting the NAAQS (*i.e.*, were attainment) and established specific planning requirements in section 172 for areas not meeting the NAAQS. In 1990, many areas still had air quality not meeting the NAAQS and Congress again amended the CAA and added yet another layer of more prescriptive planning requirements for each of the NAAQS. At that same time, Congress modified section 110 to remove references to the section 110 SIP providing for attainment, including removing pre-existing section 110(a)(2)(A) in its entirety and renumbering subparagraph (B) as section 110(a)(2)(A). Additionally, Congress replaced the clause "as may be necessary to insure attainment and maintenance [of the NAAQS]" with "as may be necessary or appropriate to meet the applicable requirements of this chapter."² Thus, the CAA has significantly evolved in the more than 40 years since it was originally enacted. While at one time section 110 of the CAA did provide the only detailed SIP planning provisions for states and specified that such plans must provide for attainment of the NAAQS, under the structure of the current CAA, section 110 is only the initial stepping-stone in the planning process for a specific NAAQS. More detailed, later-enacted

² The Commenter misses the mark by citing the word "attain" in CAA section 110(a)(2)(H) as evidence that the emission limits submitted to satisfy the infrastructure requirements of 110(a)(2)(A) must ensure attainment of the NAAQS. That portion of section 110(a)(2)(H) is referencing CAA section 110(k)(5)—the "SIP call" process—which allows the Administrator to make a finding of substantial inadequacy with respect to a SIP. As discussed at proposal, the existence of section 110(k)(5) bolsters the reasonableness of EPA's approach to infrastructure SIP requirements, which is based on a reasonable reading of sections 110(a)(1) and 110(a)(2). Section 110(k)(5) is one of the avenues and mechanisms Congress provided to address specific substantive deficiencies in existing SIPs. The SIP call process allows EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(a)(2)(H)(ii) ensures that the relevant state agency has the authority to revise the SIP in response to a SIP call.

provisions govern the substantive planning process, including planning for attainment of the NAAQS.

Thus, section 110 of the CAA is only one provision of the complicated overall structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and must be interpreted in the context of that structure and the historical evolution of that structure. In light of the revisions to section 110 since 1970 and the later promulgated and more specific planning requirements of the CAA, EPA reasonably interprets the requirement in section 110(a)(2)(A) of the CAA that the plan provide for “implementation, maintenance and enforcement” to mean that the SIP must contain enforceable emission limits that will aid in attaining and/or maintaining the NAAQS and that the state demonstrate that it has the necessary tools to implement and enforce a NAAQS, such as adequate state personnel and an enforcement program. EPA has interpreted the requirement for emission limitations in section 110 to mean that a state may rely on measures already in place to address the pollutant at issue or any new control measures that the state may choose to submit. Finally, as EPA has stated in the 2013 Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2) (“2013 Infrastructure SIP Guidance”), which specifically provides guidance to states in addressing the 2010 SO₂ NAAQS, “[t]he conceptual purpose of an infrastructure SIP submission is to assure that the air agency’s SIP contains the necessary structural requirements for the new or revised NAAQS, whether by establishing that the SIP already contains the necessary provisions, by making a substantive SIP revision to update the SIP, or both.” 2013 Infrastructure SIP Guidance at p. 1–2.³

2. The Legislative History of the CAA

Comment 2: The Commenter cites two excerpts from the legislative history of the 1970 CAA, claiming they support an interpretation that SIP revisions under CAA section 110 must include emissions limitations sufficient to show

³ Thus, EPA disagrees with the Commenter’s general assertion that the main objective of infrastructure SIPs is to ensure all areas of the country meet the NAAQS, as we believe the infrastructure SIP process is the opportunity to review the structural requirements of a state’s air program. While the NAAQS can be a foundation upon which emission limitations are set, as explained in responses to subsequent comments, these emission limitations are generally set in the attainment planning process envisioned by part D of title I of the CAA, including, but not limited to, CAA sections 172, 181–182, and 191–192.

maintenance of the NAAQS in all areas of the state. The Commenter also contends that the legislative history of the CAA supports the interpretation that infrastructure SIPs under section 110(a)(2) must include enforceable emission limitations, citing the Senate Committee Report and the subsequent Senate Conference Report accompanying the 1970 CAA.

Response 2: As provided in the previous response, the CAA, as enacted in 1970, including its legislative history, cannot be interpreted in isolation from the later amendments that refined that structure and deleted relevant language from section 110 concerning demonstrating attainment. *See also* 79 FR at 17046 (responding to comments on Virginia’s ozone infrastructure SIP). In any event, the two excerpts of legislative history the Commenter cites merely provide that states should include enforceable emission limits in their SIPs, and they do not mention or otherwise address whether states are required to include maintenance plans for all areas of the state as part of the infrastructure SIP.

3. Case Law

Comment 3: The Commenter also discusses several cases applying the CAA which the Commenter claims support its contention that courts have been clear that section 110(a)(2)(A) requires enforceable emissions limits in infrastructure SIPs to prevent exceedances of the NAAQS. The Commenter first cites to language in *Train v. Natural Resources Defense Council*, 421 U.S. 60, 78 (1975), addressing the requirement for “emission limitations” and stating that emission limitations “are the specific rules to which operators of pollution sources are subject, and which if enforced should result in ambient air which meets the national standards.” The Commenter also cites *Pennsylvania Department of Environmental Resources v. EPA*, 932 F.2d 269, 272 (3d Cir. 1991), for the proposition that the CAA directs EPA to withhold approval of a SIP where it does not ensure maintenance of the NAAQS, and to *Mision Industrial, Inc. v. EPA*, 547 F.2d 123, 129 (1st Cir. 1976), which quoted section 110(a)(2)(B) of the CAA of 1970. The Commenter contends that the 1990 Amendments do not alter how courts have interpreted the requirements of section 110, quoting *Alaska Department of Environmental Conservation v. EPA*, 540 U.S. 461, 470 (2004), which in turn quoted section 110(a)(2)(A) of the CAA and also stated that “SIPs must include certain measures Congress specified” to ensure attainment of the NAAQS. The

Commenter also quotes several additional opinions in this vein, including *Montana Sulphur & Chemical Co. v. EPA*, 666 F.3d 1174, 1180 (9th Cir. 2012) (“The Clean Air Act directs states to develop implementation plans—SIPs—that ‘assure’ attainment and maintenance of national ambient air quality standards (‘NAAQS’) through enforceable emission limitations.”) and *Hall v. EPA*, 273 F.3d 1146, 1161 (9th Cir. 2001) (EPA’s analysis is required to “reflect consideration of the prospects of meeting current attainment requirements under a revised air quality plan.”). Finally, the Commenter cites *Michigan Department of Environmental Quality v. Browner*, for the proposition that an infrastructure SIP must “include[] emission limitations that result in compliance with the NAAQS.” 230 F.3d 181, 185 (6th Cir. 2000) (citing *Train*, 421 U.S. at 79).

Response 3: None of the cases the Commenter cites support its contention that section 110(a)(2)(A) is clear that infrastructure SIPs must include detailed plans providing for attainment and maintenance of the NAAQS in all areas of the state, nor do they shed light on how section 110(a)(2)(A) may reasonably be interpreted. With the exception of *Train*, none of the cases the Commenter cites concerned the interpretation of CAA section 110(a)(2)(A) (or section 110(a)(2)(B) of the pre-1990 Act). Rather, the courts reference section 110(a)(2)(A) (or section 110(a)(2)(B) of the pre-1990 CAA) in the background sections of decisions in the context of a challenge to an EPA action on revisions to a SIP that was required and approved or disapproved as meeting other provisions of the CAA or in the context of an enforcement action.

In *Train*, the Court was addressing a state revision to an attainment plan submission made pursuant to section 110 of the CAA, the sole statutory provision at that time regulating such submissions. The issue in that case concerned whether changes to requirements that would occur before attainment was required were variances that should be addressed pursuant to the provision governing SIP revisions or were “postponements” that must be addressed under section 110(f) of the CAA of 1970, which contained prescriptive criteria. The Court concluded that EPA reasonably interpreted section 110(f) not to restrict a state’s choice of the mix of control measures needed to attain the NAAQS and that revisions to SIPs that would not impact attainment of the NAAQS by the attainment date were not subject to the limits of section 110(f). Thus, the issue was not whether a section 110 SIP

needs to provide for attainment or whether emissions limits providing such are needed as part of the SIP; rather the issue was which statutory provision governed when the state wanted to revise the emission limits in its SIP if such revision would not impact attainment or maintenance of the NAAQS. To the extent the holding in the case has any bearing on how section 110(a)(2)(A) might be interpreted, it is important to realize that in 1975, when the opinion was issued, section 110(a)(2)(B) (the predecessor to section 110(a)(2)(A)) expressly referenced the requirement to attain the NAAQS, a reference that was removed in 1990.

The decision in *Pennsylvania Department of Environmental Resources* was also decided based on the pre-1990 provision of the CAA. At issue was whether EPA properly rejected a revision to an approved plan where the inventories relied on by the state for the updated submission had gaps. The Court quoted section 110(a)(2)(B) of the pre-1990 CAA in support of EPA's disapproval, but did not provide any interpretation of that provision. Yet, even if the Court had interpreted that provision, EPA notes that it was modified by Congress in 1990; thus, this decision has little bearing on the issue here.

At issue in *Mision* was the definition of "emissions limitation," not whether section 110 requires the state to demonstrate how all areas of the state will attain and maintain the NAAQS as part of their infrastructure SIPs. The language from the opinion the Commenter quotes does not interpret but rather merely describes section 110(a)(2)(A); the decision in this case has no bearing here.⁴ In *Montana Sulphur*, the Court was not reviewing an infrastructure SIP, but rather EPA's disapproval of a SIP and promulgation of a federal implementation plan (FIP) after a long history of the state failing to submit an adequate SIP in response to EPA's finding under section 110(k)(5) that the previously approved SIP was substantially inadequate to attain or maintain the NAAQS. The Court cited generally to sections 107 and 110(a)(2)(A) of the CAA for the proposition that SIPs should assure attainment and maintenance of NAAQS through emission limitations, but this

language was not part of the Court's holding in the case, which focused instead on whether EPA's finding of SIP inadequacy, disapproval of the state's required responsive attainment demonstration under section 110(k)(5), and adoption of a remedial FIP under section 110(c) were lawful. The Commenter suggests that *Alaska Department of Environmental Conservation* stands for the proposition that the 1990 CAA Amendments do not alter how courts interpret section 110. This claim is inaccurate. Rather, the Court quoted section 110(a)(2)(A), which, as noted previously, differs from the pre-1990 version of that provision and the Court made no mention of the changed language. Furthermore, the Commenter also quotes the Court's statement that "SIPs must include certain measures Congress specified," but that statement specifically referenced the requirement in section 110(a)(2)(C), which requires an enforcement program and a program for the regulation of the modification and construction of new sources. Notably, at issue in that case was the state's "new source" permitting program, not its infrastructure SIP.

Two of the other cases the Commenter cites, *Michigan Department of Environmental Quality and Hall*, interpret CAA section 110(I), the provision governing "revisions" to plans, and not the initial plan submission requirement under section 110(a)(2) for a new or revised NAAQS, such as the infrastructure SIP at issue in this instance. In those cases, the courts cited to section 110(a)(2)(A) solely for the purpose of providing a brief background of the CAA.

EPA does not believe any of these court decisions addressed required measures for infrastructure SIPs and believes nothing in the opinions addressed whether infrastructure SIPs need to contain measures to ensure attainment and maintenance of the NAAQS.

4. EPA Regulations, Such as 40 CFR 51.112(a)

Comment 4: The Commenter cites to 40 CFR 51.112(a), providing that each plan "must demonstrate that the measures, rules and regulations contained in it are adequate to provide for the timely attainment and maintenance of the [NAAQS]." The Commenter asserts that this regulation requires infrastructure SIPs to include emissions limits necessary to ensure attainment and maintenance of the NAAQS. The Commenter states the provisions of 40 CFR 51.112 are not limited to nonattainment SIPs and

instead apply to infrastructure SIPs, which are required to attain and maintain the NAAQS in all areas of a state. The Commenter relies on a statement in the preamble to the 1986 action restructuring and consolidating provisions in part 51, in which EPA stated that "[i]t is beyond the scope of th[is] rulemaking to address the provisions of Part D of the Act . . ." 51 FR 40656, 40656 (Nov. 7, 1986). The Commenter asserts 40 CFR 51.112(a) "identifies the plans to which it applies as those that *implement* the NAAQS," which it contends means that § 51.112(a) is applicable to infrastructure SIPs.

Response 4: The Commenter's reliance on 40 CFR 51.112 to support its argument that infrastructure SIPs must contain emission limits adequate to ensure attainment and maintenance of the NAAQS is not supported. As an initial matter, EPA notes this regulatory provision was initially promulgated and later restructured and consolidated prior to the CAA Amendments of 1990, in which Congress removed all references to "attainment" in section 110(a)(2)(A). And, it is clear on its face that 40 CFR 51.112 applies to plans specifically designed to attain the NAAQS. EPA interprets these provisions to apply when states are developing "control strategy" SIPs such as the detailed attainment and maintenance plans required under other provisions of the CAA, as amended in 1977 and again in 1990, such as sections 175A, 181–182, and 191–192. The Commenter suggests that these provisions must apply to section 110 SIPs because in the preamble to EPA's action "restructuring and consolidating" provisions in part 51, EPA stated the new attainment demonstration provisions in the 1977 Amendments to the CAA were "beyond the scope" of the rulemaking. It is important to note, however, that EPA's action in 1986 was not to establish new substantive planning requirements, but rather was meant merely to consolidate and restructure provisions that had previously been promulgated. EPA noted that it had already issued guidance addressing the new "Part D" attainment planning obligations. Also, as to maintenance regulations, EPA expressly stated that it was not making any revisions other than to re-number those provisions. 51 FR at 40657.

Although EPA was explicit that it was not establishing requirements interpreting the provisions of new "Part D" of the CAA, it is clear the regulations being restructured and consolidated were intended to address control strategy plans. In the preamble, EPA clearly stated that 40 CFR 51.112 was

⁴ To the extent the comments could be read to include an assertion that New Hampshire's SIP does not contain any "emissions limitations" relevant to SO₂, it should be noted that state regulations at Env-A Chapter 400, Sulfur Content Limits in Fuels, which EPA previously approved into the state's SIP, see 40 CFR 52.1520(c), are similar to the regulations that the *Mision* court found to be an "emission limitation" in 1976. See 547 F.2d at 129.

replacing 40 CFR 51.13 (“Control strategy: SO_x and PM (portion)”), 51.14 (“Control strategy: CO, HC, O_x and NO₂ (portion)”), 51.80 (“Demonstration of attainment: Pb (portion)”), and 51.82 (“Air quality data (portion)”). *Id.* at 40,660. Thus, the present-day 40 CFR 51.112 contains consolidated provisions that are focused on control strategy SIPs, and the infrastructure SIP is not such a plan.

5. EPA Interpretations in Other Rulemakings

Comment 5: The Commenter references a prior EPA rulemaking action where EPA disapproved a SIP and claims that action shows EPA relied on section 110(a)(2)(A) and 40 CFR 51.112 to reject the SIP. The Commenter points to a 2006 partial approval and partial disapproval of revisions to Missouri’s existing control strategy plans addressing the SO₂ NAAQS. The Commenter claims EPA cited section 110(a)(2)(A) for disapproving a revision to the state plan on the basis that the State failed to demonstrate the SIP was sufficient to ensure maintenance of the SO₂ NAAQS after revision of an emission limit and claims EPA cited to 40 CFR 51.112 as requiring that a plan demonstrates the rules in a SIP are adequate to attain the NAAQS. The Commenter claims the revisions to Missouri’s control strategy SIP for SO₂ were rejected by EPA because the revised control strategy limits were also in Missouri’s infrastructure SIP and thus the weakened limits would have impacted the infrastructure SIP’s ability to aid in attaining and maintaining the NAAQS.

Response 5: EPA does not agree the prior Missouri rulemaking action referenced by the Commenter establishes how EPA reviews infrastructure SIPs. It is clear from the final Missouri rule that EPA was not reviewing initial infrastructure SIP submissions under section 110 of the CAA, but rather reviewing revisions that would make an already approved SIP designed to demonstrate attainment of the NAAQS less stringent. EPA’s partial approval and partial disapproval of revisions to restrictions on emissions of sulfur compounds for the Missouri SIP in 71 FR 12623 addressed a control strategy SIP and not an infrastructure SIP. Nothing in that action addresses the necessary content of the initial infrastructure SIP for a new or revised NAAQS.

B. Sierra Club Comments on New Hampshire SIP SO₂ Emission Limits

The Commenter contends that the New Hampshire 2010 SO₂ infrastructure

SIP revisions did not revise the existing SO₂ emission limits in response to the 2010 SO₂ NAAQS and fail to comport with assorted CAA requirements for SIPs to establish enforceable emission limits that are adequate to prohibit NAAQS exceedances in areas not designated nonattainment.

Comment 6: Citing section 110(a)(2)(A) of the CAA, the Commenter contends that EPA may not approve New Hampshire’s proposed 2010 SO₂ infrastructure SIP, because it does not include SO₂ emissions limits or other required measures sufficient to ensure attainment and maintenance of the SO₂ NAAQS in areas not designated nonattainment, which the Commenter claims is required by section 110(a)(2)(A), and because it does not include SO₂ emission limits “set in light of the 2010 SO₂ NAAQS or even analyzed in light of the standard.” The Commenter also contended that section 110(a)(2)(A) requires not only that the state air agency has the authority to adopt future emission limitations, but that the SIP include existing substantive emission limitations. The Commenter also provided results from a refined air dispersion modeling analysis that evaluated SO₂ impacts from Schiller Station, which the commenters asserts demonstrate that SO₂ emission limits relied on in the infrastructure SIP are insufficient to prevent exceedances of the NAAQS in both New Hampshire and Maine and claims that emissions from this source can in theory, and have in practice, resulted in exceedances of the 2010 SO₂ NAAQS. Lastly, the commenters asserted the structure of the Act makes clear that Congress did not intend states to be relieved of their infrastructure SIP obligations under section 110(a)(2)(A) until designations occur. For all of these reasons, the Commenter maintained that EPA should disapprove New Hampshire’s SO₂ infrastructure SIP and promulgate a FIP.

Response 6: EPA disagrees with the Commenter that EPA must disapprove New Hampshire’s SO₂ infrastructure SIP for the reasons provided by the Commenter, including the Commenter’s modeling results and the state’s allegedly insufficient SO₂ emission limits. EPA is not in this action making a determination regarding the State’s current air quality status or regarding whether its control strategy is sufficient to attain and maintain the NAAQS. Therefore, EPA is not in this action making any judgment on whether the Commenter’s submitted modeling demonstrates the NAAQS exceedances that the Commenter claims. EPA believes that section 110(a)(2)(A) of the CAA is reasonably interpreted to require

states to submit infrastructure SIPs that reflect the first step in their planning for attainment and maintenance of a new or revised NAAQS. These SIP revisions should contain a demonstration the state has the available tools and authority to develop and implement plans to attain and maintain the NAAQS and show that the SIP has enforceable control measures. In light of the structure of the CAA, EPA’s longstanding position regarding infrastructure SIPs is that they are general planning SIPs to ensure that the state has adequate resources and authority to implement a NAAQS in general throughout the state and not detailed attainment and maintenance plans for each individual area of the state. As mentioned above, EPA has interpreted this to mean with regard to the requirement for emission limitations that states may rely on measures already in place to address the pollutant at issue or any new control measures that *the state* may choose to submit. As stated in response to a previous more general comment, section 110 of the CAA is only one provision that is part of the complicated structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and it must be interpreted in the context of not only that structure, but also of the historical evolution of that structure. In light of the revisions to section 110 since 1970 and the later-promulgated and more specific planning requirements of the CAA, EPA reasonably interprets the requirement in section 110(a)(2)(A) of the CAA that the plan provide for “implementation, maintenance and enforcement” to mean that the SIP must contain enforceable emission limits that will aid in attaining and/or maintaining the NAAQS and that the State demonstrate that it has the necessary tools to implement and enforce a NAAQS, such as adequate state personnel and an enforcement program. As discussed above, EPA has interpreted the requirement for emission limitations in section 110 to mean the state may rely on measures already in place to address the pollutant at issue or any new control measures that the state may choose to submit. Finally, as EPA stated in the 2013 Infrastructure SIP Guidance, which specifically provides guidance to states in addressing the 2010 SO₂ NAAQS, “[t]he conceptual purpose of an infrastructure SIP submission is to assure that the air agency’s SIP contains the necessary structural requirements for the new or revised NAAQS, whether by establishing that the SIP already contains the necessary provisions, by

making a substantive SIP revision to update the SIP, or both.” 2013 Infrastructure SIP Guidance at p. 2. On April 12, 2012, EPA explained its expectations regarding implementation of the 2010 SO₂ NAAQS via letters to each of the states. EPA communicated in the April 2012 letters that all states were expected to submit SIPs meeting the “infrastructure” SIP requirements under section 110(a)(2) of the CAA by June 2013. At the time, EPA was undertaking a stakeholder outreach process to continue to develop possible approaches for determining attainment status under the SO₂ NAAQS and implementing this NAAQS. EPA made abundantly clear in the April 2012 letters that EPA did not expect states to submit substantive attainment demonstrations or modeling demonstrations showing attainment for areas not designated nonattainment in infrastructure SIPs due in June 2013. Although EPA had previously suggested in its 2010 SO₂ NAAQS preamble and in prior draft implementation guidance in 2011 that states should, in the unique SO₂ context, use the section 110(a) SIP process as the vehicle for demonstrating attainment of the NAAQS, this approach was never adopted as a binding requirement and was subsequently discarded in the April 2012 letters to states. The April 2012 letters recommended states focus infrastructure SIPs due in June 2013, such as New Hampshire’s SO₂ infrastructure SIP, on traditional “infrastructure elements” in section 110(a)(1) and (2) rather than on modeling demonstrations for future attainment for areas not designated as nonattainment.⁵ Therefore, EPA asserts

⁵ In EPA’s final SO₂ NAAQS preamble, 75 FR 35520 (June 22, 2010), and subsequent draft guidance in March and September 2011, EPA had expressed its expectation that many areas would be initially designated as unclassifiable due to limitations in the scope of the ambient monitoring network and the short time available before which states could conduct modeling to support their designations recommendations due in June 2011. In order to address concerns about potential violations in these unclassifiable areas, EPA initially recommended that states submit substantive attainment demonstration SIPs based on air quality modeling by June 2013 (under section 110(a)) that show how their unclassifiable areas would attain and maintain the NAAQS in the future. *Implementation of the 2010 Primary 1-Hour SO₂ NAAQS, Draft White Paper for Discussion*, May 2012 (“2012 Draft White Paper”) (for discussion purposes with Stakeholders at meetings in May and June 2012), available at <http://www.epa.gov/airquality/sulfurdioxide/implement.html>. However, EPA clearly stated in this 2012 Draft White Paper its clarified implementation position that it was no longer recommending such attainment demonstrations for unclassifiable areas for June 2013 infrastructure SIPs. *Id.* EPA had stated in the preamble to the NAAQS and in the prior 2011 draft guidance that EPA intended to develop and seek public comment on guidance for modeling and development of SIPs for sections 110 and 191 of the

that evaluations of modeling demonstrations such as the one submitted by the Commenter are more appropriately considered in actions that make determinations regarding states’ current air quality status or regarding future air quality status. EPA also asserts that SIP revisions for SO₂ nonattainment areas, including measures and modeling demonstrating attainment, are due by the dates statutorily prescribed under subpart 5 under part D. Those submissions are due no later than 18 months after an area is designated nonattainment for SO₂ under CAA section 191(a). Thus, the CAA directs states to submit these SIP requirements that are specific for nonattainment areas on a separate schedule from the “structural requirements” of 110(a)(2) which are due within three years of adoption or revision of a NAAQS and which apply statewide. The infrastructure SIP submission requirement does not move up the date for any required submission of a part D plan for areas designated nonattainment for the new NAAQS. Thus, elements relating to demonstrating attainment for areas not attaining the NAAQS are not necessary for infrastructure SIP submissions,⁶ and the CAA does not provide explicit requirements for demonstrating attainment for areas that have not yet been designated regarding attainment with a particular NAAQS. As stated previously, EPA believes that the proper inquiry at this juncture is whether New Hampshire has met the basic structural SIP requirements appropriate at the point in time EPA is acting upon the infrastructure submittal. Emissions limitations and other control measures needed to attain the NAAQS in areas designated nonattainment for that NAAQS are due on a different schedule from the section 110 infrastructure elements. A state, like New Hampshire, may reference preexisting SIP emission limits or other rules contained in part D

CAA. Section 191 of the CAA requires states to submit SIPs in accordance with section 172 for areas designated nonattainment with the SO₂ NAAQS. After seeking such comment, EPA has now issued guidance for the nonattainment area SIPs due pursuant to sections 191 and 172. *See Guidance for 1-Hour SO₂ Nonattainment Area SIP Submissions*, Stephen D. Page, Director, EPA’s Office of Air Quality Planning and Standards, to Regional Air Division Directors Regions 1–10, April 23, 2014. In September 2013, EPA had previously issued specific guidance relevant to infrastructure SIP submissions due for the NAAQS, including the 2010 SO₂ NAAQS. *See* 2013 Infrastructure SIP Guidance.

⁶ For this reason, EPA disagrees with the comment that the infrastructure SIP process is the appropriate mechanism in which to demonstrate that emission limitations for Merrimack Station are sufficient to ensure the Central New Hampshire nonattainment area attains the standard.

plans for previous NAAQS in an infrastructure SIP submission. New Hampshire’s existing rules and emission reduction measures in the SIP that control emissions of SO₂ were discussed in the state’s submittal.⁷ These provisions have the ability to reduce SO₂ overall. Although the New Hampshire SIP relies on measures and programs used to implement previous SO₂ NAAQS, these provisions are not limited to reducing SO₂ levels to meet one specific NAAQS and will continue to provide benefits for the 2010 SO₂ NAAQS. Additionally, as discussed in the NPR, New Hampshire has the ability to revise its SIP when necessary (e.g. in the event the Administrator finds the plan to be substantially inadequate to attain the NAAQS or otherwise meet all applicable CAA requirements) as required under element H of section 110(a)(2).

The requirements for emission reduction measures for an area designated nonattainment for the 2010 primary SO₂ NAAQS are in sections 172 and 191–192 of the CAA, and therefore, the appropriate avenue for implementing requirements for necessary emission limitations for demonstrating attainment with the 2010 SO₂ NAAQS is through the attainment planning process contemplated by those sections of the CAA. On August 5, 2013, EPA designated as nonattainment most areas in locations where existing monitoring data from 2009–2011 indicated violations of the 1-hour SO₂ standard. 78 FR 47191. At that time, one area in New Hampshire had monitoring data from 2009–2011 indicating violations of the 1-hour SO₂ standard, and this area was designated nonattainment in New Hampshire. *See* 40 CFR 81.330. On March 2, 2015 the United States District Court for the Northern District of California entered a Consent Decree among the EPA, Sierra Club and Natural Resources Defense Council to resolve litigation concerning the deadline for completing designations for the 2010 SO₂ NAAQS. Pursuant to the terms of the Consent Decree, EPA will complete additional designations for all remaining areas of the country including remaining areas in New Hampshire.⁸

⁷ New Hampshire cites to several SIP approved emission limitations relevant to SO₂ to demonstrate compliance with section 110(a)(2)(A), including Chapter Env-A 400 (Sulfur Content Limits in Fuels)(renumbered Env-A 1600). Thus, to the extent the Commenter meant to suggest that New Hampshire only has authority to set future emission limitations, but that the SIP contains none relevant to the 2010 SO₂ NAAQS, we disagree.

⁸ The Consent Decree, entered March 2, 2015 by the United States District Court for the Northern

For the area designated nonattainment in New Hampshire in August 2013, the attainment SIP was due by April 4, 2015 and must contain a demonstration that the area will attain the 2010 SO₂ NAAQS as expeditiously as practicable, but no later than October 4, 2018 pursuant to sections 172, 191 and 192 of the CAA, including a plan for enforceable measures to reach attainment of the NAAQS. Similar attainment planning SIPs for any additional areas which EPA subsequently designates nonattainment with the 2010 SO₂ NAAQS will be due for such areas within the timeframes specified in CAA section 191. EPA believes it is not appropriate to interpret the overall section 110(a)(2) infrastructure SIP obligation to require bypassing the attainment planning process by imposing separate requirements outside the attainment planning process. Such actions would be disruptive and premature absent exceptional circumstances and would interfere with a state's planning process. *See In the Matter of EME Homer City Generation LP and First Energy Generation Corp.*, Order on Petitions Numbers III–2012–06, III–2012–07, and III 2013–01 (July 30, 2014) (hereafter, *Homer City/Mansfield Order*) at 10–19 (finding Pennsylvania SIP did not require imposition of 1-hour SO₂ emission limits on sources independent of the part D attainment planning process contemplated by the CAA). The history of the CAA and intent of Congress for the CAA as described above demonstrate clearly that it is within the section 172 and general part D attainment planning process that New Hampshire must include SO₂ emission limits on sources, where needed, for the area designated nonattainment to reach attainment with the 2010 1-hour SO₂ NAAQS and for any additional areas EPA may subsequently designate nonattainment. EPA agrees that the structure of the Act makes clear that Congress did not intend to postpone a state's obligation to submit and infrastructure SIP under section 110(a)(2)(A) until designations occur. EPA disagrees, however, with the Commenter's interpretation that section 110(a)(2)(A) requires a state to submit SO₂ emission limitations for individual sources during this infrastructure SIP planning process that ensure attainment and maintenance of the 2010 SO₂ NAAQS. As stated above, in light of the revisions to section 110 since 1970 and

the later-promulgated and more specific planning requirements of the CAA, EPA reasonably interprets the requirement in section 110(a)(2)(A) that the plan provide for "implementation, maintenance and enforcement" to mean that the SIP must contain enforceable emission limits that will aid in attaining and/or maintaining the NAAQS and that the State demonstrate that it has the necessary tools to implement and enforce a NAAQS.

As noted in EPA's preamble for the 2010 SO₂ NAAQS, determining compliance with the SO₂ NAAQS will likely be a source-driven analysis and EPA has explored options to ensure that the SO₂ designations process realistically accounts for anticipated SO₂ reductions at sources that we expect will be achieved by current and pending national and regional rules. *See* 75 FR 35520 (June 22, 2010). As mentioned previously, EPA will act in accordance with the entered Consent Decree's schedule for conducting additional designations for the 2010 SO₂ NAAQS and any areas designated nonattainment must meet the applicable part D requirements for these areas. However, because the purpose of an infrastructure SIP submission is for more general planning purposes, EPA does not believe New Hampshire was obligated during this infrastructure SIP planning process to account for controlled SO₂ levels at individual sources to satisfy section 110(a)(2)(A). *See Homer City/Mansfield Order* at 10–19. Regarding the air dispersion modeling conducted by the Commenter pursuant to AERMOD for Schiller Station, EPA does not find the modeling information relevant at this time for review of an infrastructure SIP. While EPA has extensively discussed the use of modeling for attainment demonstration purposes and for designations, EPA has affirmatively stated such modeling was not needed to demonstrate attainment for the SO₂ infrastructure SIPs under the 2010 SO₂ NAAQS. *See* April 12, 2012 letters to states regarding SO₂ implementation and *Implementation of the 2010 Primary 1-Hour SO₂ NAAQS, Draft White Paper for Discussion*, May 2012, available at <http://www.epa.gov/airquality/sulfurdioxide/implement.html>.⁹ EPA's Data Requirements Rule contains a

⁹EPA has provided draft guidance for states regarding modeling analyses to support the designations process for the 2010 SO₂ NAAQS. *SO₂ NAAQS Designations Modeling Technical Assistance Document (draft)*, EPA Office of Air and Radiation and Office of Air Quality Planning and Standards, December 2013, available at <http://www.epa.gov/airquality/sulfurdioxide/implement.html>.

process by which state air agencies characterize air quality around SO₂ sources through ambient monitoring and/or air quality modeling techniques and submit such data to the EPA. *See, e.g.*, 80 FR 51502 (Aug. 21, 2015). The rule includes a discussion of how EPA anticipates addressing modeling that informs determinations of states' air quality status under the 2010 SO₂ NAAQS. As stated above, EPA believes it is not appropriate to bypass the attainment planning process by imposing separate attainment planning process requirements outside part D and into the infrastructure SIP process.

In conclusion, EPA disagrees with the Commenter's statements that EPA must disapprove New Hampshire's infrastructure SIP submission because it does not establish specific enforceable SO₂ emission limits, either on coal-fired EGUs or other large SO₂ sources, in order to demonstrate attainment and maintenance with the NAAQS at this time.¹⁰ Because we are approving New Hampshire's infrastructure SIP submission with respect to section 110(a)(2)(A), we need not promulgate a federal implementation plan. *See* CAA section 110(c)(1).

Comment 7: The Commenter claims that New Hampshire's proposed SO₂ infrastructure SIP lacks emission limitations for Schiller Station informed by air dispersion modeling as well as other large SO₂ sources outside of the nonattainment area and therefore fails to ensure New Hampshire will attain and maintain the 2010 SO₂ NAAQS. The Commenter claims EPA must disapprove the SO₂ infrastructure SIP as it does not "prevent exceedances" or ensure attainment and maintenance of the SO₂ NAAQS.

Response 7: EPA agrees with the Commenter that air dispersion modeling, such as AERMOD, can be an important tool in the CAA section 107 designations process for SO₂ and in developing SIPs for nonattainment areas as required by sections 172 and 191–192, including supporting required attainment demonstrations. EPA agrees that prior EPA statements, EPA guidance, and case law support the use of air dispersion modeling in the SO₂ designations process and attainment demonstration process, as well as in analyses of the interstate impact of transported emissions and whether existing approved SIPs remain adequate

¹⁰Finally, EPA does not disagree with the Commenter's claim that coal-fired EGUs are a large source of SO₂ emissions in New Hampshire based on the 2011 NEL. However, EPA does not agree that this information is relevant to our approval of the infrastructure SIP, which EPA has explained meets requirements in CAA section 110(a)(2).

District of California in *Sierra Club and NRDC v. EPA*, Case 3:13-cv-03953-SI (N.D. Cal.) is available at <http://www3.epa.gov/so2designations/pdfs/201503FinalCourtOrder.pdf>.

to show attainment and maintenance of the SO₂ NAAQS. However, as provided in the previous responses, EPA disagrees with the Commenter that EPA must disapprove the New Hampshire SO₂ infrastructure SIP for its alleged failure to include source-specific SO₂ emission limits that show no exceedances of the NAAQS when modeled or ensure attainment and maintenance of the NAAQS.

In acting to approve or disapprove an infrastructure SIP, EPA is not required to make findings regarding current air quality status of areas within the state, such area's projected future air quality status, or whether existing emissions limits in such area are sufficient to meet a NAAQS in the area. The attainment planning process detailed in part D of the CAA, including sections 172 and 191–192 attainment SIPs, is the appropriate place for the state to evaluate measures needed to bring in-state nonattainment areas into attainment with a NAAQS and to impose additional emission limitations such as SO₂ emission limits on specific sources.

EPA had initially recommended that states submit substantive attainment demonstration SIPs based on air quality modeling in the final 2010 SO₂ NAAQS preamble, 75 FR 35520 (June 22, 2010), and in subsequent draft guidance issued in September 2011 for the section 110(a) SIPs due in June 2013 in order to show how areas then-expected to be designated as unclassifiable would attain and maintain the NAAQS. These initial statements in the preamble and 2011 draft guidance, presented only in the context of the new 1-hour SO₂ NAAQS and not suggested as a matter of general infrastructure SIP policy, were based on EPA's expectation at the time that, by June 2012, most areas would initially be designated as unclassifiable due to limitations in the scope of the ambient monitoring network and the short time available before which states could conduct modeling to support designations recommendations in 2011. However, after conducting extensive stakeholder outreach and receiving comments from the states regarding these initial statements and the timeline for implementing the NAAQS, EPA subsequently stated in the April 12, 2012 letters and in the 2012 Draft White Paper that EPA was clarifying its 2010 SO₂ NAAQS implementation position and was no longer recommending such attainment demonstrations supported by air dispersion modeling for unclassifiable areas (which had not yet been designated) for the June 2013 infrastructure SIPs. Instead, EPA

explained that it expected states to submit infrastructure SIPs that followed the general policy EPA had applied under other NAAQS. EPA then reaffirmed this position in the February 6, 2013 memorandum, "Next Steps for Area Designations and Implementation of the Sulfur Dioxide National Ambient Air Quality Standard."¹¹ As previously mentioned, EPA had stated in the preamble to the NAAQS and in the prior 2011 draft guidance that EPA intended to develop and seek public comment on guidance for modeling and development of SIPs for sections 110, 172 and 191–192 of the CAA. After receiving such further comment, EPA has now issued guidance for the nonattainment area SIPs due pursuant to sections 172 and 191–192. See April 23, 2014 *Guidance for 1-Hour SO₂ Nonattainment Area SIP Submissions*. In addition, modeling may be an appropriate consideration for states and EPA in further designations for the SO₂ NAAQS in accordance with the Sierra Club and NRDC Consent Decree and the data requirements rule mentioned previously.¹² While the EPA guidance for attainment SIPs and for designations for CAA section 107 and the process for characterizing SO₂ emissions from larger sources discuss the use of air dispersion modeling, EPA's 2013 Infrastructure SIP Guidance did not suggest that states use air dispersion modeling for purposes of the section 110(a)(2) infrastructure SIP. Therefore, as discussed previously, EPA believes the New Hampshire SO₂ infrastructure SIP submittal contains the structural requirements to address elements in section 110(a)(2) as discussed in the proposed approval. EPA believes infrastructure SIPs are general planning SIPs to ensure that a state has adequate resources and authority to implement a NAAQS. Infrastructure SIP submissions are not intended to act or fulfill the obligations of a detailed attainment and/or maintenance plan for each individual

¹¹ The February 6, 2013 "Next Steps for Area Designations and Implementation of the Sulfur Dioxide National Ambient Air Quality Standard," one of the April 12, 2012 state letters, and the May 2012 *Draft White Paper* are available at <http://www.epa.gov/airquality/sulfurdioxide/implementation.html>.

¹² The Consent Decree in *Sierra Club and NRDC v. EPA*, Case 3:13-cv-03953-SI (N.D. Cal.) is available at <http://www.epa.gov/airquality/sulfurdioxide/designations/pdfs/201503FinalCourtOrder.pdf>. See 80 FR 51052, August 21, 2015 (EPA's data requirements rule). See also *Updated Guidance for Area Designations for the 2010 Primary Sulfur Dioxide National Ambient Air Quality Standard*, Stephen D. Page, Director, EPA's Office of Air Quality Planning Standards, March 20, 2015, available at <http://www.epa.gov/airquality/sulfurdioxide/pdfs/20150320SO2designations.pdf>.

area of the state that is not attaining the NAAQS. While infrastructure SIPs must address modeling authorities in general for section 110(a)(2)(K), EPA believes 110(a)(2)(K) requires infrastructure SIPs to provide the state's authority for air quality modeling and for submission of modeling data to EPA, not specific air dispersion modeling for large stationary sources of pollutants. In the proposal for this rulemaking action, EPA provided an explanation of New Hampshire's ability and authority to conduct air quality modeling when required and its authority to submit modeling data to the EPA. The comments relating to EPA's use of AERMOD or modeling in general in designations pursuant to section 107 are likewise irrelevant as EPA's present approval of New Hampshire's infrastructure SIP is unrelated to the section 107 designations process. As outlined in the August 23, 2010 clarification memo, "Applicability of Appendix W Modeling Guidance for the 1-hour SO₂ National Ambient Air Quality Standard" (U.S. EPA, 2010a), AERMOD is the preferred model for single source modeling to address the 1-hour SO₂ NAAQS as part of the NSR/PSD permit programs. Therefore, as attainment SIPs, designations, and NSR/PSD actions are outside the scope of a required infrastructure SIP for the 2010 SO₂ NAAQS for section 110(a), EPA provides no further response to the Commenter's discussion of air dispersion modeling for these applications. If the Commenter resubmits its air dispersion modeling for the New Hampshire EGU, or updated modeling information in the appropriate context, EPA will address the resubmitted modeling or updated modeling at that time.

The Commenter, citing administrative law principles regarding consideration of comments provided during a rulemaking process,¹³ contends that EPA *must* consider the modeling data the Commenter has submitted "over the years which demonstrate the inadequacy of New Hampshire's rules." For the reasons previously explained, however, the purpose for which the Commenter submitted the modeling—namely, to assert that current air quality in the area in which Schiller Station is located does not meet the NAAQS—is not relevant to EPA's action on this infrastructure SIP, and consequently EPA is not required to consider the modeling in evaluating the approvability of the infrastructure SIP.

¹³ The Commenter cites to *Motor Vehicle Manufacturers Association v. State Farm Mutual Auto Insurance Co.*, 463 U.S. 29, 43 (1983) and *NRDC v. EPA*, 571 F.3d 1245, 1254 (D.C. Cir. 2009).

EPA does not believe infrastructure SIPs must contain emission limitations informed by air dispersion modeling in order to meet the requirements of section 110(a)(2)(A). Thus, EPA has evaluated the persuasiveness of the Commenter's submitted modeling in finding that it is not relevant to the approvability of New Hampshire's proposed infrastructure SIP for the 2010 SO₂ NAAQS, but EPA has made no judgment regarding whether the Commenter's submitted modeling is sufficient to show violations of the NAAQS.

While EPA does not believe that infrastructure SIP submissions are required to contain emission limits assuring in-state attainment of the NAAQS, as suggested by the Commenter, EPA does recognize that in the past, states have, in their discretion, used infrastructure SIP submittals as a 'vehicle' for incorporating regulatory revisions or source-specific emission limits into the state's plan. See 78 FR 73442 (December 6, 2013) (approving regulations Maryland submitted for incorporation into the SIP along with the 2008 ozone infrastructure SIP to address ethics requirements for State Boards in sections 128 and 110(a)(2)(E)(ii)). While these SIP revisions are intended to help the state meet the requirements of section 110(a)(2), these "ride-along" SIP revisions are not intended to signify that all infrastructure SIP submittals must, in order to be approved by EPA, have similar regulatory revisions or source-specific emission limits. Rather, the regulatory provisions and source-specific emission limits the state relies on when showing compliance with section 110(a)(2) have, in many cases, likely already been incorporated into the state's SIP prior to each new infrastructure SIP submission; in some cases this was done for entirely separate CAA requirements, such as attainment plans required under section 172, or for previous NAAQS.

Comment 8: The Commenter asserts that EPA may not approve the proposed New Hampshire SO₂ infrastructure SIP because it fails to include enforceable emission limitations with a 1-hour averaging time (or, if longer averaging periods are used, more stringent numerical emission limits) that apply at all times. For support, the Commenter cites to the definition of "emission limitation" at CAA section 302(k). The Commenter also claims EPA has stated that 1-hour averaging times are necessary for the 2010 SO₂ NAAQS citing to EPA's April 23, 2014 *Guidance for 1-Hour SO₂ Nonattainment Area SIP Submissions*, a February 3, 2011, EPA

Region 7 letter to the Kansas Department of Health and Environment regarding the need for 1-hour SO₂ emission limits in a PSD permit, an EPA Environmental Appeals Board (EAB) decision rejecting use of a 3-hour averaging time for a SO₂ limit in a PSD permit,¹⁴ and EPA's disapproval of a Missouri SIP that relied on annual averaging for SO₂ emission rates.¹⁵ Thus, the Commenter contends EPA must disapprove New Hampshire's infrastructure SIP, which the Commenter claims fails to require emission limits with adequate averaging times.

Response 8: EPA disagrees that EPA must disapprove the proposed New Hampshire infrastructure SIP because the SIP does not contain enforceable SO₂ emission limitations with 1-hour averaging periods that apply at all times, as this issue is not appropriate for resolution at this stage. The comment does not assert that the SO₂ emission limits in New Hampshire's SIP are not enforceable or that they do not apply at all times, instead the comment focuses on the lack of 1-hour averaging times. As EPA has noted previously, the purpose of the section 110(a)(2) SIP is to ensure that the State has the necessary structural components to implement programs for attainment and maintenance of the NAAQS.¹⁶

While EPA does agree that the averaging time is a critical consideration for purposes of substantive SIP revisions, such as attainment demonstrations, the averaging time of existing rules in the SIP is not relevant for determining that the State has met the applicable requirements of section 110(a)(2) with respect to the infrastructure elements addressed in the present SIP action.¹⁷ Therefore, because

¹⁴ *In re Mississippi Lime Co.*, 15 E.A.D. 349, 379–82 (EAB Aug. 9, 2011).

¹⁵ 71 FR 12623, 12,624 (Mar. 13, 2006) (disapproving a control strategy SO₂ SIP).

¹⁶ As EPA has stated, some areas are designated nonattainment areas pursuant to CAA section 107 for the 2010 SO₂ NAAQS in the State. Thus, while the State, at this time, has an obligation to submit attainment plans for the 2010 SO₂ NAAQS for sections 172, 191 and 192, EPA believes the appropriate time for examining necessity of the averaging periods within any submitted SO₂ emission limits on specific sources is within the attainment planning process.

¹⁷ For a discussion on emission averaging times for emissions limitations for SO₂ attainment SIPs, see the April 23, 2014 *Guidance for 1-Hour SO₂ Nonattainment Area SIP Submissions*. EPA explained that it is possible, in specific cases, for states to develop control strategies that account for variability in 1-hour emissions rates through emission limits with averaging times that are longer than 1-hour, using averaging times as long as 30-days, but still provide for attainment of the 2010 SO₂ NAAQS as long as the limits are of at least comparable stringency to a 1-hour limit at the

EPA finds New Hampshire's SO₂ infrastructure SIP approvable without the additional SO₂ emission limitations showing in-state attainment of the NAAQS, EPA finds the issues of appropriate averaging periods for such future limitations not relevant at this time. The Commenter has cited to prior EPA discussion on emission limitations required in PSD permits (from an EAB decision and EPA's letter to Kansas' permitting authority) pursuant to part C of the CAA, which is neither relevant nor applicable to the present SIP action. In addition, as previously discussed, the EPA disapproval of the 2006 Missouri SIP was a disapproval relating to a control strategy SIP required pursuant to part D attainment planning and is likewise not relevant to the analysis of infrastructure SIP requirements.

Comment 9: The Commenter states that enforceable emission limits in SIPs are necessary to avoid additional nonattainment designations in areas where modeling or monitoring shows SO₂ levels exceed the 1-hour SO₂ NAAQS and cites to a February 6, 2013 EPA document, *Next Steps for Area Designations and Implementation of the Sulfur Dioxide National Ambient Air Quality Standard*, which the Commenter contends discusses how states could avoid future nonattainment designations. The Commenter claims the modeling it conducted for Schiller Station indicates exceedances over a wide area in both New Hampshire and Maine. The Commenter states that additional areas in New Hampshire will have to be designated nonattainment "if source-specific enforceable emissions limits are not placed on PSNH Schiller Station through this I-SIP." In summary, the Commenter asserts that, "in order to implement the NAAQS, comply with section 110(a)(2)(A), and avoid additional nonattainment designations for areas impacted by" Schiller Station, EPA must disapprove the New Hampshire infrastructure SIP and ensure that emission limits "relied upon in the Infrastructure SIP" will not allow large sources of SO₂ to cause exceedances of the 2010 SO₂ NAAQS.

Response 9: EPA appreciates the Commenter's concern with avoiding nonattainment designations in New Hampshire for the 2010 SO₂ NAAQS. However, Congress designed the CAA such that states have the primary responsibility for achieving and maintaining the NAAQS within their geographic areas by submitting SIPs

critical emission value. EPA has not yet evaluated any specific submission of such a limit, and so is not at this time prepared to take final action to implement.

which will specify the details of how the states will meet the NAAQS. Pursuant to section 107(d), the states make initial recommendations of designations for areas within each state and EPA then promulgates the designations after considering the state's submission and other information. EPA promulgated initial designations for the 2010 SO₂ NAAQS in August 2013 for areas in which monitoring at that time showed violations of the NAAQS, but has not yet issued designations for other areas and will complete the required designations pursuant to the schedule contained in the recently entered Consent Decree. EPA will designate additional areas for the 2010 SO₂ NAAQS in accordance with CAA section 107 and existing EPA policy and guidance. New Hampshire may, on its own accord, decide to impose additional SO₂ emission limitations to avoid future designations to nonattainment. If additional New Hampshire areas are designated nonattainment, New Hampshire will then have the initial opportunity to develop additional emissions limitations needed to attain the NAAQS, and EPA would be charged with reviewing whether the SIP is adequate to demonstrate attainment. See *Commonwealth of Virginia v. EPA*, 108 F.3d 1397, 1410 (D.C. Cir. 1997) (citing *Nat. Res. Def. Council, Inc. v. Browner*, 57 F.3d 1122, 1123 (D.C. Cir. 1995)) (discussing that states have primary responsibility for determining an emission reductions program for its areas subject to EPA approval dependent upon whether the SIP as a whole meets applicable requirements of the CAA). However, such considerations are not required of New Hampshire at the infrastructure SIP stage of NAAQS implementation, as the Commenter's statements concern the separate designations process under section 107.¹⁸ EPA disagrees that the

infrastructure SIP must be disapproved for not including enforceable emissions limitations to prevent future 1-hour SO₂ nonattainment designations.

Comment 10: The commenter notes that New Hampshire did not include a submittal to satisfy CAA section 110(a)(2)(D)(i)(I) (the so-called "Good Neighbor" provision) and asserts that, as a result, "EPA must take immediate action here to disapprove the SO₂ I-SIP Certification . . . and initiate the FIP [Federal Implementation Plan] process with regard to the I-SIP's 'Good Neighbor' provisions."

Response 10: EPA is not taking any action at this time with respect to Element D(i)(I), which addresses emissions that significantly contribute to nonattainment or interfere with maintenance of the NAAQS in another state, also known as "good neighbor" SIPs or "interstate transport" SIPs. As the commenter notes, New Hampshire did not include any provisions to address the requirements of section 110(a)(2)(D)(i)(I) in its September 13, 2013 infrastructure SIP submittal for the 2010 SO₂ NAAQS. In the NPR, EPA did not propose to take any action with respect to New Hampshire's obligations pursuant to section 110(a)(2)(D)(i)(I) for the September 13, 2013 infrastructure SIP submittal.

Because New Hampshire did not make a submission in its September 13, 2013 SIP submittal to address the requirements of section 110(a)(2)(D)(i)(I), EPA is not required to have proposed or to take final SIP approval or disapproval action on this element under section 110(k) of the CAA. In this case, there has been no substantive submission for EPA to evaluate under section 110(k). Nor does the lack of a submission addressing section 110(a)(2)(D)(i)(I) require EPA to disapprove New Hampshire's September 13, 2013 SIP submittal as to the other elements of section 110(a)(2). EPA interprets its authority under section 110(k)(3) of the CAA as affording EPA the discretion to approve, or conditionally approve, individual elements of New Hampshire's infrastructure SIP submissions, separate and apart from any action with respect to the requirements of section 110(a)(2)(D)(i)(I) of the CAA. EPA views discrete infrastructure SIP requirements in section 110(a)(2), such as the requirements of 110(a)(2)(D)(i)(I), as severable from the other infrastructure elements and interprets section 110(k)(3) as allowing it to act on individual severable measures in a plan submission.

On August 21, 2012, the D.C. Circuit issued a decision in *EME Homer City*

Generation, L.P. v. EPA, 696 F.3d 7, 31 (D.C. Cir. 2012), holding, among other things, that states had no obligation to submit good neighbor SIPs until the EPA had first quantified each state's good neighbor obligation. Accordingly, under that decision the submission deadline for good neighbor SIPs under the CAA would not necessarily be tied to the promulgation of a new or revised NAAQS. While the EPA sought review first with the D.C. Circuit *en banc* and then with the United States Supreme Court, the EPA complied with the D.C. Circuit's ruling during the pendency of its appeal. The D.C. Circuit declined to consider EPA's appeal *en banc*, but, on April 29, 2014, the Supreme Court reversed the D.C. Circuit's *EME Homer City* opinion and held, among other things, that under the plain language of the CAA, states must submit SIPs addressing the good neighbor requirement in CAA section 110(a)(2)(D)(i)(I) within three years of promulgation of a new or revised NAAQS, regardless of whether the EPA first provides guidance, technical data or rulemaking to quantify the state's obligation.

Pursuant to CAA section 110(c)(1), EPA is authorized and obligated to promulgate a FIP, if EPA takes any of the following actions: (1) Finds that a state has failed to make a required SIP submission; (2) finds that a required submission was incomplete; or (3) disapproves a required SIP submission in whole or in part. With respect to the 2010 SO₂ NAAQS, EPA has not issued a finding of failure to submit, issued a finding of incompleteness, or disapproved the submission in whole or in part. Consequently, the two-year FIP clock has not yet begun to run. EPA agrees in general that sections 110(a)(1) and (a)(2) of the CAA require states to submit, within three years of promulgation of a new or revised NAAQS, a plan that addresses cross-state air pollution under section 110(a)(2)(D)(i)(I). In this rulemaking, however, EPA is only approving portions of New Hampshire's infrastructure SIP submissions for the 2010 SO₂ NAAQS, which did not include provisions for interstate transport under section 110(a)(2)(D)(i)(I). A finding of failure to submit a SIP submission for the 2010 SO₂ NAAQS addressing section 110(a)(2)(D)(i)(I) could occur in a separate rulemaking. As that issue was not addressed in the July 17, 2015 NPR,¹⁹ and is thus not pertinent to this

¹⁸EPA also notes that in EPA's final rule regarding the 2010 SO₂ NAAQS, EPA noted that it anticipates several forthcoming national and regional rules, such as the Industrial Boilers standard under CAA section 112, are likely to require significant reductions in SO₂ emissions over the next several years. See 75 FR 35520. EPA continues to believe similar national and regional rules will lead to SO₂ reductions that will help achieve compliance with the 2010 SO₂ NAAQS. If it appears that states with areas designated nonattainment in 2013 will nevertheless fail to attain the NAAQS as expeditiously as practicable (but no later than October 2018) during EPA's review of attainment SIPs required by section 172, the CAA provides authorities and tools for EPA to solve such failure, including, as appropriate, disapproving submitted SIPs and promulgating federal implementation plans. Likewise, for any areas designated nonattainment after 2013, EPA has the same authorities and tools available to address any areas which do not timely attain the NAAQS.

¹⁹ See 80 FR 42446, 42452 (July 17, 2015) ("In today's rulemaking, EPA is not proposing to

rulemaking, EPA provides no further response. In sum, New Hampshire's and EPA's obligations regarding interstate transport of pollution for the 2010 SO₂ NAAQS will be addressed in later rulemakings.

III. Final Action

EPA is approving a SIP submission from New Hampshire certifying the state's current SIP is sufficient to meet

the required infrastructure elements under sections 110(a)(1) and (2) for the 2010 SO₂ NAAQS, with the exception of certain aspects relating to the state's PSD program which we are conditionally approving. On September 25, 2015, we conditionally approved the portion of New Hampshire's PSD program that pertains to providing notification to neighboring states of

certain permitting actions in New Hampshire. See 80 FR 57722. Therefore, we are conditionally approving herein the related portions of New Hampshire's infrastructure SIP submittals affected by our September 25, 2015 conditional approval. A summary of EPA's actions regarding these infrastructure SIP requirements are contained in Table 1 below.

TABLE 1—ACTION TAKEN ON NH INFRASTRUCTURE SIP SUBMITTALS FOR LISTED NAAQS

Element	2010 SO ₂
(A): Emission limits and other control measures	A
(B): Ambient air quality monitoring and data system	A
(C)(i): Enforcement of SIP measures	A
(C)(ii): PSD program for major sources and major modifications	A*
(C)(iii): Permitting program for minor sources and minor modifications	A
(D)(i)(I): Contribute to nonattainment/interfere with maintenance of NAAQS (prongs 1 and 2)	NS
(D)(i)(II): PSD (prong 3)	A*
(D)(i)(III): Visibility Protection (prong 4)	A
(D)(ii): Interstate Pollution Abatement	A*
(D)(iii): International Pollution Abatement	A
(E)(i): Adequate resources	A
(E)(ii): State boards	A
(E)(iii): Necessary assurances with respect to local agencies	NA
(F): Stationary source monitoring system	A
(G): Emergency power	A
(H): Future SIP revisions	A
(I): Nonattainment area plan or plan revisions under part D	+
(J)(i): Consultation with government officials	A
(J)(ii): Public notification	A
(J)(iii): PSD	A*
(J)(iv): Visibility protection	+
(K): Air quality modeling and data	A
(L): Permitting fees	A
(M): Consultation and participation by affected local entities	A

In the above table, the key is as follows:

A—Approve

A*—Approve, but conditionally approve aspect of PSD program relating to notification to neighboring states

+—Not germane to infrastructure SIPs

NS—No Submittal

NA—Not applicable

Additionally, we are updating the classification of two air quality control regions in New Hampshire at 40 CFR 52.1521. The classification of the Androscoggin Valley Interstate control region is being revised from Priority 1A to Priority III and the Merrimack Valley—Southern New Hampshire Interstate control region is being revised from Priority I to Priority III based on recent air quality monitoring data collected by the state.

EPA is conditionally approving an aspect of New Hampshire's SIP revision submittals pertaining to the state's PSD

program. The outstanding issue with the PSD program concerns the lack of a requirement that neighboring states be notified of the issuance of a PSD permit by the New Hampshire Department of Environmental Services. On September 25, 2015, we conditionally approved New Hampshire's PSD program for this reason. See 80 FR 57722. Accordingly, we are also conditionally approving this aspect of New Hampshire's infrastructure SIP revisions for the 2010 SO₂ NAAQS. New Hampshire must submit to EPA a SIP submittal addressing the above mentioned deficiency in the state's PSD program within the timeframe provided within our September 25, 2015 action. If the State fails to do so, the elements we are conditionally approving in this rulemaking will be disapproved 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 New Hampshire

SIP. EPA subsequently will publish a document in 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 aspect of New Hampshire's PSD program will also be disapproved at that time. If EPA approves the revised PSD program submittal, then the portions of New Hampshire's infrastructure SIP submittals that were conditionally approved will be fully approved in their entirety and replace the conditional approval in the SIP. In addition, final disapproval of an infrastructure SIP submittal triggers the Federal implementation plan (FIP) requirement under section 110(c).

approve or disapprove New Hampshire's compliance with section 110(a)(2)(D)(i)(I) with respect to the 2008 ozone, 2010 NO₂ and 2010 SO₂

NAAQS, since New Hampshire's infrastructure SIPs for these NAAQS do not include a submittal with

respect to transport for sub-element 1, prongs 1 and 2.'').

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 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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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, 2016. 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)).

NEW HAMPSHIRE NONREGULATORY

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxides.

Dated: June 15, 2016.

H. Curtis Spalding,

Regional Administrator, EPA New England.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart EE—New Hampshire

■ 2. Section 52.1519 is amended by adding paragraph (a)(11) to read as follows:

§ 52.1519 Identification of plan—conditional approval.

(a) * * *

(11) 2010 Sulfur Dioxide NAAQS: The 110(a)(2) infrastructure SIP submitted on September 13, 2013, is conditionally approved for Clean Air Act (CAA) elements 110(a)(2)(C)(ii), (D)(i)(II), D(ii), and (J)(iii) only as it relates to the aspect of the PSD program pertaining to providing notification to neighboring states of certain permitting activity being considered by New Hampshire. This conditional approval is contingent upon New Hampshire taking actions to address these requirements as detailed within a final conditional approval dated September 25, 2015.

* * * * *

■ 3. In § 52.1520, the table in paragraph (e) is amended by revising the entry for "Infrastructure SIP for the 2010 SO₂ NAAQS" to read as follows:

§ 52.1520 Identification of plan.

* * * * *

(e) * * *

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approved date ³	Explanations
* Infrastructure SIP for the 2010 SO ₂ NAAQS.	* Statewide	* 9/13/2013	* 7/8/2016 [Insert Federal Register citation]	* Approved submittal, except for certain aspects relating to PSD which were conditionally approved. See 52.1519.

NEW HAMPSHIRE NONREGULATORY—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approved date ³	Explanations
*	*	*	*	*

³In 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.

■ 4. In § 52.1521, the table is amended by revising the entries for “Androscoggin Valley Interstate” and

“Merrimack Valley—Southern New Hampshire Interstate” to read as follows:

§ 52.1521 Classification of regions.

* * * * *

Air quality control region	Pollutant				
	Particulate matter	Sulfur oxides	Nitrogen dioxide	Carbon monoxide	Ozone
Androscoggin Valley Interstate	IA	III	III	III	III
* * * * *	*	*	*	*	*
Merrimack Valley—Southern New Hampshire Interstate	I	III	III	III	I

[FR Doc. 2016–15623 Filed 7–7–16; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register

Vol. 81, No. 131

Friday, July 8, 2016

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

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR PART 102

[Docket No. USCBP–2016–0041]

RIN 1515–AD78

North American Free Trade Agreement; Preference Override

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.
ACTION: Notice of proposed rulemaking.

SUMMARY: The United States, Canada and Mexico have agreed to liberalize provisions of the North American Free Trade Agreement (NAFTA) preference rules of origin that relate to certain goods, including certain spices. However, such liberalization cannot take effect unless U.S. Customs and Border Protection (CBP) amends its regulations to allow the NAFTA preference override to apply to certain spice products and other food products. This document proposes such an amendment.

DATES: Comments must be received on or before September 6, 2016.

ADDRESSES: You may submit comments, identified by docket number, by *one* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments via docket number USCBP–2016–0041.
- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any

personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Monika Brenner, Chief, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade, (202) 325–0038.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rulemaking. Comments that will provide the most assistance to CBP will reference a specific portion of the proposed rulemaking, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. See **ADDRESSES** above for information on how to submit comments.

Background

On December 17, 1992, the United States, Canada, and Mexico (the parties) entered into the North American Free Trade Agreement (NAFTA). The provisions of the NAFTA were adopted by the United States with enactment of the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (December 8, 1993). Under Article 401 of the NAFTA, an imported good qualifies as

an originating good of a NAFTA party if: (1) It is wholly obtained or produced in one or more of the NAFTA parties; (2) it is produced entirely in one or more of the NAFTA parties exclusively from materials that originate in those parties; or (3) each of the non-originating materials used in the production of the good undergoes an applicable change in tariff classification as a result of production occurring entirely in the territory of one or more of the parties and satisfies any other applicable requirement (which may include a regional value-content requirement). The NAFTA preference change in tariff classification (or “tariff-shift”) rules are set forth in General Note 12(t) of the Harmonized Tariff Schedule of the United States (HTSUS).

General Note 12(a), HTSUS, provides that an imported good is eligible for preferential tariff treatment under the NAFTA only if it is an originating good of a NAFTA party *and* it qualifies to be marked as a good of Canada or Mexico under the rules for determining the country of origin of a good for purposes of Annex 311 of the NAFTA. The rules for determining the country of origin for marking in such cases are included in part 102, CBP regulations (19 CFR part 102). In situations in which an imported good is determined under Article 401 of the NAFTA to be originating but fails to qualify as a good of Canada or Mexico under the other applicable provisions set forth in 19 CFR part 102, the NAFTA preference override in § 102.19 may provide a basis for enabling the good to qualify as a good of Canada or Mexico. Under § 102.19, if a good which has NAFTA originating status is not determined to be a good of Canada or Mexico under § 102.11(a) or (b) or § 102.21, the country of origin of the good is determined to be the last NAFTA country in which the good underwent production *other than minor processing*, provided that a NAFTA Certificate of Origin has been completed and signed for the good (emphasis added). “Production” is broadly defined in § 102.1(n) as “growing, mining, harvesting, fishing, trapping, hunting, manufacturing, processing or assembling a good.” “Minor processing” is defined in § 102.1(m) and includes “[p]utting up in measured doses, packing, repacking, packaging, repackaging.”

Thus in certain instances § 102.19 allows the originating status of a good to “override” a determination that it is not a good of Canada or Mexico. In other words, it allows NAFTA preferential tariff treatment to be granted to certain goods that otherwise would be ineligible for such treatment due to the General Note 12(a)’s requirement that originating goods qualify to be marked as goods of Canada or Mexico under the NAFTA Marking Rules. However, under § 102.19, as it currently reads, minor processing would not be a type of production that would qualify a good to be labeled as a product of the country in which the labeling took place and thus would not enable the good to take advantage of NAFTA tariff preferences.

Explanation of Amendments

Since the NAFTA entered into effect, the three parties to the Agreement have agreed to liberalizations to the NAFTA preference rules of origin for various goods. As a result, a lesser degree of processing in a NAFTA party is required to constitute “production” which will confer originating status to certain non-NAFTA materials. The United States took steps to implement these changes by amending the NAFTA preference tariff-shift rules in General Note 12(t), HTSUS, through Presidential Proclamations 7870 dated February 9, 2005 (published in the **Federal Register** on February 14, 2005 (70 FR 7611)), 8067 dated October 11, 2006 (published in the **Federal Register** on October 13, 2006 (71 FR 60649)), and 8405 dated August 31, 2009 (published in the **Federal Register** on September 2, 2009 (74 FR 45529)).

For spices and certain other food products, Presidential Proclamation 7870 specifically liberalized various rules of origin in General Note 12(t) to permit minor processing operations in a NAFTA party, such as packaging, to confer originating status on a good. For example, the NAFTA preference rule for tea (heading 0902, HTSUS) was changed to permit blending and/or packaging to confer NAFTA originating status. Similarly, changes to the preference rules of origin for products such as peppers (subheading 0904.12, HTSUS), cloves (heading 0907, HTSUS), poppy seeds (subheading 1207.91, HTSUS), and certain other spices were also liberalized by Proclamation 7870 to allow these goods to become NAFTA originating as a result of packaging operations in a NAFTA party. It is noted that blending is considered to be more than a minor processing operation for purposes of the NAFTA Marking Rules. *See, for example*, CBP Headquarters

Ruling Letter (HQ) 561986 dated August 21, 2001.

However, contrary to the intentions of the NAFTA parties, these goods are not receiving NAFTA preferential tariff treatment when imported into the United States from Canada or Mexico because they do not qualify to be marked as goods of Canada or Mexico under the NAFTA Marking Rules in 19 CFR part 102, as required by General Note 12(a), HTSUS. This anomalous result stems, in part, from the fact that, in regard to those goods that obtain originating status as a result of minor processing in a NAFTA party, the pertinent NAFTA marking rules in 19 CFR 102.20 are more stringent than the comparable liberalized NAFTA preference rules set forth in General Note 12(t), HTSUS. As discussed above, the NAFTA preference override provision in § 102.19(a) fails to resolve this problem since, as discussed above, this provision overrides a determination that a good is not a good of Canada or Mexico only in situations in which the good undergoes production other than minor processing, in a NAFTA country.

CBP notes that 19 CFR 102.17 provides that a foreign material will not be considered to have undergone an applicable change in tariff classification specified in § 102.20 or § 102.21 or to have met any other applicable requirements of those sections merely by reason of having been subjected to certain specified operations, including “[s]imple packing, repacking or retail packaging without more than minor processing.” This provision clearly is not an impediment to the proposed amendment set forth in this document as the “non-qualifying operations” specified in § 102.17 relate only to the application of the rules set forth in §§ 102.20 and 102.21 and not to the NAFTA preference override in § 102.19.

CBP understands that, as a result of actions taken or interpretations adopted by the Governments of Canada and Mexico, the above-referenced spices and other food products subject to the NAFTA liberalizations are receiving NAFTA preferential tariff treatment when imported from the United States into Canada and Mexico (assuming compliance with all applicable requirements). To rectify the problem discussed above with respect to imports from Canada and Mexico, CBP is proposing to amend § 102.19 by adding a new paragraph (c) to allow the NAFTA preference override to apply to these specific goods. This proposed change, if finalized, will give effect to the intentions of the NAFTA parties by extending NAFTA preferential tariff treatment to certain goods imported

from Canada and Mexico that, under the liberalized rules of origin in General Note 12(t), are considered NAFTA originating as a result of minor processing operations (e.g., packaging) performed in a NAFTA party.

Statutory and Regulatory Requirements

A. Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rulemaking is not a “significant regulatory action,” under section 3(f) of the Executive Order 12866. Accordingly, OMB has not reviewed this proposed rule.

B. Regulatory Flexibility Act

This section examines the impact of the rule on small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA). A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

The proposed rule, if finalized, will extend NAFTA preferential tariff treatment to certain goods imported from Mexico and Canada that currently are not receiving such treatment, despite the fact that these goods presently qualify as NAFTA originating under General Note 12(t), HTSUS. Therefore, the proposed amendment would benefit importers of such goods from Canada and Mexico by eliminating the customs duties and merchandise processing fees that presently are due for these importations. To the extent that this rulemaking affects small entities, these entities would experience a cost savings. Therefore, CBP certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

As there is no collection of information proposed in this document, the provisions of the Paperwork Reduction Act (44 U.S.C. 3507) are inapplicable.

Signing Authority

This document is being issued in accordance with § 0.1(a)(1) of the CBP Regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

List of Subjects in 19 CFR Part 102

Canada, Customs duties and inspections, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements.

Proposed Amendments to the CBP Regulations

For the reasons set forth above, part 102 of title 19 of the Code of Federal Regulations (19 CFR part 102) is proposed to be amended as set forth below.

PART 102—RULES OF ORIGIN

■ 1. The authority citation for part 102, CBP regulations, continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624, 3314, 3592.

§ 102.19 [Amended]

■ 2. In § 102.19:

■ a. Paragraph (a) is amended by adding the words “or (c)” after the words “paragraph (b)”; and

■ b. Paragraph (c) is added to read as follows:

(c) If a good classifiable under heading 0907, 0908, 0909, or subheading 0910.11, 0910.12, 0910.30, 0910.99 or 1207.91, HTSUS, is originating within the meaning of section 181.1(q) of this chapter, but is not determined under section 102.11(a) or (b) to be a good of a single NAFTA country, the country of origin of such good is the last NAFTA country in which that good underwent production, provided that a Certificate of Origin (see § 181.11 of this Chapter) has been completed and signed for the good.

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

Approved: July 1, 2016.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016-16088 Filed 7-7-16; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 1 and 301**

[REG-109086-15]

RIN 1545-BN50

Premium Tax Credit NPRM VI

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the health insurance premium tax credit (premium tax credit) and the individual shared responsibility provision. These proposed regulations affect individuals who enroll in qualified health plans through Health Insurance Exchanges (Exchanges, also called Marketplaces) and claim the premium tax credit, and Exchanges that make qualified health plans available to individuals and employers. These proposed regulations also affect individuals who are eligible for employer-sponsored health coverage and individuals who seek to claim an exemption from the individual shared responsibility provision because of unaffordable coverage. Although employers are not directly affected by rules governing the premium tax credit, these proposed regulations may indirectly affect employers through the employer shared responsibility provisions and the related information reporting provisions.

DATES: Written (including electronic) comments and requests for a public hearing must be received by September 6, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-109086-15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-109086-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (REG-109086-15).

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Shareen Pflanz, (202) 317-4727; concerning the submission of comments and/or requests for a public hearing, Oluwafunmilayo Taylor, (202) 317-6901 (not toll-free calls).

SUPPLEMENTARY INFORMATION:**Paperwork Reduction Act**

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by September 6, 2016. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in § 1.36B-5. The collection of information is necessary to reconcile advance payments of the premium tax credit and determine the allowable premium tax credit. The collection of information is required to comply with the provisions of section 36B of the Internal Revenue Code (Code). The likely respondents are Marketplaces that enroll individuals in qualified health plans.

The burden for the collection of information contained in these proposed regulations will be reflected in the burden on Form 1095-A, *Health Insurance Marketplace Statement*, which is the form that will request the information from the Marketplaces in the proposed regulations.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Background

Beginning in 2014, under the Patient Protection and Affordable Care Act,

Public Law 111–148 (124 Stat. 119 (2010)), and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)) (collectively, the Affordable Care Act), eligible individuals who purchase coverage under a qualified health plan through an Exchange may claim a premium tax credit under section 36B of the Code. Section 36B was subsequently amended by the Medicare and Medicaid Extenders Act of 2010, Public Law 111–309 (124 Stat. 3285 (2010)); the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, Public Law 112–9 (125 Stat. 36 (2011)); and the Department of Defense and Full-Year Continuing Appropriations Act, 2011, Public Law 112–10 (125 Stat. 38 (2011)).

The Affordable Care Act also added section 5000A to the Code. Section 5000A was subsequently amended by the TRICARE Affirmation Act of 2010, Public Law 111–159 (124 Stat. 1123 (2010)) and Public Law 111–173 (124 Stat. 1215 (2010)). Section 5000A provides that, for months beginning after December 31, 2013, a nonexempt individual must have qualifying health care coverage (called minimum essential coverage) or make an individual shared responsibility payment.

Applicable Taxpayers

To be eligible for a premium tax credit, an individual must be an applicable taxpayer. Among other requirements, under section 36B(c)(1) an applicable taxpayer is a taxpayer whose household income for the taxable year is between 100 percent and 400 percent of the Federal poverty line (FPL) for the taxpayer's family size (or is a lawfully present non-citizen who has income below 100 percent of the FPL and is ineligible for Medicaid). A taxpayer's family size is equal to the number of individuals in the taxpayer's family. Under section 36B(d)(1), a taxpayer's family consists of the individuals for whom the taxpayer claims a personal exemption deduction under section 151 for the taxable year. Taxpayers may claim a personal exemption deduction for themselves, a spouse, and each of their dependents.

Under section 1412 of the Affordable Care Act, advance payments of the premium tax credit (advance credit payments) may be made directly to insurers on behalf of eligible individuals. The amount of advance credit payments made on behalf of a taxpayer in a taxable year is determined by a number of factors including projections of the taxpayer's household

income and family size for the taxable year. Taxpayers who receive the benefit of advance credit payments are required to file an income tax return to reconcile the amount of advance credit payments made during the year with the amount of the credit allowable for the taxable year.

Under § 1.36B–2(b)(6), in general, a taxpayer whose household income for a taxable year is less than 100 percent of the applicable FPL is nonetheless treated as an applicable taxpayer if (1) the taxpayer or a family member enrolls in a qualified health plan, (2) an Exchange estimates at the time of enrollment that the taxpayer's household income for the taxable year will be between 100 and 400 percent of the applicable FPL, (3) advance credit payments are authorized and paid for one or more months during the taxable year, and (4) the taxpayer would be an applicable taxpayer but for the fact that the taxpayer's household income for the taxable year is below 100 percent of the applicable FPL.

Premium Assistance Credit Amount

Under section 36B(a), a taxpayer's premium tax credit is equal to the premium assistance credit amount for the taxable year. Section 36B(b)(1) and § 1.36B–3(d) generally provide that the premium assistance credit amount is the sum of the premium assistance amounts for all coverage months in the taxable year for individuals in the taxpayer's family. The premium assistance amount for a coverage month is the lesser of (1) the premiums for the month for one or more qualified health plans that cover a taxpayer or family member (enrollment premium), or (2) the excess of the adjusted monthly premium for the second lowest cost silver plan (as described in section 1302(d)(1)(B) of the Affordable Care Act (42 U.S.C. 18022(d)(1)(B)) offered through the Exchange for the rating area where the taxpayer resides that would provide coverage to the taxpayer's coverage family (the benchmark plan), over 1/12 of the product of the taxpayer's household income and the applicable percentage for the taxable year (the contribution amount). In general, the benchmark plan's adjusted monthly premium is the premium an insurer would charge for the plan adjusted only for the ages of the covered individuals. The applicable percentage is provided in a table that is updated annually and represents the portion of a taxpayer's household income that the taxpayer is expected to pay if the taxpayer's coverage family enrolls in the benchmark plan. See, for example, Rev. Proc. 2014–62, 2014–2 C.B. 948

(providing the applicable percentage table for taxable years beginning in 2016) and Rev. Proc. 2014–37, 2014–2 C.B. 363 (providing the applicable percentage table for taxable years beginning in 2015). A taxpayer's coverage family refers to all members of the taxpayer's family who enroll in a qualified health plan in a month and are not eligible for minimum essential coverage as defined in section 5000A(f) (other than coverage in the individual market) for that month.

Under section 1301(a)(1)(B) of the Affordable Care Act, a qualified health plan must offer the essential health benefits package described in section 1302(a). Under section 1302(b)(1)(J) of the Affordable Care Act, the essential health benefits package includes pediatric services, including oral and vision care. Section 1302(b)(4)(F) of the Affordable Care Act provides that, if an Exchange offers a plan described in section 1311(d)(2)(B)(ii)(I) of the Affordable Care Act (42 U.S.C. 13031(d)(2)(B)(ii)(I)) (a stand-alone dental plan), other health plans offered through the Exchange will not fail to be qualified health plans solely because the plans do not offer pediatric dental benefits.

For purposes of calculating the premium assistance amount for a taxpayer who enrolls in both a qualified health plan and a stand-alone dental plan, section 36B(b)(3)(E) provides that the enrollment premium includes the portion of the premium for the stand-alone dental plan properly allocable to pediatric dental benefits that are included in the essential health benefits required to be provided by a qualified health plan.

Section 36B(b)(3)(B) provides that the benchmark plan with respect to an applicable taxpayer is the second lowest cost silver plan offered by the Marketplace through which the applicable taxpayer (or a family member) enrolled and which provides (1) self-only coverage, in the case of unmarried individuals (other than a surviving spouse or head of household) who do not claim any dependents, or any other individual who enrolls in self-only coverage, and (2) family coverage, in the case of any other applicable taxpayer. Section 1.36B–1(l) provides that self-only coverage means health insurance that covers one individual. Section 1.36B–1(m) provides that family coverage means health insurance that covers more than one individual.

Under § 1.36B–3(f)(3), if there are one or more silver-level plans offered through the Exchange for the rating area where the taxpayer resides that do not cover all members of a taxpayer's

coverage family under one policy (for example, because of the relationships within the family), the benchmark plan premium is the second lowest-cost option for covering all members of the taxpayer's family, which may be either a single silver-level policy or more than one silver-level policy.

Section 1.36B-3(d)(2) provides that, if a qualified health plan is terminated before the last day of a month or an individual is enrolled in coverage effective on the date of the individual's birth, adoption, or placement for adoption or in foster care, or on the effective date of a court order, the premium assistance amount for the month is the lesser of the enrollment premiums for the month (reduced by any amounts that were refunded) or the excess of the benchmark plan premium for a full month of coverage over the full contribution amount for the month.

Coverage Month

Under section 36B(c)(2)(A) and § 1.36B-3(c)(1), a coverage month is generally any month for which the taxpayer or a family member is covered by a qualified health plan enrolled in through an Exchange on the first day of the month and the premium is paid by the taxpayer or through an advance credit payment. However, section 36B(c)(2) provides that a month is not a coverage month for an individual who is eligible for minimum essential coverage other than coverage in the individual market. Under section 36B(c)(2)(B)(ii), minimum essential coverage is defined by reference to section 5000A(f). Minimum essential coverage includes government-sponsored programs such as most Medicaid coverage, Medicare part A, the Children's Health Insurance Program (CHIP), most TRICARE programs, most coverage provided to veterans under title 38 of the United States Code, and the Nonappropriated Fund Health Benefits Program of the Department of Defense. See section 5000A(f)(1) and § 1.5000A-2(b). Section 1.36B-2(c)(3)(i) provides that, for purposes of section 36B, the government-sponsored programs described in section 5000A(f)(1)(A) are not considered eligible employer-sponsored plans.

Under § 1.36B-2(c)(2)(i), an individual generally is treated as eligible for government-sponsored minimum essential coverage as of the first day of the first full month that the individual meets the criteria for coverage and is eligible to receive benefits under the government program. However, under § 1.36B-2(c)(2)(v) an individual is treated as not eligible for Medicaid, CHIP, or a similar program

for a period of coverage under a qualified health plan if, when the individual enrolls in the qualified health plan, an Exchange determines or considers (within the meaning of 45 CFR 155.302(b)) the individual to be ineligible for such program. In addition, § 1.36B-2(c)(2)(iv) provides that if an individual receiving the benefit of advance credit payments is determined to be eligible for a government-sponsored program, and that eligibility is effective retroactively, then, for purposes of the premium tax credit, the individual is treated as eligible for the program no earlier than the first day of the first calendar month beginning after the approval.

Coverage under an eligible employer-sponsored plan is minimum essential coverage. In general, an eligible employer-sponsored plan is coverage provided by an employer to its employees (and their dependents) under a group health plan maintained by the employer. See section 5000A(f)(2) and § 1.5000A-2(c). Under section 5000A(f)(3) and § 1.5000A-2(g), minimum essential coverage does not include any coverage that consists solely of excepted benefits described in section 2791(c)(1), (c)(2), (c)(3), or (c)(4) of the Public Health Service Act (PHS Act) (42 U.S.C. 300gg-91(c)), or regulations issued under those provisions (45 CFR 148.220). In general, excepted benefits are benefits that are limited in scope or are conditional.

Under section 36B(c)(2)(C) and § 1.36B-2(c)(3)(i), except as provided in the next paragraph of this preamble, an individual is treated as eligible for coverage under an eligible employer-sponsored plan only if the employee's share of the premium is affordable and the coverage provides minimum value. Under section 36B(c)(2)(C), an eligible employer-sponsored plan is treated as affordable for an employee if the amount of the employee's required contribution (within the meaning of section 5000A(e)(1)(B)) for self-only coverage does not exceed a specified percentage of the employee's household income. The affordability of coverage for individuals related to an employee is determined in the same manner. Thus, under section 36B(c)(2)(C)(i) and § 1.36B-2(c)(3)(v)(A)(2), an eligible employer-sponsored plan is treated as affordable for an individual eligible for the plan because of a relationship to an employee if the amount of the employee's required contribution for self-only coverage does not exceed a specified percentage of the employee's household income.

Under § 1.36B-2(c)(3)(v)(A)(3), an eligible employer-sponsored plan is not

considered affordable if, when an individual enrolls in a qualified health plan, the Marketplace determines that the eligible employer-sponsored plan is not affordable. However, that rule does not apply for an individual who, with reckless disregard for the facts, provides incorrect information to a Marketplace concerning the employee's portion of the annual premium for coverage under the eligible employer-sponsored plan. In addition, under section 36B(c)(2)(C)(iii) and § 1.36B-2(c)(3)(vii)(A), an individual is treated as eligible for employer-sponsored coverage if the individual actually enrolls in an eligible employer-sponsored plan, even if the coverage is not affordable or does not provide minimum value.

Section 1.36B-2(c)(3)(iii)(A) provides that, subject to the rules described above, an employee or related individual may be considered eligible for coverage under an eligible employer-sponsored plan for a month during a plan year if the employee or related individual could have enrolled in the plan for that month during an open or special enrollment period. Under § 1.36B-2(c)(3)(ii), plan year means an eligible employer-sponsored plan's regular 12-month coverage period (or the remainder of a 12-month coverage period for a new employee or an individual who enrolls during a special enrollment period).

Although coverage in the individual market is minimum essential coverage under section 5000A(f)(1)(C), under section 36B(c)(2)(B)(i), an individual who is eligible for or enrolled in coverage in the individual market (whether or not obtained through the Marketplace) nevertheless may have a coverage month for purposes of the premium tax credit.

Required Contribution for Employer-Sponsored Coverage

Under section 36B(c)(2)(C) and § 1.36B-2(c)(3)(v)(A)(1) and (2), an eligible employer-sponsored plan is treated as affordable for an employee or a related individual if the amount the employee must pay for self-only coverage whether by salary reduction or otherwise (the employee's required contribution) does not exceed a specified percentage of the employee's household income. Under section 36B(c)(2)(C)(i)(II), an employee's required contribution has the same meaning for purposes of the premium tax credit as in section 5000A(e)(1)(B).

Section 5000A provides that, for each month, taxpayers must have minimum essential coverage, qualify for a health coverage exemption, or make an individual shared responsibility

payment when they file a Federal income tax return. Section 5000A(e)(1) and § 1.5000A-3(e)(1) provide that an individual is exempt for a month when the individual cannot afford minimum essential coverage. For this purpose, an individual cannot afford coverage if the individual's required contribution (determined on an annual basis) for minimum essential coverage exceeds a specified percentage of the individual's household income. Under section 5000A(e)(1)(B)(i) and § 1.5000A-3(e)(3)(ii)(A), for employees eligible for coverage under an eligible employer-sponsored plan, the employee's required contribution is the amount an employee would have to pay for self-only coverage (whether paid through salary reduction or otherwise) under the plan. For individuals eligible to enroll in employer-sponsored coverage because of a relationship to an employee (related individual), under section 5000A(e)(1)(C) and § 1.5000A-3(e)(3)(ii)(B), the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost family coverage that would cover the employee and all related individuals who are included in the employee's family and are not otherwise exempt under § 1.5000A-3.

Notice 2015-87, 2015-52 I.R.B. 889, provides guidance on determining the affordability of an employer's offer of eligible employer-sponsored coverage for purposes of sections 36B, 5000A, and 4980H (and the related information reporting under section 6056).¹ In relevant part, Notice 2015-87 addresses how to determine the affordability of an employer's offer of eligible employer-sponsored coverage if an employer also makes available an opt-out payment, which is a payment that (1) is available

¹ An assessable payment under section 4980H(b) may arise if at least one full-time employee (as defined in § 54.4980H-1(a)(21)) of the applicable large employer (as defined in § 54.4980H-1(a)(4)) receives the premium tax credit. A full-time employee generally is ineligible for the premium tax credit if the employee is offered minimum essential coverage under an eligible employer-sponsored plan that is affordable and provides minimum value. The determination of whether an applicable large employer has made an offer of affordable coverage under an eligible employer-sponsored plan for purposes of section 4980H(b) generally is based on the standard set forth in section 36B, which provides that an offer is affordable if the employee's required contribution is at or below 9.5 percent (as indexed) of the employee's household income. However, because an employer generally will not know the taxpayer employee's household income, § 54.4980H-5(e)(2) sets forth three safe harbors under which an employer may determine affordability (solely for purposes of section 4980H) based on information that is readily available to the employer (that is, Form W-2 wages, the rate of pay, or the Federal poverty line).

only if the employee declines coverage (which includes waiving coverage in which the employee would otherwise be enrolled) under the employer-sponsored plan, and (2) cannot be used to pay for coverage under the employer-sponsored plan. The arrangement under which the opt-out payment is made available is an opt-out arrangement.

As Notice 2015-87 explains, the Treasury Department and the IRS have determined that it is generally appropriate to treat an opt-out payment that is made available under an unconditional opt-out arrangement in the same manner as a salary reduction contribution for purposes of determining an employee's required contribution under sections 36B and 5000A and any related consequences under sections 4980H(b) and 6056. Accordingly, Notice 2015-87 provides that the Treasury Department and the IRS intend to propose regulations reflecting this rule and to request comments on those regulations. For this purpose, an unconditional opt-out arrangement refers to an arrangement providing payments conditioned solely on an employee declining coverage under employer-sponsored coverage and not on an employee satisfying any other meaningful requirement related to the provision of health care to employees, such as a requirement to provide proof of coverage through a plan of a spouse's employer.

Notice 2015-87 also provides that the Treasury Department and the IRS anticipate requesting comments on the treatment of conditional opt-out arrangements, meaning opt-out arrangements under which payments are conditioned not only on the employee declining employer-sponsored coverage but also on satisfaction of one or more additional meaningful conditions (such as the employee providing proof of enrollment in coverage provided by a spouse's employer or other coverage).

Notice 2015-87 provides that, until the applicability date of any final regulations (and in any event for plan years beginning before 2017), individuals may treat opt-out payments made available under unconditional opt-out arrangements as increasing the employee's required contribution for purposes of sections 36B and 5000A.² In

² Notice 2015-87 also provides that the Treasury Department and the IRS anticipate that the regulations generally will apply only for periods after the issuance of final regulations and that for the period prior to the applicability date of the final regulations, employers are not required to increase the amount of an employee's required contribution by the amount of an opt-out payment made available under an opt-out arrangement (other than

addition, for the same period, an individual who can demonstrate that he or she meets the condition(s) (in addition to declining the employer's health coverage) that must be satisfied to receive an opt-out payment (such as demonstrating that the employee has coverage under a spouse's group health plan) may treat the amount of the conditional opt-out payment as increasing the employee's required contribution for purposes of sections 36B and 5000A. See the section of this preamble entitled "*Effective/Applicability Date*" for additional related discussion.

Notice 2015-87 included a request for comments on opt-out arrangements. The Treasury Department and the IRS received a number of comments, and the comments are discussed in section 2.f. of this preamble entitled "*Opt-out arrangements and an employee's required contribution.*"

Information Reporting

Section 36B(f)(3) provides that Exchanges must report to the IRS and to taxpayers certain information required to administer the premium tax credit. Section 1.36B-5(c)(1) provides that the information required to be reported annually includes (1) identifying information for each enrollee, (2) identifying information for the coverage, (3) the amount of enrollment premiums and advance credit payments for the coverage, (4) the premium for the benchmark plan used to calculate the amount of the advance credit payments made on behalf of the taxpayer or other enrollee, if advance credit payments were made, and the benchmark plan premium that would apply to all individuals enrolled in the coverage if advance credit payments were not made, and (5) the dates the coverage started and ended. Section 1.36B-5(c)(3)(i) provides that an Exchange must report this information for each family enrolled in the coverage.

Explanation of Provisions

1. *Effective/Applicability Date*

Except as otherwise provided in this section, these regulations are proposed to apply for taxable years beginning after December 31, 2016. As indicated in

a payment made available under a non-relief-eligible opt-out arrangement) for purposes of section 6056 (Form 1095-C), and an opt-out payment made available under an opt-out arrangement (other than a payment made available under a non-relief-eligible opt-out arrangement) will not be treated as increasing an employee's required contribution for purposes of any potential consequences under section 4980H(b). For a discussion of non-relief-eligible opt-out arrangements see Notice 2015-87, Q&A-9.

this section, taxpayers may rely on certain provisions of the proposed regulations for taxable years ending after December 31, 2013. In addition, several rules are proposed to apply for taxable years beginning after December 31, 2018. See the later section of this preamble entitled “*Effective/Applicability Date*” for information on the applicability date for the regulations on opt-out arrangements.

2. Eligibility

a. Applicable Taxpayers

To avoid repayments of advance credit payments for taxpayers who experience an unforeseen decline in income, the existing regulations provide that if an Exchange determines at enrollment that the taxpayer’s household income will be at least 100 percent but will not exceed 400 percent of the applicable FPL, the taxpayer will not lose his or her status as an applicable taxpayer solely because household income for the year turns out to be below 100 percent of the applicable FPL. To reduce the likelihood that individuals who recklessly or intentionally provide inaccurate information to an Exchange will benefit from an Exchange determination, the proposed regulations provide that a taxpayer whose household income is below 100 percent of the FPL for the taxpayer’s family size is not treated as an applicable taxpayer if, with intentional or reckless disregard for the facts, the taxpayer provided incorrect information to an Exchange for the year of coverage.

b. Exchange Determination of Ineligibility for Medicaid or CHIP

Similar to the rule for taxpayers who received the benefit of advance credit payments but ended the taxable year with household income below 100 percent of the applicable FPL, the existing regulations do not require a repayment of advance credit payments for taxpayers with household income within the range for eligibility for certain government-sponsored programs if an Exchange determined or considered (within the meaning of 45 CFR 155.302(b)) the taxpayer or a member of the taxpayer’s family to be ineligible for the program. To reduce the likelihood that individuals who recklessly or intentionally provide inaccurate information to an Exchange will benefit from an Exchange determination, the proposed regulations provide that an individual who was determined or considered by an Exchange to be ineligible for Medicaid, CHIP, or a similar program (such as a

Basic Health Program) may be treated as eligible for coverage under the program if, with intentional or reckless disregard for the facts, the individual (or a person claiming a personal exemption for the individual) provided incorrect information to the Exchange.

c. Nonappropriated Fund Health Benefits Program

The existing regulations under section 36B provide that government-sponsored programs described in section 5000A(f)(1)(A), which include the Nonappropriated Fund Health Benefits Program of the Department of Defense, established under section 349 of the National Defense Authorization Act for Fiscal Year 1995 (Public Law 103–337; 10 U.S.C. 1587 note), are not eligible employer-sponsored plans. However, § 1.5000A–2(c)(2) provides that, because the Nonappropriated Fund Health Benefits Program (Program) is offered by an instrumentality of the Department of Defense to its employees, the Program is an eligible employer-sponsored plan. The proposed regulations conform the section 36B regulations to the section 5000A regulations and provide that the Program is treated as an eligible employer-sponsored plan for purposes of determining if an individual is eligible for minimum essential coverage under section 36B. Thus, if coverage under the Program does not provide minimum value (under § 1.36B–2(c)(3)(vi)) or is not affordable (under § 36B–2(c)(3)(v)) for an individual who does not enroll in the coverage, he or she is not treated as eligible for minimum essential coverage under the Program for purposes of premium tax credit eligibility.

d. Eligibility for Employer-Sponsored Coverage for Months During a Plan Year

The existing regulations under section 36B provide that an individual is eligible for minimum essential coverage through an eligible employer-sponsored plan if the individual had the opportunity to enroll in the plan and the plan is affordable and provides minimum value. The Treasury Department and the IRS are aware that in some instances individuals may not be allowed an annual opportunity to decide whether to enroll in eligible employer-sponsored coverage. This lack of an annual opportunity to enroll in employer-sponsored coverage should not limit an individual’s annual choice from available coverage options through the Marketplace with the possibility of benefitting from the premium tax credit. Thus, the proposed regulations clarify that if an individual declines to enroll in employer-sponsored coverage for a

plan year and does not have the opportunity to enroll in that coverage for one or more succeeding plan years, for purposes of section 36B, the individual is treated as ineligible for that coverage for the succeeding plan year or years for which there is no enrollment opportunity.³

e. Excepted Benefits

Under section 36B and § 1.36B–2(c)(3)(vii)(A), an individual is treated as eligible for minimum essential coverage through an eligible employer-sponsored plan if the individual actually enrolls in the coverage, even if the coverage is not affordable or does not provide minimum value. Although health coverage that consists solely of excepted benefits may be a group health plan and, therefore, is an eligible employer-sponsored plan under section 5000A(f)(2) and § 1.5000A–2(c)(1), section 5000A(f)(3) provides that health coverage that consists solely of excepted benefits is not minimum essential coverage. Therefore, individuals enrolled in a plan consisting solely of excepted benefits still must obtain minimum essential coverage to satisfy the individual shared responsibility provision. The proposed regulations clarify that for purposes of section 36B an individual is considered eligible for coverage under an eligible employer-sponsored plan only if that plan is minimum essential coverage. Accordingly, an individual enrolled in or offered a plan consisting solely of excepted benefits is not denied the premium tax credit by virtue of that excepted benefits offer or coverage. Taxpayers may rely on this rule for all taxable years beginning after December 31, 2013.

f. Opt-Out Arrangements and an Employee’s Required Contribution

Sections 1.36B–2(c)(3)(v) and 1.5000A–3(e)(3)(ii)(A) provide that, in determining whether employer-sponsored coverage is affordable to an employee, an employee’s required contribution for the coverage includes the amount by which the employee’s salary would be reduced to enroll in the

³ Note that for purposes of section 4980H, in general, an applicable large employer will not be treated as having made an offer of coverage to a full-time employee for a plan year if the employee does not have an effective opportunity to elect to enroll in the coverage at least once with respect to the plan year. For this purpose, a plan year must be twelve consecutive months, unless a short plan year of less than twelve consecutive months is permitted for a valid business purpose. For additional rules on the definition of “offer” and “plan year” under section 4980H, see §§ 54.4980H–1(a)(35), 54.4980H–4(b), and 54.4980H–5(b).

coverage.⁴ If an employer makes an opt-out payment available to an employee, the choice between cash and health coverage presented by the opt-out arrangement is analogous to the cash-or-coverage choice presented by the option to pay for coverage by salary reduction. In both cases, the employee may purchase the employer-sponsored coverage only at the price of forgoing a specified amount of cash compensation that the employee would otherwise receive—salary, in the case of a salary reduction, or an equal amount of other compensation, in the case of an opt-out payment. Therefore, the economic cost to the employee of the employer-sponsored coverage is the same under both arrangements. Accordingly, the employee's required contribution generally should be determined similarly regardless of the type of payment that an employee must forgo.

Notice 2015-87 requested comments on the proposed treatment of opt-out arrangements outlined in Q&A-9 of that notice. Several commenters objected to the proposal that the amount of an available unconditional opt-out payment increases the employee's required contribution on the basis that forgoing opt-out payments as part of enrolling in coverage has not traditionally been viewed by employers or employees as economically equivalent to making a salary reduction election and that such a rule would discourage employers from making opt-out payments available. None of the commenters, however, offered a persuasive economic basis for distinguishing unconditional opt-out payments from other compensation that an employee must forgo to enroll in employer-sponsored coverage, such as a salary reduction. Because forgoing an unconditional opt-out payment is economically equivalent to forgoing salary pursuant to a salary reduction election, and because §§ 1.36B-2(c)(3)(v) and 1.5000A-3(e)(3)(ii)(A) provide that the employee's required contribution includes the amount of any salary reduction, the proposed regulations adopt the approach described in Notice 2015-87 for opt-out payments made available under

unconditional opt-out arrangements and provide that the amount of an opt-out payment made available to the employee under an unconditional opt-out arrangement increases the employee's required contribution.⁵

Notice 2015-87 provides that, for periods prior to the applicability date of any final regulations, employers are not required to increase the amount of an employee's required contribution by amounts made available under an opt-out arrangement for purposes of section 4980H(b) or section 6056 (in particular Form 1095-C, *Employer-Provided Health Insurance Offer and Coverage*), except that, for periods after December 16, 2015, the employee's required contribution must include amounts made available under an unconditional opt-out arrangement that is adopted after December 16, 2015. However, Notice 2015-87 provided that, for this purpose, an opt-out arrangement will not be treated as adopted after December 16, 2015, under limited circumstances, including in cases in which a board, committee, or similar body or an authorized officer of the employer specifically adopted the opt-out arrangement before December 16, 2015.

Some commenters requested clarification that an unconditional opt-out arrangement that is required under the terms of a collective bargaining agreement in effect before December 16, 2015, should be treated as having been adopted prior to December 16, 2015, and that amounts made available under such an opt-out arrangement should not be included in an employee's required contribution for purposes of sections 4980H(b) or 6056 through the expiration of the collective bargaining agreement that provides for the opt-out arrangement. The Treasury Department and the IRS now clarify that, under Notice 2015-87, for purposes of sections 4980H(b) and 6056, an unconditional opt-out arrangement that is required under the terms of a collective bargaining agreement in effect before December 16, 2015, will be treated as having been adopted prior to December 16, 2015. In addition, until the later of (1) the beginning of the first plan year

that begins following the expiration of the collective bargaining agreement in effect before December 16, 2015 (disregarding any extensions on or after December 16, 2015), or (2) the applicability date of these regulations with respect to sections 4980H and 6056, employers participating in the collective bargaining agreement are not required to increase the amount of an employee's required contribution by amounts made available under such an opt-out arrangement for purposes of sections 4980H(b) or 6056 (Form 1095-C). The Treasury Department and the IRS further adopt these commenters' request that this treatment apply to any successor employer adopting the opt-out arrangement before the expiration of the collective bargaining agreement in effect before December 16, 2015 (disregarding any extensions on or after December 16, 2015). Commenters raised the issue of whether other types of agreements covering employees may need a similar extension of the relief through the end of the agreement's term. The Treasury Department and the IRS request comments identifying the types of agreements raising this issue due to their similarity to collective bargaining agreements because, for example, the agreement is similar in scope to a collective bargaining agreement, binding on the parties involved for a multi-year period, and subject to a statutory or regulatory regime.

Several commenters suggested that, notwithstanding the proposal on unconditional opt-out arrangements, the amount of an opt-out payment made available should not increase an employee's required contribution if the opt-out payment is conditioned on the employee having minimum essential coverage through another source, such as a spouse's employer-sponsored plan. These commenters argued that the amount of such a conditional opt-out payment should not affect the affordability of an employer's offer of employer-sponsored coverage for an employee who does not satisfy the applicable condition because that employee is ineligible to receive the opt-out payment. Moreover, commenters argued that an employee who satisfies the condition (that is, who has alternative minimum essential coverage) is ineligible for the premium tax credit and does not need to determine the affordability of the employer's coverage offer. Thus, the commenters asserted, an amount made available under such an arrangement should be excluded from the required contribution.

While it is clear that the availability of an unconditional opt-out payment increases an individual's required

⁴ Section 5000A(e)(1)(C) and § 1.5000A-3(e)(3)(ii)(B) provide that, for purposes of the individual shared responsibility provision, the required contribution for individuals eligible to enroll in employer coverage because of a relationship to an employee (related individual) is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost family coverage that would cover the employee and all related individuals who are included in the employee's family and are not otherwise exempt under § 1.5000A-3.

⁵ To distinguish between opt-out payments and employer contributions to a section 125 cafeteria plan (which in some cases could be paid in cash to an employee who declines coverage in the health plan or other available benefits), the proposed regulations further clarify that an amount provided as an employer contribution to a cafeteria plan and that may be used by the employee to purchase minimum essential coverage is not an opt-out payment, whether or not the employee may receive the amount as a taxable benefit. This provision clarifies that the effect on an employee's required contribution of employer contributions to a cafeteria plan is determined under § 1.36B-2(c)(3)(v)(A)(6) rather than § 1.36B-2(c)(3)(v)(A)(7).

contribution, the effect of the availability of a conditional opt-out payment is less obvious. In particular, under an unconditional opt-out arrangement, an individual who enrolls in the employer coverage loses the opt-out payment as a direct result of enrolling in the employer coverage. By contrast, in the case of a conditional opt-out arrangement, the availability of the opt-out payment may depend on information that is not generally available to the employer (who, if it is an applicable large employer, must report the required contribution under section 6056 and whose potential liability under section 4980H may be affected). Because of this difficulty of ascertaining which individuals could have met the condition and, therefore, would actually forgo the opt-out payment when enrolling in employer-sponsored coverage, it generally is not feasible to have a rule under which the required contribution perfectly captures the cost of coverage for each specific individual offered a conditional opt-out payment.

Similarly, another way to view opt-out payments that are conditioned on alternative coverage is that, rather than raising the cost to the employee of the employer's coverage, they reduce the cost to the employee of the alternative coverage. However, because employers generally do not have information about the existence and cost of other options available to the individual, it is not practical to take into account any offer of coverage other than the offer made by the employer in determining the required contribution with respect to the employer coverage (that is, the coverage that the employee must decline to receive the opt-out payment).

While commenters indicated that the required contribution with respect to the employer coverage does not matter for an individual enrolled in any other minimum essential coverage because the individual would be ineligible for the premium tax credit, this statement is not true if the other coverage is individual market coverage. In particular, while enrollment in most types of minimum essential coverage results in an individual being ineligible for a premium tax credit, that is not the case for coverage in the individual market. Moreover, for individual market coverage offered through a Marketplace, the required contribution with respect to the employer coverage frequently will be relevant in determining whether the individual is eligible for a premium tax credit. In such cases, as in the case of an unconditional opt-out payment, the availability of a conditional opt-out payment effectively increases the cost to

the individual of enrolling in the employer coverage (at least relative to Marketplace coverage).

Further, an opt-out arrangement that is conditioned on an employee's ability to obtain other coverage (if that coverage can be coverage in the individual market, whether inside or outside the Marketplace) does not generally raise the issues described earlier in this section of the preamble regarding the difficulty of ascertaining which individuals could meet the condition under a conditional opt-out arrangement. This is because generally all individuals are able to obtain coverage in the individual market, pursuant to the guaranteed issue requirements in section 2702 of the PHS Act. Thus, in the sense that all individuals can satisfy the applicable condition, such an opt-out arrangement is similar to an unconditional opt-out arrangement.

In an effort to provide a workable rule that balances these competing concerns, the proposed regulations provide that amounts made available under conditional opt-out arrangements are disregarded in determining the required contribution if the arrangement satisfies certain conditions (an "eligible opt-out arrangement"), but otherwise the amounts are taken into account. The proposed regulations define an "eligible opt-out arrangement" as an arrangement under which the employee's right to receive the opt-out payment is conditioned on (1) the employee declining to enroll in the employer-sponsored coverage and (2) the employee providing reasonable evidence that the employee and all other individuals for whom the employee reasonably expects to claim a personal exemption deduction for the taxable year or years that begin or end in or with the employer's plan year to which the opt-out arrangement applies (employee's expected tax family) have or will have minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) during the period of coverage to which the opt-out arrangement applies. For example, if an employee's expected tax family consists of the employee, the employee's spouse, and two children, the employee would meet this requirement by providing reasonable evidence that the employee, the employee's spouse, and the two children, will have coverage under the group health plan of the spouse's

employer for the period to which the opt-out arrangement applies.⁶

The Treasury Department and the IRS invite comments on this proposed rule, including suggestions for other workable rules that result in the required contribution more accurately reflecting the individual's cost of coverage while minimizing undesirable consequences and incentives.

For purposes of the proposed eligible opt-out arrangement rule, reasonable evidence of alternative coverage includes the employee's attestation that the employee and all other members of the employee's expected tax family, if any, have or will have minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) or other reasonable evidence. Notwithstanding the evidence of alternative coverage required under the arrangement, to qualify as an eligible opt-out arrangement, the arrangement must also provide that any opt-out payment will not be made (and the payment must not in fact be made) if the employer knows or has reason to know that the employee or any other member of the employee's expected tax family does not have (or will not have) the required alternative coverage. An eligible opt-out arrangement must also require that the evidence of coverage be provided no less frequently than every plan year to which the eligible opt-out arrangement applies, and that the evidence be provided no earlier than a reasonable period before the commencement of the period of coverage to which the eligible opt-out arrangement applies. Obtaining the reasonable evidence (such as an attestation) as part of the regular annual open enrollment period that occurs within a few months before the commencement of the next plan year of employer-sponsored coverage meets this reasonable period requirement. Alternatively, the eligible opt-out arrangement would be permitted to require evidence of alternative coverage to be provided later, such as after the plan year starts, which would enable the employer to require evidence that the employee and other members of the

⁶ The Treasury Department and the IRS note that if an opt-out payment is conditioned on an employee obtaining individual market coverage, that opt-out arrangement could act as a reimbursement arrangement for some or all of the employee's premium for that individual market coverage; therefore, the opt-out arrangement could operate as an employer payment plan as discussed in Notice 2015-87, Notice 2015-17, 2015-14 I.R.B. 845, and Notice 2013-54, 2013-40 I.R.B. 287. Nothing in these proposed regulations is intended to affect the prior guidance on employer payment plans.

employee's expected tax family have already obtained the alternative coverage.

Commenters on Notice 2015–87 generally stated that typical conditions under an opt-out arrangement include a requirement that the employee have alternative coverage through employer-sponsored coverage of a spouse or another relative, such as a parent. Provided that, as required under the opt-out arrangement, the employee provided reasonable evidence of this alternative coverage for the employee and the other members of the employee's expected tax family, and met the related conditions described in this preamble, these types of opt-out arrangements would be eligible opt-out arrangements, and opt-out payments made available under such arrangements would not increase the employee's required contribution.

The Treasury Department and the IRS did not receive comments on opt-out arrangements indicating that the meaningful conditions imposed include any requirement other than one relating to alternative coverage. Therefore, the proposed rules do not address other opt-out conditions and would not treat an opt-out arrangement based on other conditions as an eligible opt-out arrangement. However, the Treasury Department and the IRS invite comments on whether opt-out payments are made subject to additional types of conditions in some cases, whether those types of conditions should be addressed in further guidance, and, if so, how.

One commenter suggested that, if opt-out payments conditioned on alternative coverage are not included in an employee's required contribution, rules will be needed for cases in which an employee receives an opt-out payment and that employee's alternative coverage subsequently terminates. The commenter suggested that, in that case, the termination of the alternative coverage should have no impact on the determination of the employee's required contribution for the employer-sponsored coverage from which the employee opted out. In response, under the proposed regulations, provided that the reasonable evidence requirement is met, the amount of an opt-out payment made available under an eligible opt-out arrangement may continue to be excluded from the employee's required contribution for the remainder of the period of coverage to which the opt-out payment originally applied. The opt-out payment may be excluded for this period even if the alternative coverage subsequently terminates for the employee or any other member of the employee's expected tax family,

regardless of whether the opt-out payment is required to be adjusted or terminated due to the loss of alternative coverage, and regardless of whether the employee is required to provide notice of the loss of alternative coverage to the employer.

The Treasury Department and the IRS are aware that the way in which opt-out arrangements affect the calculation of affordability is important not only to an employee and the other members of the employee's expected tax family in determining whether they may be eligible for a premium tax credit or whether an individual may be exempt under the individual shared responsibility provisions, but also to an employer subject to the employer shared responsibility provisions under section 4980H in determining whether the employer may be subject to an assessable payment under section 4980H(b). An employer subject to the employer shared responsibility provisions will be subject to a payment under section 4980H(b) only with respect to a full-time employee who receives a premium tax credit, and an employee will not be eligible for the premium tax credit if the employer's offer of coverage was affordable and provided minimum value.⁷ Commenters expressed concern that if the rule adopted for conditional opt-outs required an employee to provide reasonable evidence that the employee has or will have minimum essential coverage, the employer may not know whether the employee is being truthful and has obtained (or will obtain) such coverage, or how long such coverage will continue. Under these proposed regulations, however, the employee's required contribution will not be increased by an opt-out payment made available under an eligible opt-out arrangement, provided that the arrangement provides that the employer makes the payment only if the employee provides reasonable evidence of alternative coverage and the employer does not know or have reason to know that the employee or any other member of the employee's expected tax family fails or will fail to meet the requirement to have alternative coverage (other than individual market coverage, whether or not obtained through the Marketplace).

Some commenters requested exceptions for special circumstances

⁷ The affordability rules under section 36B, including rules regarding opt-out payments, may also affect the application of section 4980H(a) because one element that is required for an applicable large employer to be subject to an assessable payment under section 4980H(a) is that at least one full-time employee must receive the premium tax credit.

from the general rule that the employee's required contribution is increased by the amount of an opt-out payment made available. These circumstances include (1) conditional opt-out payments that are required under the terms of a collective bargaining agreement and (2) opt-out payments that are below a de minimis amount. Regarding opt-out arrangements contained in collective bargaining agreements, the Treasury Department and the IRS anticipate that the proposed treatment of eligible opt-out arrangements, generally, will address the concerns raised in the comments. Accordingly, the Treasury Department and the IRS do not propose to provide a permanent exception for opt-out arrangements provided under collective bargaining agreements. Earlier in this section of the preamble, however, the Treasury Department and the IRS clarify and expand the transition relief provided under Notice 2015–87 for opt-out arrangements provided under collective bargaining agreements in effect before December 16, 2015. As for an exception for de minimis amounts, the Treasury Department and the IRS decline to adopt such an exception because there is neither a statutory nor an economic basis for establishing a de minimis threshold under which an unconditional opt-out payment would be excluded from the employee's required contribution.

g. Effective Date of Eligibility for Minimum Essential Coverage When Advance Credit Payments Discontinuance Is Delayed

Section 36B and the regulations under section 36B provide that an individual who may enroll in minimum essential coverage outside the Marketplace (other than individual market coverage) for a month is generally not allowed a premium tax credit for that month. Consequently, individuals enrolled in a qualified health plan with advance credit payments must return to the Exchange to report eligibility for other minimum essential coverage so the Exchange can discontinue the advance credit payments for Marketplace coverage. Similarly, individuals enrolled in a qualified health plan with advance credit payments may be determined eligible for coverage under a government-sponsored program, such as Medicaid. In some cases, individuals may inform the Exchange of their opportunity to enroll in other minimum essential coverage or receive approval for coverage under a government-sponsored program after the time for which the Exchange can discontinue advance credit payments for the next

month. Because taxpayers should generally not have to repay the advance credit payments for that next month in these circumstances, the proposed regulations provide a rule for situations in which an Exchange's discontinuance of advance credit payments is delayed. Under the proposed regulations, if an individual who is enrolled in a qualified health plan for which advance credit payments are made informs the Exchange that the individual is or will soon be eligible for other minimum essential coverage and that advance credit payments should be discontinued, but the Exchange does not discontinue advance credit payments for the first calendar month beginning after the month the individual notifies the Exchange, the individual is treated as eligible for the other minimum essential coverage no earlier than the first day of the second calendar month beginning after the first month the individual may enroll in the other minimum essential coverage. Similarly, if a determination is made that an individual is eligible for Medicaid or CHIP but advance credit payments are not discontinued for the first calendar month beginning after the eligibility determination, the individual is treated as eligible for Medicaid or CHIP no earlier than the first day of the second calendar month beginning after the determination. Taxpayers may rely on this rule for all taxable years beginning after December 31, 2013.

3. Premium Assistance Amount

a. Payment of Taxpayer's Share of Premiums for Advance Credit Payments Following Appeal Determinations

Under § 1.36B-3(c)(1)(ii), a month in which an individual who is enrolled in a qualified health plan is a coverage month for the individual only if the taxpayer's share of the premium for the individual's coverage for the month is paid by the unextended due date of the taxpayer's income tax return for the year of coverage, or the premium is fully paid by advance credit payments.

One of the functions of an Exchange is to make determinations as to whether an individual who enrolls in a qualified health plan is eligible for advance credit payments for the coverage. If an Exchange determines that the individual is not eligible for advance credit payments, the individual may appeal that decision. An individual who is initially determined ineligible for advance credit payments, does not enroll in a qualified health plan under the contested determination, and is later determined to be eligible for advance credit payments through the appeals

process, may elect to be retroactively enrolled in a health plan through the Exchange. In that case, the individual is treated as having been enrolled in the qualified health plan from the date on which the individual would have enrolled had he or she initially been determined eligible for advance credit payments. If retroactively enrolled, the deadline for paying premiums for the retroactive coverage may be after the unextended due date for filing an income tax return for the year of coverage. Consequently, the proposed regulations provide that a taxpayer who is eligible for advance credit payments pursuant to an eligibility appeal for a member of the taxpayer's coverage family who, based on the appeals decision, retroactively enrolls in a qualified health plan, is considered to have met the requirement in § 1.36B-3(c)(1)(ii) for a month if the taxpayer pays the taxpayer's share of the premium for coverage under the plan for the month on or before the 120th day following the date of the appeals decision. Taxpayers may rely on this rule for all taxable years beginning after December 31, 2013.

b. Month That Coverage Is Terminated

Section 1.36B-3(d)(2) provides that if a qualified health plan is terminated before the last day of a month, the premium assistance amount for the month is the lesser of the enrollment premiums for the month (reduced by any amounts that were refunded), or the excess of the benchmark plan premium for a full month of coverage over the full contribution amount for the month. Section 1.36B-3(c)(2) provides that an individual whose enrollment in a qualified health plan is effective on the date of the individual's birth or adoption, or placement for foster care, or upon the effective date of a court order, is treated as enrolled as of the first day of the month and, therefore, the month of enrollment may be a coverage month. The regulations, however, do not expressly address how the premium assistance amount is computed when a covered individual disenrolls before the last day of a month but the plan is not terminated because other individuals remain enrolled. For purposes of the premium tax credit, the premium assistance amount for an individual who is not enrolled for an entire month should be the same regardless of the circumstances causing the partial-month coverage, provided that the individual was enrolled, or is treated as enrolled, as of the first day of the month (that is, so long as the month is a coverage month). Accordingly, to provide consistency for all individuals who have

a coverage month that is less than a full calendar month, the proposed regulations provide that the premium assistance amount for a month is the lesser of the enrollment premiums for the month (reduced by any amounts that were refunded), or the excess of the benchmark plan premium over the contribution amount for the month. Taxpayers may rely on this rule for all taxable years beginning after December 31, 2013.

4. Benchmark Plan Premium

a. Effective/Applicability Date of Benchmark Plan Rules

The rules relating to the benchmark plan in this section are proposed to apply for taxable years beginning after December 31, 2018.

b. Pediatric Dental Benefits

Under section 1311(d)(2)(B) of the Affordable Care Act, only qualified health plans, including stand-alone dental plans offering pediatric dental benefits, may be offered through a Marketplace. In general, a qualified health plan is required to provide coverage for all ten essential health benefits described in section 1302(b) of the Affordable Care Act, including pediatric dental coverage. However, under section 1302(b)(4)(F), a plan that does not provide pediatric dental benefits may nonetheless be a qualified health plan if it covers each essential health benefit described in section 1302(b) other than pediatric dental benefits and if it is offered through a Marketplace in which a stand-alone dental plan offering pediatric dental benefits is offered as well.

Section 36B(b)(3)(E) and § 1.36B-3(k) provide that if an individual enrolls in both a qualified health plan and a stand-alone dental plan, the portion of the premium for the stand-alone dental plan properly allocable to pediatric dental benefits is treated as a premium payable for the individual's qualified health plan. Thus, in determining a taxpayer's premium assistance amount for a month in which a member of the taxpayer's coverage family is enrolled in a stand-alone dental plan, the taxpayer's enrollment premium includes the portion of the premium for the stand-alone dental plan allocable to pediatric dental benefits. The existing regulations do not provide a similar adjustment for the taxpayer's applicable benchmark plan premium to reflect the cost of pediatric dental benefits in cases where the second-lowest cost silver plan does not provide pediatric dental benefits.

Section 36B(b)(3)(B) provides that the applicable benchmark plan with respect

to a taxpayer is the second lowest cost silver plan available through the applicable Marketplace that provides “self-only coverage” or “family coverage,” depending generally on whether the coverage family includes one or more individuals. Neither the Code nor the Affordable Care Act defines the terms “self-only coverage” or “family coverage” for this purpose.

Under the existing regulations, the references in section 36B(b)(3)(B) to plans that provide self-only coverage and family coverage are interpreted to refer to all qualified health plans offered through the applicable Marketplace, regardless of whether the coverage offered by those plans includes all ten essential health benefits. Because qualified health plans that do not offer pediatric dental benefits tend to be cheaper than qualified health plans that cover all ten essential health benefits, the second lowest-cost silver plan (and therefore the premium tax credit) for taxpayers purchasing coverage through a Marketplace in which stand-alone dental plans are offered is likely to not account for the cost of obtaining pediatric dental coverage.

The Treasury Department and the IRS believe that the current rule frustrates the statute’s goal of making coverage that provides the essential health benefits affordable to individuals eligible for the premium tax credit. Accordingly, the proposed regulations reflect a modification in the interpretation of the terms “self-only coverage” and “family coverage” in section 36B(b)(3)(B) to refer to coverage that provides each of the essential health benefits described in section 1302(b) of the Affordable Care Act. This coverage may be obtained from either a qualified health plan alone or from a qualified health plan in combination with a stand-alone dental plan. In particular, self-only coverage refers to coverage obtained from such plans where the coverage family is a single individual. Similarly, family coverage refers to coverage obtained from such plans where the coverage family includes more than one individual.

Consistent with this interpretation, the proposed regulations provide that for taxable years beginning after December 31, 2018, if an Exchange offers one or more silver-level qualified health plans that do not cover pediatric dental benefits, the applicable benchmark plan is determined by ranking (1) the premiums for the silver-level qualified health plans that include pediatric dental benefits offered by the Exchange and (2) the aggregate of the premiums for the silver-level qualified health plans offered by the Exchange

that do not include pediatric dental benefits plus the portion of the premium allocable to pediatric dental benefits for stand-alone dental plans offered by the Exchange. In constructing this ranking, the premium for the lowest-cost silver plan that does not include pediatric dental benefits is added to the premium allocable to pediatric dental benefits for the lowest cost stand-alone dental plan, and similarly, the premium for the second lowest-cost silver plan that does not include pediatric dental benefits is added to the premium allocable to pediatric dental benefits for the second lowest-cost stand-alone dental plan. The second lowest-cost amount from this combined ranking is the taxpayer’s applicable benchmark plan premium.

c. Coverage Family Members Residing in Different Locations

Under § 1.36B–3(f), a taxpayer’s applicable benchmark plan is the second lowest cost silver plan offered at the time a taxpayer or family member enrolls in a qualified health plan through the Exchange for the rating area where the taxpayer resides. Under § 1.36B–3(f)(4), if members of a taxpayer’s family reside in different states and enroll in separate qualified health plans, the premium for the taxpayer’s applicable benchmark plan is the sum of the premiums for the applicable benchmark plans for each group of family members living in the same state.

Referring to the residence of the taxpayer to establish the cost for a benchmark health plan is appropriate when the taxpayer and all members of the taxpayer’s coverage family live in the same location because it reflects the cost of available coverage for the taxpayer’s coverage family. However, because premiums and plan availability may vary based on location, the existing rule for a taxpayer whose family members reside in different locations in the same state may not accurately reflect the cost of available coverage. In addition, the rules for calculating the premium tax credit should operate the same for families residing in multiple locations within a state and families residing in multiple states. Accordingly, § 1.36B–3(f)(4) of the proposed regulations provides that if a taxpayer’s coverage family members reside in multiple locations, whether within the same state or in different states, the taxpayer’s benchmark plan is determined based on the cost of available coverage in the locations where members of the taxpayer’s coverage family reside. In particular, if members of a taxpayer’s coverage family reside in different locations, the

taxpayer’s benchmark plan premium is the sum of the premiums for the applicable benchmark plans for each group of coverage family members residing in different locations, based on the plans offered to the group through the Exchange for the rating area where the group resides. If all members of a taxpayer’s coverage family reside in a single location that is different from where the taxpayer resides, the taxpayer’s benchmark plan premium is the premium for the applicable benchmark plan for the coverage family, based on the plans offered to the taxpayer’s coverage family through the Exchange for the rating area where the coverage family resides.

d. Aggregation of Silver-Level Policies

Section 1.36B–3(f)(3) provides that if one or more silver-level plans offered through an Exchange do not cover all members of a taxpayer’s coverage family under one policy (for example, because an issuer will not cover a taxpayer’s dependent parent on the same policy the taxpayer enrolls in), the premium for the applicable benchmark plan may be the premium for a single policy or for more than one policy, whichever is the second lowest-cost silver option. This rule does not specify which combinations of policies must be taken into account for this purpose, suggesting that all such combinations must be considered, which is unduly complex for taxpayers, difficult for Exchanges to implement, and difficult for the IRS to administer. Accordingly, to clarify and simplify the benchmark premium determination for situations in which a silver-level plan does not cover all the members of a taxpayer’s coverage family under one policy, the proposed regulations delete the existing rule and provide a new rule in its place.

Under the proposed regulations, if a silver-level plan offers coverage to all members of a taxpayer’s coverage family who reside in the same location under a single policy, the plan premium taken into account for purposes of determining the applicable benchmark plan is the premium for that policy. In contrast, if a silver-level plan would require multiple policies to cover all members of a taxpayer’s coverage family who reside in the same location, the plan premium taken into account for purposes of determining the applicable benchmark plan is the sum of the premiums for self-only policies under the plan for each member of the coverage family who resides in the same location. Under the proposed regulations, similar rules would apply to the portion of premiums for stand-alone dental plans allocable to pediatric

dental coverage taken into account for purposes of determining the premium for a taxpayer's applicable benchmark plan.

Comments are requested on the rule contained in the proposed regulations, as well as on an alternative rule under which the plan premium taken into account for purposes of determining a taxpayer's applicable benchmark plan would be equal to the sum of the self-only policies under a plan for each member of the taxpayer's coverage family, regardless of whether all members of the taxpayer's coverage family could be covered under a single policy under the plan.

e. Silver-Level Plan Not Available for Enrollment

Section 1.36B-3(f)(5) provides that if a qualified health plan is closed to enrollment for a taxpayer or a member of the taxpayer's coverage family, that plan is disregarded in determining the taxpayer's applicable benchmark plan. Similarly, § 1.36B-3(f)(6) provides that a plan that is the applicable benchmark plan for a taxpayer does not cease to be the applicable benchmark plan solely because the plan or a lower cost plan terminates or closes to enrollment during the taxable year. Because stand-alone dental plans are considered in determining a taxpayer's applicable benchmark plan under the proposed regulations, the proposed regulations provide consistency in the treatment of qualified health plans and stand-alone dental plans that are closed to enrollment or that terminate during the taxable year.

f. Only One Silver-Level Plan Offered to the Coverage Family

In general, § 1.36B-3(f)(1) provides that a taxpayer's applicable benchmark plan is the second lowest-cost silver-level plan available to the taxpayer for self-only or family coverage. However, for taxpayers who reside in certain locations, only one silver-level plan providing such coverage may be available. Section 1.36B-3(f)(8) of the proposed regulations clarifies that if there is only one silver-level qualified health plan offered through the Exchange that would cover all members of the taxpayer's coverage family (whether under one policy or multiple policies), that silver-level plan is used for purposes of the taxpayer's applicable benchmark plan. Similarly, if there is only one stand-alone dental plan offered through the Exchange that would cover all members of the taxpayer's coverage family (whether under one policy or multiple policies), the portion of the premium of that plan that is allocable to

pediatric dental benefits is used for purposes of determining the taxpayer's applicable benchmark plan.

5. Reconciliation of Advance Credit Payments

Section 301.6011-8 provides that a taxpayer who receives the benefit of advance credit payments must file an income tax return for that taxable year on or before the due date for the return (including extensions of time for filing) and reconcile the advance credit payments. In addition, the regulations under section 36B provide that if advance credit payments are made for coverage of an individual for whom no taxpayer claims a personal exemption deduction, the taxpayer who attests to the Exchange to the intention to claim a personal exemption deduction for the individual as part of the determination that the taxpayer is eligible for advance credit payments for coverage of the individual must reconcile the advance credit payments.

Questions have been raised concerning how these two rules apply, and consequently which individual must reconcile advance credit payments, when a taxpayer (a parent, for example) attests that he or she will claim a personal exemption deduction for an individual, the advance payments are made with respect to coverage for the individual, the taxpayer does not claim a personal exemption deduction for the individual, and the individual does not file a tax return for the year. The intent of the existing regulation is that the taxpayer, not the individual for whose coverage advance credit payments were made, must reconcile the advance credit payments in situations in which a taxpayer attests to the intention to claim a personal exemption for the individual and no one claims a personal exemption deduction for the individual. Consequently, the proposed regulations clarify that if advance credit payments are made for coverage of an individual for whom no taxpayer claims a personal exemption deduction, the taxpayer who attests to the Exchange to the intention to claim a personal exemption deduction for the individual, not the individual for whose coverage the advance credit payments were made, must file a tax return and reconcile the advance credit payments.

6. Information Reporting

a. Two or More Families Enrolled in Single Qualified Health Plan

Section 1.36B-3(h) provides that if a qualified health plan covers more than one family under a single policy (for example, a plan covers a taxpayer and

the taxpayer's child who is 25 and not a dependent of the taxpayer), the premium tax credit is computed for each applicable taxpayer covered by the plan. In addition, in computing the tax credit for each taxpayer, premiums for the qualified health plan the taxpayers purchase (the enrollment premiums) are allocated to each taxpayer in proportion to the premiums for each taxpayer's applicable benchmark plan.

The existing regulations provide that the Exchange must report the enrollment premiums for each family, but do not specify the manner in which the Exchange must divide the enrollment premiums among the families enrolled in the policy. Consequently, the proposed regulations clarify that when multiple families enroll in a single qualified health plan and advance credit payments are made for the coverage, the enrollment premiums reported by the Exchange for each family is the family's allocable share of the enrollment premiums, which is based on the proportion of each family's applicable benchmark plan premium.

b. Partial Months of Enrollment

The existing regulations do not specify how the enrollment premiums and benchmark plan premiums are reported in cases in which one or more individuals is enrolled or disenrolled in coverage mid-month. To ensure that this reporting is consistent with the rules for calculating the premium assistance amounts for partial months of coverage, the proposed regulations provide that, if an individual is enrolled in a qualified health plan after the first day of a month, generally no value should be reported for the individual's enrollment premium or benchmark plan premium for that month. However, if an individual's coverage in a qualified health plan is terminated before the last day of a month, or an individual is enrolled in coverage after the first day of a month and the coverage is effective on the date of the individual's birth, adoption, or placement for adoption or in foster care, or on the effective date of a court order, an Exchange must report the premium for the applicable benchmark plan for a full month of coverage (excluding the premium allocated to benefits in excess of essential health benefits). In addition, the proposed regulations provide that the Exchange must report the enrollment premiums for the month (excluding the premium allocated to benefits in excess of essential health benefits), reduced by any amount that was refunded due to the plan's termination.

c. Use of Electronic Media

Section 301.6011-2(b) provides that if the use of certain forms, including the Form 1095 series, is required by the applicable regulations or revenue procedures for the purpose of making an information return, the information required by the form must be submitted on magnetic media. Form 1095-A should not have been included in § 301.6011-2 because Form 1095-A is not an information return. Consequently, the proposed regulations replace the general reference in § 301.6011-2(b) to the forms in the 1095 series with specific references to Forms 1095-B and 1095-C, but not Form 1095-A.

Effective/Applicability Date

Except as otherwise provided, these regulations are proposed to apply for taxable years beginning after December 31, 2016. In addition, taxpayers may rely on certain provisions of the proposed regulations for taxable years ending after December 31, 2013, as indicated earlier in this preamble. In addition, rules relating to the benchmark plan described in section 4 of this preamble are proposed to apply for taxable years beginning after December 31, 2018.

Notwithstanding the proposed applicability date, nothing in the proposed regulations is intended to limit any relief for opt-out arrangements provided in Notice 2015-87, Q&A 9, or in section 2.f of the preamble to these proposed regulations (regarding opt-out arrangements provided for in collective bargaining agreements). For purposes of sections 36B and 5000A, although under the proposed regulations amounts made available under an eligible opt-out arrangement are not added to an employee's required contribution, for periods before the final regulations are applicable and, if later, through the end of the most recent plan year beginning before January 1, 2017, an individual who can demonstrate that he or she meets the condition for an opt-out payment under an eligible opt-out arrangement is permitted to treat the opt-out payment as increasing the employee's required contribution.⁸

For purposes of the consequences of these regulations under sections 4980H and 6056 (and in particular Form 1095-C), the regulations regarding opt-out arrangements are proposed to be first

⁸ For periods prior to the applicability date, an individual who cannot demonstrate that he or she meets the condition for an opt-out payment under an eligible opt-out arrangement is not permitted to treat the opt-out payment as increasing the employee's required contribution.

applicable for plan years beginning on or after January 1, 2017,⁹ and for the period prior to this applicability date employers are not required to increase the amount of an employee's required contribution by the amount of an opt-out payment made available under an opt-out arrangement (other than a payment made available under a non-relief-eligible opt-out arrangement¹⁰). See also section 2.f of this preamble for transition relief provided under Notice 2015-87 as clarified and expanded for opt-out arrangements contained in collective bargaining agreements in effect before December 16, 2015. See § 601.601(d)(2)(ii)(b).

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the information collection required under these regulations is imposed under section 36B. Consistent with the statute, the proposed regulations require a person that provides minimum essential coverage to an individual to file a return with the IRS reporting certain information and to furnish a statement to the responsible individual who enrolled an individual or family in the coverage. These regulations merely provide the method of filing and furnishing returns and statements under section 36B. Moreover, the proposed regulations attempt to minimize the burden associated with this collection of information by limiting reporting to the information that the IRS requires to verify minimum essential coverage and administer tax credits.

Based on these facts, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

Pursuant to section 7805(f) of the Code, this notice of proposed

⁹ Notice 2015-87, Q&A 9 provides that the Treasury Department and the IRS anticipate that the regulations on opt-out arrangements generally will apply only for periods after the issuance of final regulations. The Treasury Department and the IRS anticipate finalizing these regulations prior to the end of 2016.

¹⁰ For a discussion of non-relief-eligible opt-out arrangements see Notice 2015-87, Q&A-9.

rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. Treasury and the IRS request comments on all aspects of the proposed rules. All comments will be available at www.regulations.gov or upon request. A public hearing will be scheduled if requested in writing by any person who timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Shareen S. Pflanz and Stephen J. Toomey of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.36B-0 is amended by:

- 1. Adding the entries for §§ 1.36B-2(b)(6)(i) and (ii).
- 2. Adding entries for §§ 1.36B-2(c)(3)(v)(A)(7), (v)(A)(7)(i), (ii), (iii), (iii)(A), (iii)(B), (iii)(C), and (iv).
- 3. Redesignating entry for § 1.36B-2(c)(4) as (c)(5) and adding new entries for § 1.36B-2(c)(4), (c)(4)(i), (ii), (ii)(A), and (ii)(B).

- 4. Redesignating entry for § 1.36B–3(c)(4) as (c)(5) and adding a new entry for § 1.36B–3(c)(4).
- 5. Revising entries for §§ 1.36B–3(d)(1) and (d)(2).
- 6. Revising entries for §§ 1.36B–3(f)(3), (4), (5), (6), and (7).
- 7. Adding entries for §§ 1.36B–3(f)(8), (9), and (10).
- 8. Adding entries for §§ 1.36B–5(c)(3)(iii).

The revisions and additions read as follows:

§ 1.36B–0 Table of contents.

* * * * *
 § 1.36B–2 Eligibility for premium tax credit.

- * * * * *
- (b) * * *
- (6) * * *
- (i) In general.
- (ii) Exceptions.
- * * * * *
- (c) * * *
- (3) * * *
- (v) * * *
- (A) * * *
- (7) Opt-out arrangements.
- (i) In general.
- (ii) Eligible opt-out arrangements.
- (iii) Definitions.
- (A) Opt-out payment.
- (B) Opt-out arrangement.
- (C) Eligible opt-out arrangement.
- (iv) Examples.

- * * * * *
- (4) Special eligibility rules.
- (i) Related individuals not claimed as a personal exemption deduction.
- (ii) Exchange unable to discontinue advance credit payments.
- (A) In general.
- (B) Medicaid or CHIP.

§ 1.36B–3 Computing the premium assistance credit amount.

- * * * * *
- (c) * * *
- (4) Appeals of coverage eligibility.
- (d) * * *
- (1) Premium assistance amount.
- (2) Examples.
- * * * * *
- (f) * * *
- (3) Silver-level plan not covering pediatric dental benefits.
- (4) Family members residing in different locations.
- (5) Single or multiple policies needed to cover the family.
- (i) Policy covering a taxpayer's family.
- (ii) Policy not covering a taxpayer's family.
- (6) Plan not available for enrollment.
- (7) Benchmark plan terminates or closes to enrollment during the year.
- (8) Only one silver-level plan offered to the coverage family.
- (9) Effective date.
- (10) Examples.

§ 1.36B–5 Information reporting by Exchanges.

* * * * *

- (c) * * *
- (3) * * *
- (iii) Partial month of coverage.
- (A) In general.
- (B) Certain mid-month enrollments.

■ **Par. 3.** Section 1.36B–1 is amended by revising paragraphs (l), (m), and (o) to read as follows:

§ 1.36B–1 Premium tax credit definitions.

(l) *Self-only coverage.* Self-only coverage means health insurance that covers one individual and provides coverage for the essential health benefits as defined in section 1302(b)(1) of the Affordable Care Act (42 U.S.C. 18022).

(m) *Family coverage.* Family coverage means health insurance that covers more than one individual and provides coverage for the essential health benefits as defined in section 1302(b)(1) of the Affordable Care Act (42 U.S.C. 18022).

(o) *Effective/applicability date.* Except for paragraphs (l) and (m), this section applies to taxable years ending after December 31, 2013. Paragraphs (l) and (m) of this section apply to taxable years beginning after December 31, 2018. Paragraphs (l) and (m) of § 1.36B–1 as contained in 26 CFR part I edition revised as of April 1, 2016, apply to taxable years ending after December 31, 2013, and beginning before January 1, 2019.

■ **Par. 4.** Section 1.36B–2 is amended by:

- 1. Revise paragraph (b)(6) introductory text, (b)(6)(i) and (ii).
- 2. Adding three new sentences to the end of paragraph (c)(2)(v).
- 3. Revising paragraph (c)(3)(i).
- 4. Revising paragraph (c)(3)(iii)(A).
- 5. Adding three new sentences to the end of paragraph (c)(3)(v)(A)(3).
- 6. Adding new paragraphs (c)(3)(v)(A)(7)
- 7. Revising paragraph (c)(4).
- 8. Adding a new paragraph (e).

§ 1.36B–2 Eligibility for premium tax credit.

* * * * *

(b) * * *

(6) *Special rule for taxpayers with household income below 100 percent of the Federal poverty line for the taxable year—(i) In general.* A taxpayer (other than a taxpayer described in paragraph (b)(5) of this section) whose household income for a taxable year is less than 100 percent of the Federal poverty line for the taxpayer's family size is treated as an applicable taxpayer for the taxable year if—

(A) The taxpayer or a family member enrolls in a qualified health plan

through an Exchange for one or more months during the taxable year;

(B) An Exchange estimates at the time of enrollment that the taxpayer's household income will be at least 100 percent but not more than 400 percent of the Federal poverty line for the taxable year;

(C) Advance credit payments are authorized and paid for one or more months during the taxable year; and

(D) The taxpayer would be an applicable taxpayer if the taxpayer's household income for the taxable year was at least 100 but not more than 400 percent of the Federal poverty line for the taxpayer's family size.

(ii) *Exceptions.* This paragraph (b)(6) does not apply for an individual who, with intentional or reckless disregard for the facts, provides incorrect information to an Exchange for the year of coverage. A reckless disregard of the facts occurs if the taxpayer makes little or no effort to determine whether the information provided to the Exchange is accurate under circumstances that demonstrate a substantial deviation from the standard of conduct a reasonable person would observe. A disregard of the facts is intentional if the taxpayer knows the information provided to the Exchange is inaccurate.

* * * * *

- (c) * * *
- (2) * * *

(v) * * * This paragraph (c)(2)(v) does not apply for an individual who, with intentional or reckless disregard for the facts, provides incorrect information to an Exchange for the year of coverage. A reckless disregard of the facts occurs if the taxpayer makes little or no effort to determine whether the information provided to the Exchange is accurate under circumstances that demonstrate a substantial deviation from the standard of conduct a reasonable person would observe. A disregard of the facts is intentional if the taxpayer knows that information provided to the Exchange is inaccurate.

* * * * *

- (3) * * *

(i) *In general.* For purposes of section 36B, an employee who may enroll in an eligible employer-sponsored plan (as defined in section 5000A(f)(2) and the regulations under that section) that is minimum essential coverage, and an individual who may enroll in the plan because of a relationship to the employee (a related individual), are eligible for minimum essential coverage under the plan for any month only if the plan is affordable and provides minimum value. Except for the Nonappropriated Fund Health Benefits

Program of the Department of Defense, established under section 349 of the National Defense Authorization Act for Fiscal Year 1995 (Pub. L. 103-337; 10 U.S.C. 1587 note), government-sponsored minimum essential coverage is not an eligible employer-sponsored plan. The Nonappropriated Fund Health Benefits Program of the Department of Defense is considered eligible employer-sponsored coverage, but not government-sponsored coverage, for purposes of determining if an individual is eligible for minimum essential coverage under this section.

* * * * *

(iii) * * *

(A) *Failure to enroll in plan.* An employee or related individual may be eligible for minimum essential coverage under an eligible employer-sponsored plan for a month during a plan year if the employee or related individual could have enrolled in the plan for that month during an open or special enrollment period for the plan year. If an enrollment period relates to coverage for not only the upcoming plan year (or the current plan year in the case of an enrollment period other than an open enrollment period), but also coverage in one or more succeeding plan years, this paragraph (c)(3)(iii)(A) applies only to eligibility for the coverage in the upcoming plan year (or the current plan year in the case of an enrollment period other than an open enrollment period).

* * * * *

(v) * * *

(A) * * *

(3) * * * This paragraph (c)(3)(v)(A)(3) does not apply for an individual who, with intentional or reckless disregard for the facts, provides incorrect information to an Exchange concerning the portion of the annual premium for coverage for the employee or related individual under the plan. A reckless disregard of the facts occurs if the taxpayer makes little or no effort to determine whether the information provided to the Exchange is accurate under circumstances that demonstrate a substantial deviation from the standard of conduct a reasonable person would observe. A disregard of the facts is intentional if the taxpayer knows that the information provided to the Exchange is inaccurate.

* * * * *

(7) *Opt-out arrangements—(i) In general.* Except as otherwise provided in this paragraph (c)(3)(v)(A)(7), the amount of an opt-out payment made available to an employee under an opt-out arrangement increases the employee's required contribution for purposes of determining the

affordability of the eligible employer-sponsored plan to which the opt-out arrangement relates, regardless of whether the employee enrolls in the eligible employer-sponsored plan or declines to enroll in that coverage and is paid the opt-out payment.

(ii) *Eligible opt-out arrangements.* The amount of an opt-out payment made available to an employee under an eligible opt-out arrangement does not increase the employee's required contribution for purposes of determining the affordability of the eligible employer-sponsored plan to which the eligible opt-out arrangement relates, regardless of whether the employee enrolls in the eligible employer-sponsored plan or is paid the opt-out payment.

(iii) *Definitions.* The following definitions apply for purposes of this paragraph (c)(3)(v)(A)(7):

(A) *Opt-out payment.* The term *opt-out payment* means a payment that is available only if an employee declines coverage, including waiving coverage in which the employee would otherwise be enrolled, under an eligible employer-sponsored plan and that is not permitted to be used to pay for coverage under the eligible employer-sponsored plan. An amount provided as an employer contribution to a cafeteria plan that is permitted to be used by the employee to purchase minimum essential coverage is not an opt-out payment, whether or not the employee may receive the amount as a taxable benefit. See paragraph (c)(3)(v)(A)(6) of this section for the treatment of employer contributions to a cafeteria plan.

(B) *Opt-out arrangement.* The term *opt-out arrangement* means the arrangement under which an opt-out payment is made available.

(C) *Eligible opt-out arrangement.* The term *eligible opt-out arrangement* means an arrangement under which an employee's right to receive an opt-out payment is conditioned on the employee providing reasonable evidence that the employee and all other individuals for whom the employee reasonably expects to claim a personal exemption deduction for the taxable year or years that begin or end in or with the employer's plan year to which the opt-out arrangement applies (employee's expected tax family) have or will have minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) during the period of coverage to which the opt-out arrangement applies. For this purpose, reasonable evidence of alternative coverage may include the

employee's attestation that the employee and all other members of the employee's expected tax family have or will have minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) for the relevant period. Regardless of the evidence of alternative coverage required under the arrangement, to be an eligible opt-out arrangement, the arrangement must provide that the opt-out payment will not be made, and the employer in fact must not make the payment, if the employer knows or has reason to know that the employee or any other member of the employee's expected tax family does not have or will not have the alternative coverage. The arrangement must also require that the evidence of the alternative coverage be provided no less frequently than every plan year to which the eligible opt-out arrangement applies, and that it must be provided no earlier than a reasonable period of time before the commencement of the period of coverage to which the eligible opt-out arrangement applies. If the reasonable evidence (such as an attestation) is obtained as part of the regular annual open enrollment period that occurs within a few months before the commencement of the next plan year of employer-sponsored coverage, it will qualify as being provided no earlier than a reasonable period of time before commencement of the applicable period of coverage. An eligible opt-out arrangement is also permitted to require evidence of alternative coverage to be provided at a later date, such as after the plan year starts, which would enable the employer to require evidence that the employee and all other members of the employee's expected tax family have already obtained the alternative coverage. Nothing in this rule prohibits an employer from requiring reasonable evidence of alternative coverage other than an attestation in order for an employee to qualify for an opt-out payment under an eligible opt-out arrangement. Further, provided that the reasonable evidence requirement is met, the amount of an opt-out payment made available under an eligible opt-out arrangement continues to be excluded from the employee's required contribution for the remainder of the period of coverage to which the opt-out payment originally applied even if the alternative coverage subsequently terminates for the employee or for any other member of the employee's expected tax family, regardless of whether the opt-out payment is required to be adjusted or terminated due to the loss of alternative coverage, and

regardless of whether the employee is required to provide notice of the loss of alternative coverage to the employer.

(iv) *Examples.* The following examples illustrate the provisions of this paragraph (c)(3)(v)(A)(7). In each example, the eligible employer-sponsored plan's plan year is the calendar year.

Example 1. Taxpayer B is an employee of Employer X, which offers its employees coverage under an eligible employer-sponsored plan that requires B to contribute \$3,000 for self-only coverage. X also makes available to B a payment of \$500 if B declines to enroll in the eligible employer-sponsored plan. Therefore, the \$500 opt-out payment made available to B under the opt-out arrangement increases B's required contribution under X's eligible employer-sponsored plan from \$3,000 to \$3,500, regardless of whether B enrolls in the eligible employer-sponsored plan or declines to enroll and is paid the opt-out payment.

Example 2. The facts are the same as in *Example 1*, except that availability of the \$500 opt-out payment is conditioned not only on B declining to enroll in X's eligible employer-sponsored plan but also on B providing reasonable evidence no earlier than the regular annual open enrollment period for the next plan year that B and all other members of B's expected tax family are or will be enrolled in minimum essential coverage through another source (other than coverage in the individual market, whether or not obtained through the Marketplace). B's expected tax family consists of B and B's spouse, C, who is an employee of Employer Y. During the regular annual open enrollment period for the upcoming plan year, B declines coverage under X's eligible employer-sponsored plan and provides X with reasonable evidence that B and C will be enrolled in Y's employer-sponsored plan, which is minimum essential coverage. The opt-out arrangement provided by X is an eligible opt-out arrangement, and, therefore, the \$500 opt-out payment made available to B does not increase B's required contribution under X's eligible employer-sponsored plan. B's required contribution for self-only coverage under X's eligible employer-sponsored plan is \$3,000.

Example 3. The facts are the same as in *Example 2*, except that B and C have two children that B expects to claim as dependents for the taxable year that coincides with the upcoming plan year. During the regular annual open enrollment period for the upcoming plan year, B declines coverage under X's eligible employer-sponsored plan and provides X with reasonable evidence that B and C will be enrolled in Y's employer-sponsored plan, which is minimum essential coverage. However, B does not provide reasonable evidence that B's children will be enrolled in minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace); therefore, X determines B is not eligible for the opt-out payment, and B does not receive it. The \$500 opt-out payment made available under the opt-out arrangement does not

increase B's required contribution under X's eligible employer-sponsored plan because the opt-out arrangement provided by X is an eligible opt-out arrangement. B's required contribution for self-only coverage under X's eligible employer-sponsored plan is \$3,000.

Example 4. Taxpayer D is married and is employed by Employer Z, which offers its employees coverage under an eligible employer-sponsored plan that requires D to contribute \$2,000 for self-only coverage. Z also makes available to D a payment of \$300 if D declines to enroll in the eligible employer-sponsored plan and provides reasonable evidence no earlier than the regular annual open enrollment period for the next plan year that D is or will be enrolled in minimum essential coverage through another source (other than coverage in the individual market, whether or not obtained through the Marketplace); the opt-out arrangement is not conditioned on whether the other members of D's expected tax family have other coverage. This opt-out arrangement is not an eligible opt-out arrangement because it does not condition the right to receive the opt-out payment on D providing reasonable evidence that D and the other members of D's expected tax family have (or will have) minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace). Therefore, the \$300 opt-out payment made available to D under the opt-out arrangement increases D's required contribution under Z's eligible employer-sponsored plan. D's required contribution for self-only coverage under Z's eligible employer-sponsored plan is \$2,300.

* * * * *

(4) *Special eligibility rules—(i) Related individual not claimed as a personal exemption deduction.* An individual who may enroll in minimum essential coverage because of a relationship to another person eligible for the coverage, but for whom the other eligible person does not claim a personal exemption deduction under section 151, is treated as eligible for minimum essential coverage under the coverage only for months that the related individual is enrolled in the coverage.

(ii) *Exchange unable to discontinue advance credit payments—(A) In general.* If an individual who is enrolled in a qualified health plan for which advance credit payments are made informs the Exchange that the individual is or will soon be eligible for other minimum essential coverage and that advance credit payments should be discontinued, but the Exchange does not discontinue advance credit payments for the first calendar month beginning after the month the individual informs the Exchange, the individual is treated as eligible for the other minimum essential coverage no earlier than the first day of the second calendar month beginning after the first month the

individual may enroll in the other minimum essential coverage.

(B) *Medicaid or CHIP.* If a determination is made that an individual who is enrolled in a qualified health plan for which advance credit payments are made is eligible for Medicaid or CHIP but the advance credit payments are not discontinued for the first calendar month beginning after the eligibility determination, the individual is treated as eligible for the Medicaid or CHIP no earlier than the first day of the second calendar month beginning after the eligibility determination.

* * * * *

(e) *Effective/applicability date.* (1) Except as provided in paragraph (f)(2) of this section, this section applies to taxable years ending after December 31, 2013.

(2) Paragraph (b)(6)(ii), the last three sentences of paragraph (c)(2)(v), paragraph (c)(3)(i), paragraph (c)(3)(iii)(A), the last three sentences of paragraph (c)(3)(v)(A)(3), paragraph (c)(3)(v)(A)(7), and paragraph (c)(4) of this section apply to taxable years beginning after December 31, 2016. Paragraphs (b)(6), (c)(3)(i), (c)(3)(iii)(A), and (c)(4) of § 1.36B-2 as contained in 26 CFR part I edition revised as of April 1, 2016, apply to taxable years ending after December 31, 2013, and beginning before January 1, 2017.

■ **Par. 5.** Section 1.36B-3 is amended by:

- 1. Redesignating paragraph (c)(4) as paragraph (c)(5) and adding a new paragraph (c)(4).
- 2. Revising paragraph (d)(1).
- 3. Revising paragraph (d)(2).
- 4. Revising paragraph (f)
- 5. Adding paragraph (n).

§ 1.36B-3 Computing the premium tax credit amount.

* * * * *

(c) * * *

(4) *Appeals of coverage eligibility.* A taxpayer who is eligible for advance credit payments pursuant to an eligibility appeal decision implemented under 45 CFR 155.545(c)(1)(ii) for coverage of a member of the taxpayer's coverage family who, based on the appeal decision, retroactively enrolls in a qualified health plan is considered to have met the requirement in paragraph (c)(1)(ii) of this section for a month if the taxpayer pays the taxpayer's share of the premiums for coverage under the plan for the month on or before the 120th day following the date of the appeals decision.

* * * * *

(d) * * *

(1) *Premium assistance amount.* The premium assistance amount for a coverage month is the lesser of—

(i) The premiums for the month, reduced by any amounts that were refunded, for one or more qualified health plans in which a taxpayer or a member of the taxpayer's family enrolls (enrollment premiums); or

(ii) The excess of the adjusted monthly premium for the applicable benchmark plan (benchmark plan premium) over 1/12 of the product of a taxpayer's household income and the applicable percentage for the taxable year (the taxpayer's contribution amount).

(2) *Examples.* The following examples illustrate the rules of paragraph (d)(1) of this section.

Example 1. Taxpayer Q is single and has no dependents. Q enrolls in a qualified health plan with a monthly premium of \$400. Q's monthly benchmark plan premium is \$500, and his monthly contribution amount is \$80. Q's premium assistance amount for a coverage month is \$400 (the lesser of \$400, Q's monthly enrollment premium, and \$420, the difference between Q's monthly benchmark plan premium and Q's contribution amount).

Example 2. (i) Taxpayer R is single and has no dependents. R enrolls in a qualified health plan with a monthly premium of \$450. The difference between R's benchmark plan premium and contribution amount for the month is \$420. R's premium assistance amount for a coverage month is \$420 (the lesser of \$450 and \$420).

(ii) The issuer of R's qualified health plan is notified that R died on September 20. The issuer terminates coverage as of that date and refunds the remaining portion of the September enrollment premiums (\$150) for R's coverage.

(iii) Under paragraph (d)(1) of this section, R's premium assistance amount for September is the lesser of the enrollment premiums for the month, reduced by any amounts that were refunded (\$300 (\$450 – \$150)) or the difference between the benchmark plan premium and the contribution amount for the month (\$420). R's premium assistance amount for September is \$300, the lesser of \$420 and \$300.

Example 3. The facts are the same as in Example 2 of this paragraph (d)(2), except that the qualified health plan issuer does not refund any enrollment premiums for September. Under paragraph (d)(1) of this section, R's premium assistance amount for September is \$420, the lesser of \$450 and \$420.

* * * * *

(f) *Applicable benchmark plan—(1) In general.* Except as otherwise provided in this paragraph (f), the applicable benchmark plan for each coverage month is the second-lowest-cost silver plan (as described in section 1302(d)(1)(B) of the Affordable Care Act

(42 U.S.C. 18022(d)(1)(B))) offered to the taxpayer's coverage family through the Exchange for the rating area where the taxpayer resides for—

(i) Self-only coverage for a taxpayer—

(A) Who computes tax under section 1(c) (unmarried individuals other than surviving spouses and heads of household) and is not allowed a deduction under section 151 for a dependent for the taxable year;

(B) Who purchases only self-only coverage for one individual; or

(C) Whose coverage family includes only one individual; and

(ii) Family coverage for all other taxpayers.

(2) *Family coverage.* The applicable benchmark plan for family coverage is the second lowest-cost silver plan that would cover the members of the taxpayer's coverage family (such as a plan covering two adults if the members of a taxpayer's coverage family are two adults).

(3) *Silver-level plan not covering pediatric dental benefits.* If one or more silver-level qualified health plans offered through an Exchange do not cover pediatric dental benefits, the premium for the applicable benchmark plan is determined based on the second lowest-cost option among—

(i) The silver-level qualified health plans that provide pediatric dental benefits offered by the Exchange to the members of the coverage family;

(ii) The lowest-cost silver-level qualified health plan that does not provide pediatric dental benefits offered by the Exchange to the members of the coverage family in conjunction with the lowest-cost portion of the premium for a stand-alone dental plan (within the meaning of section 1311(d)(2)(B)(ii) of the Affordable Care Act (42 U.S.C. 13031(d)(2)(B)(ii)) offered through the Exchange to the members of the coverage family that is properly allocable to pediatric dental benefits determined under guidance issued by the Secretary of Health and Human Services; and

(iii) The second-lowest-cost silver-level qualified health plan that does not provide pediatric dental benefits offered by the Exchange to the members of the coverage family in conjunction with the second-lowest-cost portion of the premium for a stand-alone dental plan (within the meaning of section 1311(d)(2)(B)(ii) of the Affordable Care Act (42 U.S.C. 13031(d)(2)(B)(ii)) offered through the Exchange to the members of the coverage family that is properly allocable to pediatric dental benefits determined under guidance issued by the Secretary of Health and Human Services.

(4) *Family members residing in different locations.* If members of a taxpayer's coverage family reside in different locations, the taxpayer's benchmark plan premium is the sum of the premiums for the applicable benchmark plans for each group of coverage family members residing in different locations, based on the plans offered to the group through the Exchange where the group resides. If all members of a taxpayer's coverage family reside in a single location that is different from where the taxpayer resides, the taxpayer's benchmark plan premium is the premium for the applicable benchmark plan for the coverage family, based on the plans offered through the Exchange to the taxpayer's coverage family for the rating area where the coverage family resides.

(5) *Single or multiple policies needed to cover the family—(i) Policy covering a taxpayer's family.* If a silver-level plan or a stand-alone dental plan offers coverage to all members of a taxpayer's coverage family who reside in the same location under a single policy, the premium (or allocable portion thereof, in the case of a stand-alone dental plan) taken into account for the plan for purposes of determining the applicable benchmark plan under paragraphs (f)(1), (f)(2), and (f)(3) of this section is the premium for this single policy.

(ii) *Policy not covering a taxpayer's family.* If a silver-level qualified health plan or a stand-alone dental plan would require multiple policies to cover all members of a taxpayer's coverage family who reside in the same location (for example, because of the relationships within the family), the premium (or allocable portion thereof, in the case of a stand-alone dental plan) taken into account for the plan for purposes of determining the applicable benchmark plan under paragraphs (f)(1), (f)(2), and (f)(3) of this section is the sum of the premiums (or allocable portion thereof, in the case of a stand-alone dental plan) for self-only policies under the plan for each member of the coverage family who resides in the same location.

(6) *Plan not available for enrollment.* A silver-level qualified health plan or a stand-alone dental plan that is not open to enrollment by a taxpayer or family member at the time the taxpayer or family member enrolls in a qualified health plan is disregarded in determining the applicable benchmark plan.

(7) *Benchmark plan terminates or closes to enrollment during the year.* A silver-level qualified health plan or a stand-alone dental plan that is used for purposes of determining the applicable benchmark plan under this paragraph (f)

for a taxpayer does not cease to be the applicable benchmark plan for a taxable year solely because the plan or a lower cost plan terminates or closes to enrollment during the taxable year.

(8) *Only one silver-level plan offered to the coverage family.* If there is only one silver-level qualified health plan providing pediatric dental benefits, one silver-level qualified health plan not providing pediatric dental benefits, or one stand-alone dental plan offered through an Exchange that would cover all members of a taxpayer's coverage family who reside in the same location (whether under one policy or multiple policies), that plan is used for purposes of determining the taxpayer's applicable benchmark plan.

(9) *Examples.* The following examples illustrate the rules of this paragraph (f). Unless otherwise stated, in each example the plans are open to enrollment to a taxpayer or family member at the time of enrollment and are offered through the Exchange for the rating area where the taxpayer resides:

Example 1. Single taxpayer enrolls in a qualified health plan. Taxpayer A is single, has no dependents, and enrolls in a qualified health plan. The Exchange in the rating area in which A resides offers only silver-level qualified health plans that provide pediatric dental benefits. Under paragraphs (f)(1) and (f)(2) of this section, A's applicable benchmark plan is the second lowest cost silver plan providing self-only coverage for A.

Example 2. Single taxpayer enrolls with dependent in a qualified health plan. Taxpayer B is single and claims her daughter, C, as a dependent. B purchases family coverage for herself and C. The Exchange in the rating area in which B and C reside offers qualified health plans that provide pediatric dental benefits but does not offer qualified health plans without pediatric dental benefits. Under paragraphs (f)(1) and (f)(2) of this section, B's applicable benchmark plan is the second lowest-cost silver plan providing family coverage to B and C.

Example 3. Benchmark plan for a coverage family with a family member eligible for pediatric dental benefits. (i) Taxpayer D's coverage family consists of D and D's 10-year old son, E, who is a dependent of D and eligible for pediatric dental benefits. The Exchange in the rating area in which D and E reside offers three silver-level qualified health plans, two of which provide pediatric dental benefits (S1 and S2) and one of which does not (S3), in which D and E may enroll. The Exchange also offers two stand-alone dental plans (DP1 and DP2) available to D and E. The monthly premiums allocable to essential health benefits for the silver-level plans are as follows:

S1—\$1,250
S2—\$1,200
S3—\$1,180

(ii) The monthly premiums, and the portion of the premium allocable to pediatric

dental benefits, for the two dental plans are as follows:

DP1—\$100 (\$25 allocable to pediatric dental benefits)
DP2—\$80 (\$40 allocable to pediatric dental benefits).

(iii) Under paragraph (f)(3) of this section, D's applicable benchmark plan is the second lowest cost option among the following offered by the rating area in which D resides: silver-level qualified health plans providing pediatric dental benefits (\$1,250 for S1 and \$1,200 for S2); the lowest-cost silver-level qualified health plan not providing pediatric dental benefits, in conjunction with the lowest-cost portion of the premium for a stand-alone dental plan properly allocable to pediatric dental benefits (\$1,180 for S3 in conjunction with \$25 for DP1 = \$1,205); and the second lowest cost silver-level qualified health plan not providing pediatric health benefits, in conjunction with the second lowest-cost portion of the premium for a stand-alone dental plan allocable to pediatric dental benefits (\$1,180 for S3 in conjunction with \$40 for DP2 = \$1,220). Under paragraph (f)(8) of this section, S3, as the lone silver-level qualified health plan not providing pediatric dental benefits offered by the Exchange, is treated as the second lowest-cost silver-level qualified health plan not providing pediatric dental benefits. Under paragraph (e) of this section, the adjusted monthly premium for D's applicable benchmark plan is \$1,205.

Example 4. Benchmark plan for a coverage family with no family members eligible for pediatric dental coverage. (i) The facts are the same as in *Example 3*, except Taxpayer D's coverage family consists of D and D's 22-year old son, F, who is a dependent of D and not eligible for pediatric dental coverage and the monthly premiums allocable to essential health benefits for the silver-level plans are as follows:

S1—\$1,210
S2—\$1,190
S3—\$1,180

(ii) Because no one in D's coverage family is eligible for pediatric dental benefits, \$0 of the premium for a stand-alone dental plan is allocable to pediatric dental benefits in determining A's applicable benchmark plan. Consequently, under paragraphs (f)(1), (f)(2), and (f)(3) of this section, D's applicable benchmark plan is the second lowest-cost option among the following options offered by the rating area in which D resides: silver-level qualified health plans providing pediatric dental benefits (\$1,210 for S1 and \$1,190 for S2), the lowest-cost silver-level qualified health plan not providing pediatric dental benefits, in conjunction with the lowest-cost portion of the premium for a stand-alone dental plan properly allocable to pediatric dental benefits (\$1,180 for S3 in conjunction with \$0 for DP1 = \$1,180), and the second lowest cost silver-level qualified health plan not providing pediatric health benefits, in conjunction with the second lowest-cost portion of the premium for a stand-alone dental plan allocable to pediatric dental benefits (\$1,180 for S3 in conjunction with \$0 for DP2 = \$1,180). Under paragraph (e) of this section, the adjusted monthly

premium for D's applicable benchmark plan is \$1,180.

Example 5. Single taxpayer enrolls with dependent and nondependent in a qualified health plan. Taxpayer G is single and resides with his daughter, H, and with his teenage son, I, but may only claim I as a dependent. G, H, and I enroll in coverage through the Exchange in the rating area in which they all reside. The Exchange offers only silver-level plans providing pediatric dental benefits. Under paragraphs (f)(1) and (f)(2) of this section, G's applicable benchmark plan is the second lowest-cost silver plan covering G and I. However, H may qualify for a premium tax credit if H is otherwise eligible. See paragraph (h) of this section.

Example 6. Change in coverage family. Taxpayer J is single and has no dependents when she enrolls in a qualified health plan. The Exchange in the rating area in which she resides offers only silver-level plans that provide pediatric dental benefits. On August 1, J has a child, K, whom she claims as a dependent. J enrolls in a qualified health plan covering J and K effective August 1. Under paragraphs (f)(1) and (f)(2) of this section, J's applicable benchmark plan for January through July is the second lowest-cost silver plan providing self-only coverage for J, and J's applicable benchmark plan for the months August through December is the second lowest-cost silver plan covering J and K.

Example 7. Minimum essential coverage for some coverage months. Taxpayer L claims his daughter, M, as a dependent. L and M enroll in a qualified health plan through an Exchange that offers only silver-level plans that provide pediatric dental benefits. L, but not M, is eligible for government-sponsored minimum essential coverage for September to December. Thus, under paragraph (c)(1)(iii) of this section, January through December are coverage months for M, and January through August are coverage months for L. Because, under paragraphs (d) and (f)(1) of this section, the premium assistance amount for a coverage month is computed based on the applicable benchmark plan for that coverage month, L's applicable benchmark plan for January through August is the second lowest-cost option covering L and M. Under paragraph (f)(1)(i)(C) of this section, L's applicable benchmark plan for September through December is the second lowest-cost silver plan providing self-only coverage for M.

Example 8. Family member eligible for minimum essential coverage for the taxable year. The facts are the same as in *Example 7*, except that L is not eligible for government-sponsored minimum essential coverage for any months and M is eligible for government sponsored minimum essential coverage for the entire year. Under paragraph (f)(1)(i)(C) of this section, L's applicable benchmark plan is the second lowest-cost silver plan providing self-only coverage for L.

Example 9. Benchmark plan premium for a coverage family with family members who reside in different locations. (i) Taxpayer N's coverage family consists of N and her three dependents O, P, and Q. N, O, and P reside together but Q resides in a different location. Under paragraphs (f)(1), (f)(2), and (f)(3) of

this section, the monthly applicable benchmark plan premium for N, O, and P is \$1,000 and the monthly applicable benchmark plan premium for Q is \$220.

(ii) Under paragraph (f)(4) of this section, because the members of N's coverage family reside in different locations, the monthly premium for N's applicable benchmark plan is the sum of \$1,000, the monthly premiums for the applicable benchmark plan for N, O, and P, who reside together, and \$220, the monthly applicable benchmark plan premium for Q, who resides in a different location than N, O, and P. Consequently, the premium for N's applicable benchmark plan is \$1,220.

Example 10. Aggregation of silver-level policies for plans not covering a family under a single policy. (i) Taxpayers R and S are married and live with S's mother, T, whom they claim as a dependent. The Exchange for their rating area offers self-only and family coverage at the silver level through Issuers A, B, and C, which each offer only one silver-level plan. The silver-level plans offered by Issuers A and B do not cover R, S, and T under a single policy. The silver-level plan offered by Issuer A costs the following monthly amounts for self-only coverage of R, S, and T, respectively: \$400, \$450, and \$600. The silver-level plan offered by Issuer B costs the following monthly amounts for self-only coverage of R, S, and T, respectively: \$250, \$300, and \$450. The silver-level plan offered by Issuer C provides coverage for R, S, and T under one policy for a \$1,200 monthly premium.

(ii) Under paragraph (f)(5) of this section, Issuer C's silver-level plan that covers R, S, and T under one policy (\$1,200 monthly premium) and Issuer A's and Issuer B's silver-level plans that do not cover R, S and T under one policy are considered in determining R's and S's applicable benchmark plan. In addition, under paragraph (f)(5)(ii) of this section, in determining R's and S's applicable benchmark plan, the premium taken into account for Issuer A's plan is \$1,450 (the aggregate premiums for self-only policies covering R (\$400), S (\$450), and T (\$600) and the premium taken into account for Issuer B's plan is \$1,000 (the aggregate premiums for self-only policies covering R (\$250), S (\$300), and T (\$450)). Consequently, R's and S's applicable benchmark plan is the Issuer C silver-level plan covering R's and S's coverage family and the premium for their applicable benchmark plan is \$1,200.

Example 11. Benchmark plan premium for a taxpayer with family members who cannot enroll in one policy and who reside in different locations. (i) Taxpayer U's coverage family consists of U, U's mother, V, and U's two daughters, W and X. U and V reside together in Location 1 and W and X reside together in Location 2. The Exchange in the rating area in which U and V reside does not offer a silver-level plan that covers U and V under a single policy, whereas all the silver-level plans offered through the Exchange in the rating area in which W and X reside cover W and X under a single policy. Both Exchanges offer only silver-level plans that provide pediatric dental benefits. The silver plan offered by the Exchange for the rating

area in which U and V reside that would cover U and V under self-only policies with the second-lowest aggregate premium costs \$400 a month for self-only coverage for U and \$600 a month for self-only coverage for V. The monthly premium for the second-lowest cost silver plan covering W and X that is offered by the Exchange for the rating area in which W and X reside is \$500.

(ii) Under paragraph (f)(5)(ii) of this section, because multiple policies are required to cover U and V, the members of U's coverage family who reside together in Location 1, the premium taken into account in determining U's benchmark plan is \$1,000, the sum of the premiums for the second-lowest aggregate cost of self-only policies covering U (\$400) and V (\$600) offered by the Exchange to U and V for the rating area in which U and V reside. Under paragraph (f)(5)(i) of this section, because all silver-level plans offered by the Exchange in which W and X reside cover W and X under a single policy, the premium for W and X's coverage that is taken into account in determining U's benchmark plan is \$500, the second-lowest cost silver policy covering W and X that is offered by the Exchange for the rating area in which W and X reside. Under paragraph (f)(4) of this section, because the members of U's coverage family reside in different locations, U's monthly benchmark plan premium is \$1,500, the sum of the premiums for the applicable benchmark plans for each group of family members residing in different locations (\$1,000 for U and V, who reside in Location 1, plus \$500 for W and X, who reside in Location 2).

Example 12. Qualified health plan closed to enrollment. Taxpayer Y has two dependents, Z and AA. Y, Z, and AA enroll in a qualified health plan through the Exchange for the rating area where the family resides. The Exchange, which offers only qualified health plans that include pediatric dental benefits, offers silver-level plans J, K, L, and M, which are, respectively, the first, second, third, and fourth lowest cost silver plans covering Y's family. When Y's family enrolls, Plan J is closed to enrollment. Under paragraph (f)(6) of this section, Plan J is disregarded in determining Y's applicable benchmark plan, and Plan L is used in determining Y's applicable benchmark plan.

Example 13. Benchmark plan closes to new enrollees during the year. (i) Taxpayers BB, CC, and DD each have coverage families consisting of two adults. In that rating area, Plan 2 is the second lowest cost silver plan and Plan 3 is the third lowest cost silver plan covering the two adults in each coverage family offered through the Exchange. The BB and CC families each enroll in a qualified health plan that is not the applicable benchmark plan (Plan 4) in November during the annual open enrollment period. Plan 2 closes to new enrollees the following June. Thus, on July 1, Plan 3 is the second lowest cost silver plan available to new enrollees through the Exchange. The DD family enrolls in a qualified health plan in July.

(ii) Under paragraphs (f)(1), (f)(2), (f)(3), and (f)(7) of this section, the silver-level plan that BB and CC use to determine their applicable benchmark plan for all coverage months during the year is Plan 2. The

applicable benchmark plan that DD uses to determine DD's applicable benchmark plan is Plan 3, because Plan 2 is not open to enrollment through the Exchange when the DD family enrolls.

Example 14. Benchmark plan terminates for all enrollees during the year. The facts are the same as in *Example 13*, except that Plan 2 terminates for all enrollees on June 30. Under paragraphs (f)(1), (f)(2), (f)(3), and (f)(7) of this section, Plan 2 is the silver-level plan that BB and CC use to determine their applicable benchmark plan for all coverage months during the year, and Plan 3 is the applicable benchmark plan that DD uses.

Example 15. Exchange offers only one silver-level plan. Taxpayer EE's coverage family consists of EE, his spouse FF, and their two dependent children GG and HH, who all reside together. The Exchange for the rating area in which they reside offers only one silver-level plan that EE's family may enroll in and the plan does not provide pediatric dental benefits. The Exchange also offers one stand-alone dental plan in which the family may enroll. Under paragraph (f)(8) of this section, the silver-level plan and the stand-alone dental plan offered by the Exchange are used for purposes of determining EE's applicable benchmark plan under paragraph (f)(3) of this section. Moreover, the lone silver-level plan and the lone stand-alone dental plan offered by the Exchange are used for purposes of determining EE's applicable benchmark plan regardless of whether these plans cover EE's family under a single policy or multiples policies.

* * * * *

(n) *Effective/applicability date.* (1) Except as provided in paragraph (o)(2) of this section, this section applies to taxable years ending after December 31, 2013.

(2) Paragraphs (c)(4) and (d)(2) apply to taxable years beginning after December 31, 2016. Paragraphs (f)(1), (f)(3), (f)(4), (f)(6), (f)(7), (f)(8), and (f)(9) of this section apply to taxable years beginning after December 31, 2018. Paragraphs (c)(4) and (d)(2) of § 1.36B-3 as contained in 26 CFR part I edition revised as of April 1, 2016, apply to taxable years ending after December 31, 2013, and beginning before January 1, 2017. Paragraphs (f)(1), (f)(3), (f)(4), (f)(6), and (f)(7) of § 1.36B-3 as contained in 26 CFR part I edition revised as of April 1, 2016, apply to taxable years ending after December 31, 2013, and beginning before January 1, 2019.

- **Par. 6.** Section 1.36B-5 is amended by:
 - 1. Adding a new sentence to the end of paragraph (c)(3)(i).
 - 2. Adding paragraphs (c)(3)(iii) and (h).

§ 1.36B-5 Information reporting by Exchanges.

* * * * *

(c) * * *

(3) — * * *

(i) * * * If advance credit payments are made for coverage under the plan, the enrollment premiums reported to each family under paragraph (c)(1)(viii) of this section are the premiums allocated to the family under § 1.36B-3(h) (allocating enrollment premiums to each taxpayer in proportion to the premiums for each taxpayer's applicable benchmark plan).

* * * * *

(iii) *Partial month of coverage*—(A) *In general*. Except as provided in paragraph (c)(iii)(B) of this section, if an individual is enrolled in a qualified health plan after the first day of a month, the amount reported for that month under paragraphs (c)(1)(iv), (c)(1)(v), and (c)(1)(viii) of this section is \$0.

(B) *Certain mid-month enrollments*. If an individual's qualified health plan is terminated before the last day of a month, or if an individual is enrolled in coverage after the first day of a month and the coverage is effective on the date of the individual's birth, adoption, or placement for adoption or in foster care, or on the effective date of a court order, the amount reported under paragraphs (c)(1)(iv) and (c)(1)(v) of this section is the premium for the applicable benchmark plan for a full month of coverage (excluding the premium allocated to benefits in excess of essential health benefits) and the amount reported under paragraph (c)(1)(viii) of this section is the enrollment premium for the month, reduced by any amounts that were refunded.

* * * * *

(h) *Effective/applicability date*. Except for the last sentence of paragraph (c)(3)(i) of this section and paragraph (c)(3)(iii) of this section, this section applies to taxable years ending after December 31, 2013. The last sentence of paragraph (c)(3)(i) of this section and paragraph (c)(3)(iii) of this section apply to taxable years beginning after December 31, 2016. Paragraph (c)(3)(iii) of § 1.36B-5 as contained in 26 CFR part I edition revised as of April 1, 2016, applies to taxable years ending after December 31, 2013, and beginning before January 1, 2017.

■ **Par. 7.** Section 1.5000A-3 is amended by adding a new paragraph (e)(3)(ii)(G) to read as follows:

§ 1.5000A-3 Exempt individuals.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(G) *Opt-out arrangements*—(1) *In general*. Except as otherwise provided

in this paragraph (e)(3)(ii)(G), the amount of an opt-out payment made available to an employee under an opt-out arrangement increases the employee's (or related individual's) required contribution for purposes of determining the affordability of the eligible employer-sponsored plan to which the opt-out arrangement relates, regardless of whether the employee (or related individual) enrolls in the eligible employer-sponsored plan or declines to enroll in that coverage and is paid the opt-out payment.

(2) *Eligible opt-out arrangements*. The amount of an opt-out payment made available to an employee under an eligible opt-out arrangement does not increase the employee's (or related individual's) required contribution for purposes of determining the affordability of the eligible employer-sponsored plan to which the eligible opt-out arrangement relates, regardless of whether the employee (or related individual) enrolls in the eligible employer-sponsored plan or is paid the opt-out payment.

(3) *Definitions*. The following definitions apply for purposes of this paragraph (e)(3)(ii)(G):

(A) *Opt-out payment*. The term *opt-out payment* means a payment that is available only if an employee declines coverage, including waiving coverage in which the employee would otherwise be enrolled, under an eligible employer-sponsored plan and that is not permitted to be used to pay for coverage under the eligible employer-sponsored plan. An amount provided as an employer contribution to a cafeteria plan that is permitted to be used by the employee to purchase minimum essential coverage is not an opt-out payment, whether or not the employee may receive the amount as a taxable benefit. See paragraph (e)(3)(ii)(E) of this section for the treatment of employer contributions to a cafeteria plan.

(B) *Opt-out arrangement*. The term *opt-out arrangement* means the arrangement under which an opt-out payment is made available.

(C) *Eligible opt-out arrangement*. The term *eligible opt-out arrangement* means an arrangement under which an employee's right to receive an opt-out payment is conditioned on the employee providing reasonable evidence that the employee and all other individuals for whom the employee reasonably expects to claim a personal exemption deduction for the taxable year or years that begin or end in or with the employer's plan year to which the opt-out arrangement applies (employee's expected tax family) have, or will have, minimum essential

coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) during the period of coverage to which the opt-out arrangement applies. For this purpose, reasonable evidence of alternative coverage may include the employee's attestation that the employee and all other members of the employee's expected tax family have, or will have, minimum essential coverage (other than coverage in the individual market, whether or not obtained through the Marketplace) for the relevant period. Regardless of the evidence of alternative coverage required under the arrangement, to be an eligible opt-out arrangement, the arrangement must provide that the opt-out payment will not be made, and the employer in fact must not make the payment, if the employer knows or has reason to know that the employee or any other member of the employee's expected tax family does not have, or will not have, the alternative coverage. The arrangement must also require that the evidence of the alternative coverage be provided no less frequently than every plan year to which the eligible opt-out arrangement applies, and that it must be provided no earlier than a reasonable period of time before the commencement of the period of coverage to which the eligible opt-out arrangement applies. If the reasonable evidence (such as an attestation) is obtained as part of the regular annual open enrollment period that occurs within a few months before the commencement of the next plan year of employer-sponsored coverage, it will qualify as being provided no earlier than a reasonable period of time before commencement of the applicable period of coverage. An eligible opt-out arrangement is also permitted to require evidence of alternative coverage to be provided at a later date, such as after the plan year starts, which would enable the employer to require evidence that the employee and all other members of the employee's expected tax family have already obtained the alternative coverage. Nothing in this rule prohibits an employer from requiring reasonable evidence of alternative coverage other than an attestation in order for an employee to qualify for an opt-out payment under an eligible opt-out arrangement. Further, provided that the reasonable evidence requirement is met, the amount of an opt-out payment made available under an eligible opt-out arrangement continues to be excluded from the employee's required contribution for the remainder of the period of coverage to which the opt-out payment originally applied even if the

alternative coverage subsequently terminates for the employee or for any other member of the employee's expected tax family, regardless of whether the opt-out payment is required to be adjusted or terminated due to the loss of alternative coverage, and regardless of whether the employee is required to provide notice of the loss of alternative coverage to the employer.

* * * * *

■ **Par. 8.** Section 1.5000A-5 is amended by revising paragraph (c).

§ 1.5000A-5 Administration and procedure.

* * * * *

(c) *Effective/applicability date.* (1) Except as provided in paragraph (c)(2), this section and §§ 1.5000A-1 through 1.5000A-4 apply for months beginning after December 31, 2013.

(2) Paragraph (e)(3)(ii)(G) of § 1.5000A-3 applies to months beginning after December 31, 2016.

■ **Par. 9.** Revise § 1.6011-8 to read as follows:

§ 1.6011-8 Requirement of income tax return for taxpayers who claim the premium tax credit under section 36B.

(a) *Requirement of return.* Except as otherwise provided in this paragraph (a), a taxpayer who receives the benefit of advance payments of the premium tax credit under section 36B must file an income tax return for that taxable year on or before the due date for the return (including extensions of time for filing) and reconcile the advance credit payments. However, if advance credit payments are made for coverage of an individual for whom no taxpayer claims a personal exemption deduction, the taxpayer who attests to the Exchange to the intention to claim a personal exemption deduction for the individual as part of the determination that the taxpayer is eligible for advance credit payments must file a tax return and reconcile the advance credit payments.

(b) *Effective/applicability date.* Except as otherwise provided, this section applies for taxable years beginning after December 31, 2016. Paragraph (a) of § 1.6011-8 as contained in 26 CFR part I edition revised as of April 1, 2016, applies to taxable years ending after December 31, 2013, and beginning before January 1, 2017.

§ 301.6011-2 [Amended]

■ **Par. 10.** Section 301.6011-2(b)(1) is amended by adding “1095-B, 1095-C”

after “1094 series”, and removing “1095 series”.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016-15940 Filed 7-6-16; 11:15 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8

RIN 0930-AA22

Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: On March 30, 2016, the U.S. Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking (NPRM) to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA). On July 6, 2016, HHS published a final rule based on the NPRM but delayed finalizing the reporting requirements outlined in the NPRM. In this Supplemental Notice of Proposed Rulemaking (SNPRM), HHS seeks further comment on the same reporting requirements outlined in the NPRM. These reporting requirements would require annual reporting by practitioners who are approved to treat up to 275 patients under subpart F to help HHS ensure compliance with the requirements of the “Medication Assisted Treatment for Opioid Use Disorders” final rule published elsewhere in this issue of the **Federal Register**. HHS will consider the public comments on this SNPRM as well as any comments already received on the March 30, 2016 NPRM before issuing a final rule pertaining to the reporting requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 8, 2016.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0930-AA22, by any of the following methods:

- *Electronically: Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the instructions for submitting comments.

- *Regular Mail or Hand Delivery or Courier:* Written comments mailed by regular mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *Express or Overnight Mail:* Written comments sent by hand delivery, or regular, express or overnight mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Jinhee Lee, SAMHSA, 5600 Fishers Lane, Room 13E21C, Rockville, Maryland 20857.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will become a matter of public record and will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process and viewing public comments, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Pharm.D., Public Health Advisor, Center for Substance Abuse Treatment, 240-276-0545, Email address: WaiverRegulations@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

The purpose of this Supplemental Notice of Proposed Rulemaking (SNPRM) is to solicit additional comment on the proposed reporting requirements in the U.S. Department of Health and Human Services (HHS) March 30, 2016 Notice of Proposed Rulemaking (NPRM) on Medication Assisted Treatment for Opioid Use Disorders under section 303(g)(2) of the Controlled Substances Act (CSA) (81 FR 17639). These requirements will assist HHS in ensuring practitioner compliance with the requirements of 42 CFR part 8, subpart F.

B. Summary of Major Provisions

These proposed regulatory provisions, which amend § 8.635 of 42 CFR part 8, subpart F, would establish annual reporting requirements for practitioners who are approved to treat up to 275 patients under 42 CFR part 8, subpart F.

C. Summary of Impacts

A summary of the anticipated impact of the reporting requirements, along with the other provisions of 42 CFR part 8, subpart F, was provided in the NPRM, dated March 30, 2016. Please see the NPRM, I. Executive Summary, Paragraph C (Summary of Impacts) for a summary of impacts of the reporting requirements in the context of 42 CFR part 8, subpart F.

II. Public Participation

Comments Invited

HHS invites interested parties to submit comments on all aspects of this proposal. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable and/or confidential information that is included in a comment. We post all comments received as soon as possible after they have been received on the following Web site: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received before the close of the comment period will also be available for public inspection, generally beginning approximately 3 weeks after publication of the proposed rule, at the headquarters of the Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call 240-276-1660.

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and will respond to the comments in the preamble of the final rule. Please allow sufficient time for mailed comments to be received before the close of the comment period.

III. Background

On March 30, 2016 HHS issued a Notice of Proposed Rulemaking (NPRM) entitled "Medication Assisted Treatment for Opioid Use Disorders" in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, HHS is publishing a final rule with the same title. That final rule increases access to medication-assisted treatment (MAT)

with certain medications, including buprenorphine and combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) medications, in office-based setting as authorized under 21 U.S.C. 823(g)(2). Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)) allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled substances that have been approved by the Food and Drug Administration (FDA). Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time. After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. The final rule expands access to MAT by allowing eligible practitioners to request approval to treat up to 275 patients under section 303(g)(2) of the CSA. The final rule also includes requirements to help ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.

The proposed regulatory provisions in this SNPRM will help HHS assess practitioner compliance with the requirements of 42 CFR part 8, subpart F.

IV. Summary of SNPRM

In the NPRM, HHS proposed 42 CFR, part 8, subpart F, § 8.635 to describe the reporting requirements for practitioners whose Request for Patient Limit Increase is approved under § 8.625. The purpose of the reporting requirements is to help HHS assess practitioner compliance with the additional responsibilities of practitioners who are authorized to treat up to the higher patient limit, as outlined in the MAT final rule published elsewhere in this issue of the **Federal Register**. Reporting is an integral component of HHS's approach to increase access to MAT while helping to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted. While HHS received many comments on the burden of these requirements, the comments did not provide specific suggestions on how HHS can ensure compliance in a manner that is not overly burdensome to practitioners. HHS seeks additional comment on the proposed reporting requirements:

- a. The average monthly caseload of patients receiving buprenorphine-based MAT, per year
- b. Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:
 1. Treatment initiation
 2. Change in clinical status
- c. Percentage of patients who had a prescription drug monitoring program query in the past month
- d. Number of patients at the end of the reporting year who:
 1. Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery
 2. Are not being seen by the provider due to referral by the provider to a more or less intensive level of care
 3. No longer desire to continue use of buprenorphine
 4. Are no longer receiving buprenorphine for reasons other than 1–3.

In addition, HHS seeks comment on the following questions:

Are there different or additional elements that should be reported in order to assist HHS in ensuring compliance with the final rule?

Are there ways in which some elements can be combined that will lessen the burden for reporting practitioners while maintaining the important function of collecting information that ensure compliance with the final rule?

Are there other ways that HHS can collect the necessary information to ensure compliance with the final rule?

Would it be less burdensome to report on the number of patients in treatment for each month of the reporting period that:

(i) Were provided counseling services at the same location as the practitioner, and how frequently those patients utilized the counseling services;

(ii) the practitioner referred for counseling services at a different location?

Would it be less burdensome to report on the number of patients at the end of the reporting year who had terminated utilization of covered medications?

Are there other suggested changes that would be less burdensome while maintaining the important function of collecting information that ensure compliance with the final rule?

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to

provide 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 changes to an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be

considered in rulemaking. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. This proposed rule includes changes to information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the PRA (5 CFR part 1320). Some of the provisions would involve changes from the information collections set out in the previous regulations.

Information collection requirements would be:

Reporting, 42 CFR 8.635: Reporting will be required annually to ensure that eligibility requirements are being maintained and that waiver conditions are being fulfilled. Reporting requirements may include a request for information regarding: (1) The average monthly caseload of patients receiving buprenorphine-based MAT, per year; (2) the percentage of active buprenorphine patients (patients in treatment as of

reporting date) who received psychosocial or case management services (either by direct provision or by referral) in the past year due to treatment initiation or change in clinical status; (3) Percentage of patients who had a prescription drug monitoring program query in the past month; (4) Number of patients at the end of the reporting year who: (a) Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery, (b) Are not being seen by the provider due to referral by the provider to a more or less intensive level of care, (c) No longer desire to continue use of buprenorphine, (d) Are no longer receiving buprenorphine for reasons other than (a) through (c). To facilitate public comment, we have placed a draft version of the collection template in the public docket.

Annual burden estimates for these requirements are summarized in the following table:

42 CFR Citation	Purpose of submission	Number of respondents	Responses/ respondent	Burden/ response (hour)	Total burden (hours)	Hourly wage cost (\$)	Total wage cost (\$)
8.635	Annual Report	1,350	1	3	4,050	64.47	261,104

For more detailed estimates, please refer to the public docket, which includes a copy of the draft supporting statement submitted as part of the NPRM and associated with this information collection.

VI. Regulatory Impact Analysis

HHS has examined the impact of this proposed rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act of 1980 (Pub. L. 96-354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995), and Executive Order 13132 on Federalism (August 4, 1999) and included it in the NPRM published on March 30, 2016. Please refer to the NPRM for this analysis (81 FR 17639).

List of Subjects in 42 CFR Part 8

Health professions, Methadone, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HHS proposes to amend 42 CFR part 8 as follows:

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

- 1. The authority citation for part 8 continues to read as follows:

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), 300y-11.

- 2. Add § 8.635 to read as follows:

§ 8.635 What are the reporting requirements for practitioners whose Request for Patient Limit Increase is approved?

(a) All practitioners whose Request for Patient Limit Increase is approved under § 8.625 must submit reports to SAMHSA, along with documentation and data, as requested by SAMHSA, to demonstrate compliance with § 8.620, applicable eligibility requirements specified in § 8.610, and all attestation requirements in § 8.620(b).

(b) Reporting requirements may include a request for information regarding:

(1) The average monthly caseload of patients receiving buprenorphine-based MAT, per year.

(2) Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct

provision or by referral) in the past year due to:

- (i) Treatment initiation.
- (ii) Change in clinical status.
- (3) Percentage of patients who had a prescription drug monitoring program query in the past month; and
- (4) Number of patients at the end of the reporting year who:

(i) Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery.

(ii) Are not being seen by the provider due to referral by the provider to a more or less intensive level of care.

(iii) No longer desire to continue use of buprenorphine.

(iv) Are no longer receiving buprenorphine for reasons other than paragraphs (b)(4)(i) through (iii) of this section.

(c) The report must be submitted within twelve months after the date that a practitioner's Request for Patient Limit Increase is approved under § 8.625, and annually thereafter.

(d) SAMHSA may check reports from practitioners prescribing under the higher patient limit against other existing data sources, such as PDMPs. If discrepancies between reported information and other existing data are identified, SAMHSA may require additional documentation from

practitioners whose reports are identified as including these discrepancies.

(e) Failure to submit reports under this section, or deficient reports, may be deemed a failure to satisfy the requirements for a patient limit

increase, and may result in the withdrawal of SAMHSA's approval of the practitioner's Request for Patient Limit Increase.

Dated: June 30, 2016.

Kana Enomoto,

Principal Deputy Administrator, Substance Abuse and Mental Health Services Administration.

Approved: June 30, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016-16069 Filed 7-6-16; 8:45 am]

BILLING CODE 4162-20-P

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

Food Safety and Inspection Service

[Docket No. FSIS-2016-0019]

Notice of Request To Renew an Approved Information Collection (Accredited Laboratory Contact Update Form)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to renew the approved information collection regarding the accredited laboratory contact update form. The approval for this information collection will expire on December 31, 2016.

DATES: Submit comments on or before September 6, 2016.

ADDRESSES: FSIS invites interested persons to submit comments on this information collection. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6065, South Building, Washington, DC 20250; (202) 720-5627.

SUPPLEMENTARY INFORMATION:

Title: Accredited Laboratory Program Annual Contact Update Form.

OMB Control Number: 0583-0163.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*) and the Poultry Products and Inspection Act (PPA) (21 U.S.C. 451, *et seq.*). FSIS protects the public by verifying that meat and poultry products are safe, wholesome, not adulterated, and correctly labeled.

In addition, the Food, Agriculture, Conservation, and Trade Act of 1990, as amended, (7 U.S.C. 138-138i) provides authority for the accreditation of non-Federal laboratories. Under these provisions, FSIS accredits non-Federal laboratories as eligible to perform analysis on official regulatory meat and poultry samples.

Non-Federal laboratories that are part of the FSIS Accredited Laboratory Program complete the FSIS Accredited Laboratory Program Annual Contact Update Form annually. FSIS will use the information collected by the form to maintain necessary contact information for responsibly connected personnel at the laboratories (see 9 CFR 439.20(e) and 9 CFR 439.1(w)). The completed FSIS Accredited Laboratory Program Annual Contact Update Form will also inform the Agency if a laboratory, or

responsibly connected person or entity, has been charged, indicted, or convicted of any crime listed in 9 CFR 439.52. If a laboratory or a responsibly connected person or entity has been charged or indicted of such a crime, FSIS will suspend the laboratory from the Accredited Laboratory Program (9 CFR 439.52). If a laboratory or a responsibly connected person or entity has been convicted of such a crime, FSIS will revoke the laboratory's accreditation (9 CFR 439.53).

The approval for this information collection will expire on December 31, 2016. There are no changes to the existing information collection. FSIS has made the following estimates on the basis of an information collection assessment.

Estimate of Burden: FSIS estimates that it takes respondents an average of 15 hours per year to complete the forms.

Respondents: Accredited Laboratories.

Estimated Number of Respondents: 60.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 15 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence SW., 6065, South Building, Washington, DC 20250; (202) 720-5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of

Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400

Independence Avenue SW., Washington, DC, 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC on: June 29, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016-16160 Filed 7-7-16; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2016-0020]

Notice of Request To Renew an Approved Information Collection (Industry Responses to Noncompliance Records)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to renew the approved information collection regarding industry responses to noncompliance records. The approval for this information collection will expire on December 31, 2016.

DATES: Submit comments on or before September 6, 2016.

ADDRESSES: FSIS invites interested persons to submit comments on this information collection. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-0020. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6065, South Building, Washington, DC 20250; (202) 720-5627.

SUPPLEMENTARY INFORMATION:

Title: Industry Responses to Noncompliance Records

OMB Control Number: 0583-0146.

Type of Request: Renewal of an approved information collection.

Expiration Date: 12/31/2016.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products and Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and correctly labeled.

FSIS is requesting a renewal of the previously approved information collection addressing paperwork requirements related to the collection of information on official meat or poultry establishment and egg products plant responses to noncompliance records. The noncompliance record, FSIS Form 5400-4, serves as FSIS's official record of noncompliance with one or more regulatory requirements. Inspection program personnel use the form to document their findings and provide written notification of the official establishment's or plant's failure to comply with regulatory requirements. The establishment or plant management receives a copy of the form and has an opportunity to respond in writing using the noncompliance record form.

The OMB approval of this information collection will expire on December 31, 2016. The number of estimated burden hours for this requested renewal has decreased because of a decrease in the

average number of responses to noncompliance records that were collected over the past three years. Upon approval of this request, the hours will be merged into the FSIS information collection titled Public Health Information System (0583-0153).

FSIS has made the following estimates on the basis of an information collection assessment:

Estimate of Burden: FSIS estimates that it will take respondents an average of 60 minutes per response.

Respondents: Official establishments and plants.

Estimated No. of Respondents: 7,057.

Estimated No. of Annual Responses per Respondent: 17.

Estimated Total Annual Burden on Respondents: 119,969 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence SW., 6065, South Building, Washington, DC 20250; (202) 720-5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to

provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC on, June 29, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016-16159 Filed 7-7-16; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Kenai Peninsula-Anchorage Borough Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Kenai Peninsula-Anchorage Borough Resource Advisory Committee (RAC) will meet in Girdwood, Alaska. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with title II of the Act. RAC information can be found at the following Web site: <http://www.fs.usda.gov/main/pts/specialprojects/racweb>.

DATES: The meeting will be held August 6, 2016, at 10:00 a.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at Glacier Ranger District Office, 145 Forest Station Road Girdwood, Alaska 99587. A conference line will be available, if you would like to attend the meeting via conference call, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under Supplementary Information. 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 the Glacier Ranger District. Please call ahead to facilitate entry into the building. **FOR FURTHER INFORMATION CONTACT:** Nancy O'Brien, RAC Coordinator, by phone at 907-424-4722 or via email at nobrien@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to discuss and vote on project proposals.

The meeting is open to the public. The agenda will include time for people

to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by July 30, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Nancy O'Brien, RAC Coordinator, P.O. Box 280, Cordova, Alaska 99574; by email to nobrien@fs.fed.us, or via facsimile to 907-424-7214.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: July 1, 2016.

Tim Charnon,
District Ranger.

[FR Doc. 2016-16205 Filed 7-7-16; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding (1) 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) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 8, 2016 will be considered. Written comments should be addressed to: Desk Officer for

Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC, 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: 2017 Census of Agriculture.

OMB Control Number: 0535-0226.

Summary of Collection: The National Agricultural Statistics Service (NASS) is responsible for conducting the Census of Agriculture under the authority of the Census of Agriculture Act of 1997, Public Law 105-113. The census of agriculture is required by law every five years and is the primary source of statistics concerning the nation's agricultural industry. It provides the only basis of consistent, comparable data throughout the more than 3,000 counties in the 50 States and Puerto Rico. For the outlying areas of American Samoa, Commonwealth of the Northern Mariana Islands, Guam and U.S. Virgin Islands, it is the only source of consistent, comparable agricultural data.

Need and Use of the Information: The data collection for the censuses of agriculture for the 50 states and Puerto Rico will be conducted primarily by mail-out/mail-back procedures (US Postal Service), internet, and with phone and field enumeration for targeted non-respondents. Data collection for Guam, the U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands and American Samoa will be conducted using direct enumeration methods only. The census provides data on the number and types of farms, land use, crop area and selected production, livestock inventory and sales, production contracts, production expenses, farm-related income, and other demographic characteristics. This information will serve as the basis for many agriculturally-based decisions. Census information is used by the

Administration, Congress, and the Federal Agencies to formulate and evaluate national agricultural programs and policy. The Department of Agriculture and the Bureau of Economic Analysis use Census data to compile farm sector economic indicators. State and local governments use Census data in the development of local agricultural programs.

Description of Respondents: Farms; Individuals or households.

Number of Respondents: 4,438,800.

Frequency of Responses: Reporting: Other (Every 5 years).

Total Burden Hours: 2,763,085.

Ruth Brown,

Departmental Information Collection
Clearance Officer.

[FR Doc. 2016-16179 Filed 7-7-16; 8:45 am]

BILLING CODE 3410-20-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Michigan Advisory Committee for a Meeting To Discuss Testimony Regarding Civil Rights and Civil Asset Forfeiture in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Michigan Advisory Committee (Committee) will hold a meeting on Tuesday, July 19, 2016, at 10:00 a.m. EDT for the purpose of discussing civil rights topics emerging from testimony regarding civil asset forfeiture practices in the state.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888-438-5524, conference ID: 3344476. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plans. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-

line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-977-8339 and providing the Service with the conference call number and conference ID number.

Member of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353-8324, or emailed to Carolyn Allen at callen@usccr.gov. Persons who desire additional information may contact the Midwestern Regional Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Michigan Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Welcome and Introductions
Discussion of Civil Asset Forfeiture
Testimony in Michigan
Public Comment
Future Plans and Actions
Adjournment

DATES: The meeting will be held on Tuesday, July 19, 2016, at 10:00 a.m. EDT.

Public Call Information

Dial: 888-438-5524
Conference ID: 3344476

FOR FURTHER INFORMATION CONTACT: Carolyn Allen at callen@usccr.gov or 312-353-8311.

Dated: July 1, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016-16126 Filed 7-7-16; 8:45 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission business meeting.

DATES: Friday, July 15, 2016, at 10:00 a.m. EST.

ADDRESSES: *Place:* National Place Building, 1331 Pennsylvania Ave. NW., 11th Floor, Suite 1150, Washington, DC 20245 (Entrance on F Street NW.)

FOR FURTHER INFORMATION CONTACT: Latrice Foshee, Acting Media Advisor at telephone: (202) 376-8371 or email: publicaffairs@usccr.gov.

SUPPLEMENTARY INFORMATION: This business meeting is open to the public. If you would like to listen to the business meeting, please contact the above for the call-in information. Persons with hearing impairments, please contact the above for how to access the Federal Relay Service for the meeting.

Hearing-impaired persons who will attend the briefing and require the services of a sign language interpreter should contact Pamela Dunston at (202) 376-8105 or at signlanguage@usccr.gov at least seven business days before the scheduled date of the meeting.

Meeting Agenda

I. Business Meeting

- A. Approval of Agenda
- B. Program Planning

- Discussion and Vote on 2016 Statutory Enforcement Report on Justice: Toxic Materials, Poor Economics and the Impact and the Impact of the Environment on Low-Income, Minority Communities.
- Discussion and Vote on Concept Paper for 2017 Statutory Enforcement Report.
- Discussion and vote on Commission Statement on Supreme Court's 4-4 decision in *United States v. Texas* affirming 5th Circuit Court of Appeals decision to block DAPA (Deferred Action for Parents of Americans and Lawful Permanent Residents) program and expand DACA (Deferred Action for Childhood Arrivals).
- Discussion and vote on Commission Statement on Supreme Court Decision on *Fisher v. University of Texas at Austin* allowing universities to continue considering race and ethnicity as a factor in selecting incoming students.
- Discussion and Vote on Commission letter regarding Antonio Zambrano-Montes killed by police in Washington State.

C. State Advisory Committees

- Appointment of members to Advisory Committees

- Tennessee
- Idaho
- District of Columbia
- Ohio
- Advisory Committee Presentation by the Chair of the Oklahoma Advisory Committee on their School-to-Prison Pipeline report

D. Management and Operations

- Staff Director's Report
- Status of USCCR Web site Transition
- Introduction of Brian Walch Communications & Public Engagement Director

II. Adjourn Meeting

Dated: July 6, 2016.

David Mussatt,

Regional Programs Unit Chief, U.S. Commission on Civil Rights.

[FR Doc. 2016-16370 Filed 7-6-16; 4:15 pm]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

[Docket No. 160329305-6305-01]

Privacy Act of 1974, System of Records

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of a revised Privacy Act System of Records: COMMERCE/NOAA-12, Marine Mammals, Endangered and Threatened Species, Permits and Authorizations, Applicants.

SUMMARY: This notice announces the Department of Commerce's (Department's) proposal to amend a System of Records under the 1974 Privacy Act. The National Oceanic and Atmospheric Administration's (NOAA's) National Marine Fisheries Service (NMFS) is amending their system of records for marine mammal and threatened and endangered species permit and authorization programs. Information will be collected from individuals and entities under the authority of the Marine Mammal Protection Act and the Endangered Species Act. This record system is necessary to identify permit and authorization applicants and to evaluate the qualifications of the applicants.

DATES: To be considered, written comments must be submitted on or before August 8, 2016. Unless comments are received, the amended system of records will become effective as proposed on August 17, 2016. If comments are received, the Department will publish a subsequent notice in the **Federal Register** within 10 days after

the comment period closes, stating that the current system of records will remain in effect until publication of a final action in the **Federal Register**.

ADDRESSES: Comments may be mailed to Amy Sloan, Deputy Chief, Permits and Conservation Division, NOAA, National Marine Fisheries Service, Office of Protected Resources, 1315 East-West Highway, F/PR1 Room 13824, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Amy Sloan (Phone: 301-427-8401; Email: Amy.Sloan@noaa.gov).

SUPPLEMENTARY INFORMATION: NMFS is amending its system of applicant records for use with marine mammal and threatened and endangered species permit and authorization programs to make minor administrative updates including updating addresses where records are located and how records are stored. The Marine Mammal Protection Act, Fur Seal Act, and Endangered Species Act prohibit certain actions affecting marine mammals and endangered and threatened species, with limited exceptions. Permits involving marine mammals and endangered and threatened species can be obtained for scientific research, enhancing the survival or recovery of a species or stock, commercial and educational photography, and import and capture for public display. Authorizations can be obtained for scientific research that involves minimal disturbance. Also U.S. citizens may request and obtain, authorizations for the incidental taking of marine mammals for specified activities other than commercial fishing. Owners of a commercial vessel or non-vessel gear engaging in a Category I or II fishery must obtain a marine mammal authorization certificate from NOAA Fisheries, or a designated agent, to lawfully incidentally take a marine mammal in a commercial fishery. NMFS collects information from individuals in order to issue, amend, or renew permits or authorizations.

COMMERCE/NOAA-12

SYSTEM NAME:

COMMERCE/NOAA-12, Marine Mammals, Endangered and Threatened Species, Permits and Authorizations Applicants.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

a. NMFS, Office of Protected Resources, 1315 East West Highway, Silver Spring, MD 20910.

b. NMFS, Greater Atlantic Regional Fisheries Office. 55 Great Republic Drive, Gloucester, MA 01930-2276.

c. NMFS, Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701.

d. NMFS, West Coast Region, Sustainable Fisheries Division, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

e. NMFS, West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

f. NMFS, Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, CA 92037.

g. NMFS, Pacific Islands Region, Ford Island Honolulu at 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

h. NMFS, Alaska Region, 709 West Ninth Street, Juneau, AK 99802-1668.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Researchers, wildlife managers, photographers, holders of marine mammals in captivity, corporations, partnerships, associations, organizations, Federal, state, local or tribal governments and other members of the public seeking exceptions to prohibited activities related to marine mammals and endangered and threatened species, and owners of commercial fishing vessels engaged in Category I or II fisheries seeking an exception to prohibited activities on marine mammals and endangered and threatened species.

CATEGORIES OF RECORDS IN THE SYSTEM:

This information is collected and/or maintained by all regions and divisions: Permit or authorization number, permit and authorization status information; type of application, name of applicant and of other individuals on application, affiliations, addresses, email addresses, and telephone and fax numbers. For marine mammal and threatened and endangered species special exception permits and authorizations, the following information is also included: Qualifications of individuals listed on the applications and a description of proposed activities.

For the marine mammal authorization program (MMAP), if a commercial fisherman has a state or Federal fishery license, they are not required to submit information to NMFS. Their registration is automatically renewed by mail and their registration information is not stored in this system, but in the applicable regional Sustainable Fisheries Permit Office. For those without a state or Federal fishery license, the following information is included: Name, address, and telephone number of the owner(s) of a vessel or

non-vessel gear and name and address of the operator if other than the owner; name and length of the vessel, home port, United States Coast Guard (USCG) documentation number or State registration number, State commercial license number of the fishing vessel which will operate under the authorization, and for a non-vessel fishery, a description of the gear and state commercial license number; a list of the fishery(s) in which the fisher will be engaged; for an individual, social security number and date of birth of the owner(s) of a vessel or non-vessel gear; and for a business, corporation name, employer identification number and date of incorporation. Any time there is an incidental or intentional mortality or injury to a marine mammal during commercial fishing activities, the following information must be submitted by all authorized fisheries (electronically or by mail): Name of vessel owner/operator or permit holder, mailing address, vessel name, fishery gear type and target species, and information about the marine mammal mortality/injury incident.

AUTHORITIES FOR MAINTENANCE OF THE SYSTEM:

The Marine Mammal Protection Act, 16 U.S.C. 1361 *et seq.*; the Fur Seal Act, 16 U.S.C. 1151 *et seq.*; and the Endangered Species Act, 16 U.S.C. 1531 *et seq.* [For collection of the Tax Identifying Number (Employer Identification Number or Social Security Number), 31 U.S.C. 7701.]

PURPOSES:

This information will allow NMFS to identify applicants and holders of permits and authorizations, identify vessel owners, evaluate requests by applicants, or agency actions, related to the issuance, renewal, revocation, suspension or modification of a permit or authorization.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Department. These records or information contained therein may specifically be disclosed as a routine use as stated below. The Department will, when so authorized, make the determination as to the relevancy of a record prior to its decision to disclose a document.

1. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or

potential violation of law or contract, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute or contract, rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, rule, regulation, or order issued pursuant thereto, or protecting the interest of the Department.

2. A record from this system of records may be disclosed in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed to the Department of Justice in connection with determining whether the Freedom of Information Act (5 U.S.C. 552) requires disclosure thereof.

5. A record in this system may be disclosed to the Department of Homeland Security for the purposes of determining the admissibility of certain marine mammal or threatened or endangered species or species parts imports into the United States.

6. A record in this system will be disclosed to the Department of Treasury for the purpose of reporting and recouping delinquent debts owed the United States pursuant to 31 U.S.C. 7701 (this applies to MMAP permittees only).

7. A record in this system of records may be disclosed to a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

8. A record in this system of records may be disclosed to appropriate agencies, entities, and persons when: (1) It is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or

property interests, identify theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, state or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a Department decision concerning the assignment, hiring or retention of an individual, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

10. A record from this system of records may be disclosed, as a routine use, to a Federal, state, local, or international agency, in response to its request, in connection with the assignment, hiring or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

11. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

12. A record in this system may be transferred, as a routine use, to the Office of Personnel Management: For personnel research purposes; as a data source for management information; for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; or for related manpower studies.

13. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services Administration (GSA), or his designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and

2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Online application system (Authorizations and Permits for Protected Species only for scientific research permits and authorizations; <https://apps.nmfs.noaa.gov/>); other computerized databases; CDs; paper records stored in file folders in cabinets and/or storage rooms; electronic files maintained on the agency's network server.

RETRIEVABILITY:

Records are organized and retrieved by NMFS internal identification number or permit or authorization number; name of entity or vessel name or identification number. Records can be accessed by any file element or any combination thereof.

SAFEGUARDS:

The paper systems of records are stored in buildings with doors that are locked during and after business hours. Visitors to the facilities must register with security guards and must be accompanied by Federal personnel at all times. The electronic systems of records are stored on the agency's network servers. Electronic records containing Privacy Act information are protected by a user identification/password.

All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, Security of Automated Information Resources, OMB Circular A-130; the Computer Security Act (15 U.S.C. 278g-3 and 278g-4); and the Government Information Security Reform Act, Public Law 106-398; and follows NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems; NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems; and NIST SP 800-53, Recommended Security and Privacy Controls for Federal Information Systems and Organizations.

RETENTION AND DISPOSAL:

All records are retained and disposed of in accordance with National Archive and Records Administration regulations

(36 CFR chapter XII, subchapter B—Records Management); Departmental directives and comprehensive records schedules; NOAA Administrative Order 205–01; and the NMFS Records Disposition Schedule, Chapter 1500.

SYSTEM MANAGER(S) AND ADDRESS:

For records at location a.: Office of Protected Resources, NMFS Headquarters, 1315 East-West Highway, Silver Spring, MD 20910.

For records at location b.: Office of Protected Resources, NMFS Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2276.

For records at location c.: Office of Protected Resources, NMFS Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701.

For records at location d.: Office of Protected Resources, West Coast Region, Sustainable Fisheries Division, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

For records at locations e and f.: Office of Protected Resources, NMFS West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

For records at location g.: Office of Protected Resources, NMFS, Pacific Islands Region, Ford Island Honolulu at 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

For records at location h.: Office of Protected Resources, NMFS Alaska Region, 709 West Ninth Street, Juneau, AK 99802–1668.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about them is contained in this system should address written inquiries to the national or regional Privacy Act Officer:

Privacy Act Officer, NOAA, 1315 East-West Highway, Room 9719, Silver Spring, MD 20910.

Privacy Act Officer, NMFS, 1315 East-West Highway, Room 13706, Silver Spring, MD 20910.

Privacy Act Officer, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2276.

Privacy Act Officer, NMFS Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701.

Privacy Act Officer, NMFS West Coast Region, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

Privacy Act Officer, NMFS West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

Privacy Act Officer, NMFS Pacific Islands Region, Ford Island Honolulu at 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

Privacy Act Officer, NMFS Alaska Region, P.O. Box 21668, Juneau, Alaska 99802, or delivered to the Federal Building, 709 West 9th Street, Juneau, Alaska, 99802–1668.

Written requests must be signed by the requesting individual. Requestor must make the request in writing and provide his/her name, address, and date of the request and record sought. All such requests must comply with the inquiry provisions of the Department's Privacy Act rules which appear at 15 CFR part 4, appendix A.

RECORD ACCESS PROCEDURES:

Requests for access to records maintained in this system of records should be addressed to the same address given in the Notification Procedure section. **Note:** Complete records for jointly-owned permits are made accessible to each owner upon his/her request.

CONTESTING RECORDS PROCEDURES:

The Department's rules for access, for contesting contents, and appealing initial determinations by the individual concerned are provided for in 15 CFR part 4, appendix A.

RECORD SOURCE CATEGORIES:

Information in this system will be collected from individuals or entities applying for a permit or authorization.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: July 5, 2016.

Michael J. Toland,

Department of Commerce, Freedom of Information/Privacy Act Officer.

[FR Doc. 2016–16170 Filed 7–7–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A–570–888]

Floor-Standing, Metal-Top Ironing Tables and Certain Parts Thereof From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results and Notice of Amended Final Results of the Antidumping Duty Administrative Review; 2006–2007

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On April 28, 2016, the United States Court of International Trade (the CIT or the Court) issued final judgment in *Since Hardware (Guangzhou) Co., Ltd., v. United States*, Court No. 09–00123, sustaining the Department of

Commerce's (the Department) final results of the fourth redetermination pursuant to remand.¹ Consistent with the decision of the United States Court of Appeals for the Federal Circuit (Federal Circuit) in *Timken Co., v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*), the Department is notifying the public that the final judgment in this case is not in harmony with the Department's final results of the antidumping duty administrative review of floor-standing, metal-top ironing tables and certain parts thereof from the People's Republic of China covering the period August 1, 2006, through July 31, 2007, and is amending the final results with respect to the weighted-average dumping margin assigned to Since Hardware (Guangzhou) Co., Ltd. (Since Hardware).²

DATES: *Effective Date:* May 8, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael J. Heaney or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4475 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:**Background**

On March 16, 2009, the Department published its *Final Results*.³ On March 18, 2009, Since Hardware, an exporter of the subject merchandise, timely filed a complaint with the CIT to challenge certain aspects of the *Final Results*. The litigation history of this procedure is outlined below.

On September 27, 2010, the Court remanded this matter.⁴ On February 17, 2011, the Department issued its *First Redetermination*, in which it declined to issue a separate rate to Since Hardware and continued to assign Since

¹ See Final Results of Redetermination Pursuant to Court Remand, Floor-Standing Metal-Top Ironing Tables and Certain Parts Thereof from the People's Republic of China, *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Court No. 09–00123, Slip Op. 15–15 (CIT February 18, 2015), dated June 18, 2015 (*Fourth Redetermination*), available at <http://enforcement.trade.gov/remands/index.htm>.

² See *Floor-Standing Metal-Top Ironing Tables and Certain Parts Thereof From the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 74 FR 11085 (March 16, 2009), and accompanying Issues and Decision Memorandum (*Final Results*).

³ *Id.*

⁴ *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Court No. 09–00123, Slip. Op. 10–108 (September 27, 2010) (*Since Hardware I*).

Hardware an AFA rate of 157.68 percent.⁵

Upon consideration of the *First Redetermination*, on November 29, 2011, the Court determined that the Department failed to consider record information relating to Since Hardware's application for a separate rate.⁶ In *Since Hardware II*, the Court directed the Department to determine whether Since Hardware was entitled to a separate rate and, if so, to determine that rate.⁷ On May 29, 2012, the Department issued its *Second Redetermination*, in which it determined that Since Hardware was entitled to a separate rate.⁸ However, because Since Hardware's questionnaire responses had otherwise been determined to be unreliable, the Department continued to assign an AFA rate of 157.68 percent to Since Hardware.⁹ In the *Second Redetermination*, the Department also reviewed data from U.S. Customs and Border Protection (CBP), and determined that these CBP data established that selected importers paid antidumping duties of 157.68 percent.¹⁰ Based on this finding, the Department concluded the 157.68 percent rate was relevant with regard to Since Hardware.

On May 31, 2013, in *Since Hardware III*, the Court sustained the Department's determination not to reopen the record of the proceeding.¹¹ The Court also determined that the 157.68 percent rate was reliable.¹² However, the Court found the Department did not demonstrate the relevance and commercial reality of the 157.68 percent AFA rate. On October 31, 2013, the Department issued its *Third Redetermination*, determining that the 157.68 percent rate assigned to Since Hardware was corroborated to the extent practicable by the use of CBP data.¹³

⁵ See Final Results of Redetermination Pursuant to Court Remand Floor Standing Metal-Top Ironing Tables and Certain Parts Thereof from the People's Republic of China *Since Hardware (Guangzhou) Co., Ltd. v. United States*, dated February 17, 2011 (*First Redetermination*).

⁶ See *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Court No. 09-00123, Slip Op. 11-146 (November 29, 2011) (*Since Hardware II*).

⁷ *Id.*

⁸ See Final Results of Redetermination Pursuant to Court Remand Floor Standing Metal-Top Ironing Tables and Certain Parts Thereof from the People's Republic of China *Since Hardware (Guangzhou) Co., Ltd. v. United States*, dated May 29, 2012 (*Second Redetermination*).

⁹ *Id.*

¹⁰ *Id.*

¹¹ See *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Court No., 09-00123, Slip Op. 13-71 (May 31, 2013) (*Since Hardware III*).

¹² *Id.*

¹³ See Final Results of Redetermination Pursuant to Court Remand Floor Standing Metal-Top Ironing Tables and Certain Parts Thereof from the People's

On February 18, 2015, in *Since Hardware IV*, the Court rejected the analysis concerning corroboration of the 157.68 percent rate assigned to Since Hardware, as outlined in the *Third Redetermination*.¹⁴ The Court ordered the Department to support the rate assigned to Since Hardware by demonstrating that the information had some grounding in commercial reality.¹⁵ The Court further determined that the Department's analysis of the Customs data set forth in the *Third Redetermination* was insufficient to corroborate the 157.68 percent AFA rate assigned to Since Hardware.¹⁶ On June 18, 2015, the Department issued its *Fourth Redetermination*. In the *Fourth Redetermination*, the Department, under protest, assigned a revised AFA rate of 72.29 percent to Since Hardware to better address the Court's concerns of relevance and commercial reality.¹⁷ This 72.29 percent rate was the rate assigned to Separate Rate companies in the less-than-fair value investigation.¹⁸

On April 28, 2016, the Court sustained the Department's *Fourth Redetermination*, and entered final judgment.¹⁹

Timken Notice

In its decision in *Timken*, 893 F.2d at 341, as clarified by *Diamond Sawblades*, the Federal Circuit has held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), the Department must publish a notice of a court decision not "in harmony" with a Department determination, and must suspend liquidation of entries pending a "conclusive" court decision. The Court's April 28, 2016 judgment sustaining the *Fourth Redetermination* constitutes a final decision of the Court that is not in harmony with the Department's *Final Results*. This notice is published in fulfillment of the publication requirement of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if

Republic of China *Since Hardware (Guangzhou) Co., Ltd. v. United States*, dated October 31, 2013 (*Third Redetermination*).

¹⁴ See *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Slip Op. 15-15, Court No. 09-00123 (February 18, 2015) (*Since Hardware IV*).

¹⁵ *Id.*

¹⁶ *Id.*, at 8-20.

¹⁷ See *Fourth Redetermination*.

¹⁸ See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Floor Standing Metal-Top Ironing Tables and Certain Parts Thereof From the People's Republic of China* 69 FR 47868 (August 6, 2004).

¹⁹ See *Since Hardware (Guangzhou) Co., Ltd. v. United States*, Court No. 09-00123, Slip Op. 16-42 (April 28, 2016).

appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final court decision, the Department is amending the *Final Results* with respect to the dumping margin of Since Hardware. The revised weighted-average dumping margin for Since Hardware during the period August 1, 2006, through July 31, 2007, is as follows:

Exporter	Weighted average dumping margin (percent)
Since Hardware (Guangzhou) Co., Ltd	72.29

For Since Hardware, the cash deposit rate will remain the rate established in the *2008-2009 Amended Final Results*, a subsequent review, which is 83.83 percent.²⁰

In the event the Court's ruling is not appealed, or if appealed and upheld by the Federal Circuit, the Department will instruct CBP to assess antidumping duties on entries of the subject merchandise exported by Since Hardware using the revised assessment rate calculated by the Department in the *Fourth Redetermination*.

This notice is issued and published in accordance with sections 516(A)(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: June 30, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement & Compliance.

[FR Doc. 2016-16253 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-016]

Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

²⁰ See *Floor Standing Metal-Top Ironing Tables and Certain Parts Thereof From the People's Republic of China: Notice of Court Decision Not in Harmony with Final Results and Notice of Amended Final Results of Antidumping Duty Administrative Review; 2008-2009*, 80 FR 36507, (June 25, 2015) (*2008-2009 Amended Final Results*).

SUMMARY: The Department of Commerce (the Department) is initiating a changed circumstances review (CCR) of the antidumping duty (AD) order on certain passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (PRC) with regard to Sailun Jinyu Group (HONG KONG) Co., Limited (Sailun Jinyu HK). We preliminarily determine that Sailun Jinyu HK is the successor-in-interest to Jinyu International Holding Co., Limited (Jinyu HK) for purposes of determining AD liability. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* July 8, 2016.

FOR FURTHER INFORMATION CONTACT: Toni Page, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-1398.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, the Department published in the **Federal Register** an AD order on passenger tires from the PRC.¹ On December 4, 2015, Jinyu HK, an exporter of passenger tires covered by this order, changed its name from Jinyu HK to Sailun Jinyu HK. On February 23, 2016, Sailun Jinyu HK requested that the Department conduct a changed circumstances review under section 751(b) of the Tariff Act of 1930 (the Act), as amended, 19 CFR 351.216, and 19 CFR 351.221(c)(3).² In this request, Sailun Jinyu HK asked the Department to determine that it is the successor-in-interest to Jinyu HK and, accordingly, to assign it Jinyu HK's cash deposit rate.³ Sailun Jinyu HK also requested that the Department expedite the review.⁴ Initially, the Department denied Sailun Jinyu HK's request because it failed to demonstrate good cause for conducting a changed circumstances review of a final determination in an investigation less than 24 months after the

publication of the final determination.⁵ Sailun Jinyu HK subsequently filed arguments as to why good cause exists for initiating a CCR.⁶

Scope of the Order

The products covered by the scope of this order are passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by these orders may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement market.

Subject tires have, at the time of importation, the symbol "DOT" on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Subject tires may also have the following prefixes or suffix in their tire size designation, which also appears on the sidewall of the tire:

Prefix designations:

P—Identifies a tire intended primarily for service on passenger cars

LT—Identifies a tire intended primarily for service on light trucks

Suffix letter designations:

LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service.

All tires with a "P" or "LT" prefix, and all tires with an "LT" suffix in their sidewall markings are covered by this investigation regardless of their intended use.

In addition, all tires that lack a "P" or "LT" prefix or suffix in their sidewall markings, as well as all tires that include any other prefix or suffix in their sidewall markings, are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the passenger car section or light truck section of the Tire and Rim Association Year Book, as updated annually, unless the tire falls within one of the specific exclusions set out below.

Passenger vehicle and light truck tires, whether or not attached to wheels or rims, are included in the scope.

However, if a subject tire is imported attached to a wheel or rim, only the tire is covered by the scope.

Specifically excluded from the scope are the following types of tires:

(1) Racing car tires; such tires do not bear the symbol "DOT" on the sidewall and may be marked with "ZR" in size designation;

(2) new pneumatic tires, of rubber, of a size that is not listed in the passenger car section or light truck section of the Tire and Rim Association Year Book;

(3) pneumatic tires, of rubber, that are not new, including recycled and retreaded tires;

(4) non-pneumatic tires, such as solid rubber tires;

(5) tires designed and marketed exclusively as temporary use spare tires for passenger vehicles which, in addition, exhibit each of the following physical characteristics:

(a) the size designation and load index combination molded on the tire's sidewall are listed in Table PCT-1B ("T" Type Spare Tires for Temporary Use on Passenger Vehicles) of the Tire and Rim Association Year Book,

(b) the designation "T" is molded into the tire's sidewall as part of the size designation, and,

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by Tire and Rim Association Year Book, and the rated speed is 81 MPH or a "M" rating;

(6) tires designed and marketed exclusively for specialty tire (ST) use which, in addition, exhibit each of the following conditions:

(a) the size designation molded on the tire's sidewall is listed in the ST sections of the Tire and Rim Association Year Book,

(b) the designation "ST" is molded into the tire's sidewall as part of the size designation,

(c) the tire incorporates a warning, prominently molded on the sidewall, that the tire is "For Trailer Service Only" or "For Trailer Use Only",

(d) the load index molded on the tire's sidewall meets or exceeds those load indexes listed in the Tire and Rim Association Year Book for the relevant ST tire size, and

(e) either

(i) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by Tire and Rim Association Year Book, and the rated speed does not exceed 81 MPH or an "M" rating; or

(ii) the tire's speed rating molded on the sidewall is 87 MPH or an "N" rating, and in either case the tire's maximum pressure and maximum load limit are molded on the sidewall and either

¹ See *Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 80 FR 47902 (August 10, 2015) (*AD and CVD Orders*).

² See letter from the Sailun Group, "Jinyu International Holding Co., Limited's Request for a Changed Circumstances Review in Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China, Case No. A-570-016," at 1 (February 23, 2016) (Sailun Jinyu HK CCR Request).

³ *Id.*

⁴ *Id.*

⁵ See letter from the Department, "Antidumping Duty Investigation of Passenger Vehicle and Light Truck Tires from the People's Republic of China: Request for Changed Circumstances Review" (April 4, 2016).

⁶ See letter from the Sailun Group, "Jinyu International Holding Co., Limited's Request for a Changed Circumstances Review in Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China, Case No. A-570-016," at 2-3 (April 18, 2016) (Sailun Jinyu HK CCR Good Cause Request).

(1) both exceed the maximum pressure and maximum load limit for any tire of the same size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book; or

(2) if the maximum cold inflation pressure molded on the tire is less than any cold inflation pressure listed for that size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book, the maximum load limit molded on the tire is higher than the maximum load limit listed at that cold inflation pressure for that size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book;

(7) tires designed and marketed exclusively for off-road use and which, in addition, exhibit each of the following physical characteristics:

(a) the size designation and load index combination molded on the tire's sidewall are listed in the off-the-road, agricultural, industrial or ATV section of the Tire and Rim Association Year Book,

(b) in addition to any size designation markings, the tire incorporates a warning, prominently molded on the sidewall, that the tire is "Not For Highway Service" or "Not for Highway Use",

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by the Tire and Rim Association Year Book, and the rated speed does not exceed 55 MPH or a "G" rating, and

(d) the tire features a recognizable off-road tread design.

The products covered by the orders are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.45, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60. While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Initiation and Preliminary Results of Changed Circumstances Review

Pursuant to section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), the

Department will conduct a CCR upon receipt of a request from an interested party for a review of an AD order which shows changed circumstances sufficient to warrant a review of the order. The information submitted by Sailun Jinyu HK supporting its claim that it is the successor-in-interest to Jinyu HK demonstrates changed circumstances sufficient to warrant such a review.⁷

In accordance with the above-referenced regulation, the Department is initiating a CCR to determine whether Sailun Jinyu HK is the successor-in-interest to Jinyu HK. When it concludes that expedited action is warranted, the Department may publish the notice of initiation and preliminary results for a CCR concurrently.⁸ We determined that expediting this CCR is warranted because we have the information necessary to make a preliminary finding already on the record, in accordance with our practice.⁹

In determining whether one company is the successor-in-interest to another, the Department examines a number of factors including, but not limited to, changes in management, production facilities, supplier relationships, and customer base.¹⁰ While no single factor or combination of these factors will necessarily provide a dispositive indication of a successor-in-interest relationship, the Department will generally consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.¹¹ Thus, if the evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as

⁷ See 19 CFR 351.216(d).

⁸ See 19 CFR 351.221(c)(3)(ii); see also *Certain Pasta From Italy: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review*, 80 FR 33480, 33480-41 (June 12, 2015) (*Pasta From Italy Preliminary Results*) (unchanged in *Certain Pasta From Italy: Final Results of Changed Circumstances Review*, 80 FR 48807 (August 14, 2015) (*Pasta From Italy Final Results*)).

⁹ See, e.g., *Pasta From Italy Preliminary Results*, 80 FR at 33480-41 (unchanged in *Pasta From Italy Final Results*, 80 FR at 48807).

¹⁰ See, e.g., *Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp From Thailand*, 75 FR 61702, 61703 (October 6, 2010) (*Shrimp From Thailand Preliminary Results*) (unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp From Thailand*, 75 FR 74684 (December 1, 2010) (*Shrimp From Thailand Final Results*)); and *Industrial Phosphoric Acid From Israel: Final Results of Antidumping Duty Changed Circumstances Review*, 59 FR 6944, 6946 (February 14, 1994).

¹¹ See, e.g., *Shrimp From Thailand Preliminary Results*, 75 FR at 61703 (unchanged in *Shrimp From Thailand Final Results*, 75 FR at 74684).

the prior company, the Department will assign the new company the cash deposit rate of its predecessor.¹²

In its February 23, 2016, and April 18, 2016 submissions, Sailun Jinyu HK provided information to demonstrate that it is the successor-in-interest to Jinyu HK. Sailun Jinyu HK states that there were no changes to the company's ownership, employees, managers, customers, or suppliers. To support its claims, Sailun Jinyu HK submitted the following documents: (1) A copy of Jinyu HK Internal Work Approval Sheet, dated October 29, 2015 explaining the reason for the name change from Jinyu HK to Sailun Jinyu HK; (2) a copy of a Department memorandum regarding Sailun Group Co., Ltd.'s Affiliation Single Entity Status, dated January 14, 2015; (3) a Notice of Change of Company Name, dated December 4, 2015 filed with the Hong Kong Companies Registry; (4) a Certificate of Change of Name, dated December 21, 2015, issued by the Hong Kong Companies Registry; (5) business registrations for both Jinyu HK (dated October 24, 2015) and Sailun Jinyu HK (dated October 24, 2015); (6) a listing of the company's customers before and after its name change; and (7) a letter sent to all customers explaining the name change.¹³ Sailun Jinyu HK also demonstrated good cause for initiating a CCR pursuant to 19 CFR 351.216(c) because it has only changed its name and no other aspect of the company's operations, and conducting this review ensures that the appropriate deposit rate applies to Sailun Jinyu HK.¹⁴

Based on the evidence on the record, we preliminarily find that Sailun Jinyu HK is the successor-in-interest to Jinyu HK. We find that Sailun Jinyu HK operates as the same business entity as Jinyu HK and that its ownership, management, production facilities, supplier relationships, and customers have not changed as a result of its name change. Thus, we preliminarily find that Sailun Jinyu HK should receive the same AD cash deposit rate with respect to the subject merchandise as Jinyu HK, its predecessor company.¹⁵

¹² *Id.*; see also *Notice of Final Results of Changed Circumstances Antidumping Duty Administrative Review: Polychloroprene Rubber From Japan*, 67 FR 58, 59 (January 2, 2002); and *Ball Bearings and Parts Thereof from France: Final Results of Changed-Circumstances Review*, 75 FR 34688, 34689 (June 18, 2010).

¹³ See Sailun Jinyu HK CCR Request at Exhibits 1-7.

¹⁴ See Sailun Jinyu HK CCR Good Cause Request at 2-3.

¹⁵ Jinyu HK, as part of the Sailun Group, received a 0.00 percent cash deposit rate in the investigation of the AD order on passenger tires from the PRC. See *AD and CVD Orders* at 47904 (August 10, 2015).

Should our final results remain the same as these preliminary results, we will instruct U.S. Customs and Border Protection to suspend entries of subject merchandise exported by Sailun Jinyu HK at Jinyu HK's cash deposit rate, effective on the publication date of our final results.

Public Comment

Interested parties may submit case briefs and/or written comments not later than 14 days after the publication of this notice.¹⁶ Rebuttal briefs, which must be limited to issues raised in case briefs, may be filed not later than five days after the deadline for filing case briefs.¹⁷ Parties who submit case briefs or rebuttal briefs in this changed circumstances review 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 comment on the preliminary results must file briefs electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. Eastern Time on the date the document is due.

Interested parties that wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, within 14 days of publication of this notice.¹⁸ Parties will be notified of the time and date of any hearing, if requested.¹⁹

Consistent with 19 CFR 351.216(e), we intend to issue the final results of this changed circumstance review no later than 270 days after the date on which this review was initiated, or within 45 days of publication of these preliminary results if all parties agree to our preliminary finding.

We are issuing and publishing this finding and notice in accordance with sections 751(b)(1) and 777(i)(1) of the Act, and 19 CFR 351.216 and 351.221(c)(3)(ii).

Dated: June 30, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016-16252 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE705

International Whaling Commission; 66th Meeting; Nominations

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

ACTION: Notice; request for nominations.

SUMMARY: This notice is a call for nominees for the U.S. Delegation to the October 2016 International Whaling Commission (IWC) meeting. The non-federal representative(s) selected as a result of this nomination process is (are) responsible for providing input and recommendations to the U.S. IWC Commissioner representing the positions of non-governmental organizations.

DATES: The IWC is holding its 66th meeting from October 20-28, 2016, at the Convention Center of the Grand Hotel Bernardin in Portorož, Slovenia. All written nominations for the U.S. Delegation to the IWC meeting must be received by August 26, 2016.

ADDRESSES: All nominations for the U.S. Delegation to the IWC meeting should be addressed to Mr. Ryan Wulff, Deputy U.S. Commissioner to the IWC, and sent to Jordan Carduner via email:

jordan.carduner@noaa.gov; or via post: National Marine Fisheries Service, Office of International Affairs and Seafood Inspection Program, 1315 East-West Highway, SSMC3 Room 10651, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Jordan Carduner at *jordan.carduner@noaa.gov* or 301-427-8401.

SUPPLEMENTARY INFORMATION: The Secretary of Commerce is responsible for discharging the domestic obligations of the United States under the International Convention for the Regulation of Whaling, 1946. The U.S. IWC Commissioner has responsibility for the preparation and negotiation of U.S. positions on international issues concerning whaling and for all matters involving the IWC. The U.S. IWC Commissioner is staffed by the Department of Commerce and assisted

by the Department of State, the Department of the Interior, the Marine Mammal Commission, and by other agencies. The non-federal representative(s) selected as a result of this nomination process is (are) responsible for providing input and recommendations to the U.S. IWC Commissioner representing the positions of non-governmental organizations. Generally, only one non-governmental position is selected for the U.S. Delegation.

Dated: July 5, 2016.

John Henderschedt,

Director, Office of International Affairs and Seafood Inspection Program, National Marine Fisheries Service.

[FR Doc. 2016-16178 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE714

Pacific Fishery Management Council; Public Meeting (Webinar)

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council's (Pacific Council's) Coastal Pelagic Species Management Team (CPSMT) will meet via webinar to discuss potential management options for the northern anchovy. The meeting is open to the public.

DATES: The webinar meeting will take place from 10 a.m. to 12 p.m. Pacific Daylight Time, August 3, 2016.

ADDRESSES: The meeting will be held via webinar. A public listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer; telephone: (503) 820-2409.

SUPPLEMENTARY INFORMATION: The primary purpose of the webinar is to solicit comments and questions on a draft white paper being developed by the Pacific Council's CPSMT. The Council will consider the white paper at its September 15-20 meeting in Boise, ID. Public comments during the webinar

¹⁶ See 19 CFR 351.309(c)(ii).

¹⁷ See 19 CFR 351.309(d).

¹⁸ See 19 CFR 351.310(c); see also 19 CFR 351.303 for general filing requirements.

¹⁹ See 19 CFR 351.310.

will be received from attendees at the discretion of the CPSMT Chair.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2425, at least 5 days prior to the meeting date.

Dated: July 5, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016-16213 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE721

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR Data Best Practices Standing Panel Webinar.

SUMMARY: The SEDAR Data Best Practices Panel will develop, review, and evaluate best practice recommendations for SEDAR Data Workshops. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR Data Best Practices Standing Panel webinar will be held on Thursday, July 21, 2016, from 10 a.m. to 12 p.m. (EST).

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT** below) to request an invitation providing webinar access information. Please request webinar

invitations at least 24 hours in advance of each webinar.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; www.sedarweb.org.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571-4366; email: julia.byrd@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The SEDAR Data Best Practices Standing Panel is charged with developing, reviewing, and evaluating best practice recommendations for SEDAR Data Workshops. This will be the second meeting of this group. The

items of discussion for this webinar are as follows:

1. Finalize terms of reference that specify the Panel's purpose and approach.
2. Continue discussions on SEDAR Data Best Practices living document.
3. Discuss Data Issue Inventory Format
4. Other business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 5, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016-16214 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

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: West Coast Region Federal Fisheries Permits—Northwest.

OMB Control Number: 0648-0203.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 537.

Average Hours per Response: Permit renewals, 20 minutes; Permit transfers,

30 minutes; Sablefish ownership interest form, 10 minutes ; EFP Applications, 32 hours; EFP Trip Notifications 2 minutes; EFP Harvest Plans: 16 hours; EFP Data Reports: 2 hours;; EFP Summary Reports: interim report, 4 hours; final report, 20 hours.

Burden Hours: 2,000.

Needs and Uses: This request is for extension of a currently approved information collection.

The Magnuson-Stevens Act (16 U.S.C. 1801) provides that the Secretary of Commerce is responsible for the conservation and management of marine fisheries resources in Exclusive Economic Zone (3–200 miles) of the United States (U.S.). NOAA Fisheries, West Coast Region—Northwest manages the Pacific Coast Groundfish Fishery in the Exclusive Economic Zone (EEZ) off Washington, Oregon, and California under the Pacific Coast Groundfish Fishery Management Plan. The regulations implementing the Pacific Groundfish Fishery require that those vessels participating in the limited entry fishery to be registered to a valid limited entry permit. Participation in the fishery and access to a limited entry permit has been restricted to control the overall harvest capacity. The regulations implementing the limited entry program are found at 50 CFR part 660, subpart G.

NOAA Fisheries seeks comment on the extension of permit information collections required for: (1) Renewal and transfer of Pacific Coast Groundfish limited entry permits; (2) implementation of certain provisions of the sablefish permit stacking program as provided for at 50 CFR 660.231 and 660.25; and (3) issuing and fulfilling the terms and conditions of certain exempted fishing permits (EFPs).

Also, NOAA Fisheries requires an information collection to implement certain aspects of the sablefish permit stacking program which prevents excessive fleet consolidation. As part of the annual renewal process, NOAA Fisheries requires a corporation or partnership that owns or holds (as vessel owner) a sablefish endorsed permit to provide a complete ownership interest form listing all individuals with ownership interest in the entity. Similarly, any sablefish endorsed permit transfer involving registration of a business entity requires an ownership interest form if either the permit owner or vessel owner is a corporation or partnership. This information is used to determine if individuals own or hold sablefish permits in excess of the limit of 3 permits. Also, for transfer requests made during the sablefish primary season (April 1st through October 31st),

the permit owner is required to report the remaining tier pounds not yet harvested on the sablefish endorsed permit at the time of transfer.

Applicants for an exempted fishing permit (EFP) must submit written information that allows NOAA Fisheries and the Pacific Fishery Management Council to evaluate the proposed exempted fishing project activities and weigh the benefits and costs of the proposed activities. The Council makes a recommendation on each EFP application and for successful applicants, NOAA Fisheries issues the EFPs which contains terms and conditions for the project including various reporting requirements. The information included in an application is specified at 50 CFR 600.745(b)(2) and the Council Operating Procedure #19. Permit holders are required to file preseason harvest plans, interim and/or final summary reports on the results of the project and in some cases individual vessels and other permit holders are required to provide data reports (logbooks and/or catch reports). The results of EFPs are commonly used to explore ways to reduce effort on depressed stocks, encourage innovation and efficiency in the fishery, provide access to constrained stocks which directly measuring the bycatch associated with such strategies and evaluate/revise current and proposed management measures.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions; state, local or tribal government.

Frequency: Annually, semi-annually, monthly and on occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

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* or fax to (202) 395–5806.

Dated: July 5, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–16173 Filed 7–7–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 160606490–6490–01]

Privacy Act of 1974; System of Records

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of a New Privacy Act System of Records: COMMERCE/NOAA–21, Financial Systems Division.

SUMMARY: This notice announces the Department of Commerce's (Department's) proposal for a new system of records under the Privacy Act. The National Oceanic and Atmospheric Administration's (NOAA's) National Marine Fisheries Service (NMFS) is creating a new system of records for the Financial Services Division's financial assistance programs. Information will be collected from individuals and businesses under the authority of title XI of the Merchant Marine Act of 1936, as amended and codified, and the Magnuson-Stevens Fishery Conservation and Management Act, as amended. This new record system is necessary to determine whether applicants for program financing, Fishermen's Contingency claims, or participants in Capital Construction Fund accounts or Fishery Capacity Reduction programs are eligible and are creditworthy.

DATES: To be considered, written comments must be submitted on or before August 8, 2016. Unless comments are received, the new system of records will become effective as proposed on August 17, 2016. If comments are received, the Department will publish a subsequent notice in the **Federal Register** within 10 days after the comment period closes, stating that the current system of records will remain in effect until publication of a final action in the **Federal Register**.

ADDRESSES: Comments may be mailed to: Paul Marx, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Paul Marx, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

SUPPLEMENTARY INFORMATION: NMFS will use the information contained in this system of records to determine whether applicants for the Fisheries Financing Program (FFP) are both

eligible and creditworthy; whether applicants for fishing gear reimbursements under the Fishermen's Contingency Fund (FCF) are eligible and present valid claims; whether participants under the Capital Construction Fund (CCF) are eligible to participate; and whether participants in Fisheries Capacity Reduction programs (Buyback) are providing correct information. The information collected is essential for financial assistance and program eligibility determinations. It is comparable to what is usually required by commercial lending institutions when making lending decisions, or insurance institutions when adjusting claims. Applicants with a history of credit problems (including delinquent Federal debt), litigation or bankruptcy, lack of capital, etc., may be unable to meet the FFP's stringent credit standards and may be denied financing. Applicants for CCF accounts with an ineligible vessel or an ineligible project may be unable to meet the CCF program requirements. Claimants with insufficient or incorrect documentation may be ineligible to receive reimbursements for fishing gear lost on the Outer Continental Shelf. Participants in the Capacity Reduction programs who fail to remit fees or fail to remit them timely may face penalties and late charges.

The information collection is requested from individuals and businesses under the authority of title XI of the Merchant Marine Act of 1936, as amended and codified, and the Magnuson-Stevens Fishery Conservation and Management Act, as amended. The information collection includes collecting each applicant's Tax Identification Number (TIN), either an Employer Identification Number (EIN) or Social Security Number (SSN). Collection of a TIN is required under 31 U.S.C. 7701. The primary purpose for requesting the TIN is to correctly identify the applicant for background and credit investigations and program eligibility, and may be used to report or collect any delinquent amounts arising out of an applicant's relationship with the Government.

COMMERCE/NOAA-21

SYSTEM NAME:

COMMERCE/NOAA-21, Financial Services Division.

SECURITY CLASSIFICATION:

Moderate.

SYSTEM LOCATIONS:

a. NMFS Northeast Financial Services Branch, MB51, 55 Great Republic Drive,

Suite 02-700, Gloucester, MA 01930-2209.

b. NMFS Southeast Financial Services Branch, MB52, 263-13th Avenue South, St. Petersburg, FL 33702-2432.

c. NMFS Northwest Financial Services Branch, MB53, 7600 Sand Point Way NW., Bin C15700, Building #1, Seattle, WA 98115.

d. NMFS Financial Services Division, 1315 East West Highway, Silver Spring, MD 20910.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for Fisheries Finance Program financial assistance, including: Direct loans for vessels, shoreside facilities, aquaculture, mariculture, and individual fishing quota (IFQ) loans; applicants for Capital Construction Fund (CCF) accounts; fishers and fish buyers participating in Capacity Reduction loan (Buyback) programs; and claimants under the Fishermen's Contingency Fund.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system will include general personal and financial data including: The loan applicant's identity (including full name, address, and, as applicable, the SSN or EIN); the amount of financing applied for, the purpose of the loan; an appraisal of the vessel, facility or project being financed; Coast Guard documentation or Abstracts of title to vessels; income and financial information, including the applicant's last three Federal tax returns; LLC or Partnership agreements; a list of creditors and buyers with relevant credit terms; identification of authorized representatives (accountant, attorney, insurance agent); loan servicing actions and financial transactions; and the applicant's legal and credit history (status regarding bankruptcy, litigation, delinquency on debt, etc.). This information will be collected and maintained by the Financial Services Division and its branches.

The system will also include the CCF account holder's identity (including full name, address, and as applicable, the SSN or EIN); the nature of the account, banking information, the description of the project for which the account is to be created; income, business and financial information including the applicant and/or account holder's tax return, LLC and Partnership agreements; Coast Guard documentation, bills of sale, mortgages, etc.; identification of authorized representatives (accountant, attorney); and reports of account activity including all deposits and withdrawals. The system of records will include FCF claimants' identity (including full name,

address, and, as applicable, the SSN or EIN); Vessel name and characteristics; fishing results for the three most recent trips; receipts for gear and equipment replaced; and information about the claimant's prior claims. The system of records will include Capacity Reduction program participants' identity (including full name, address, and, as applicable, the SSN or EIN); processor number, fish ticket information, receipt and payment information, and banking information.

AUTHORITIES FOR MAINTENANCE OF THE SYSTEM:

Title XI of the Merchant Marine Act of 1936 as amended and codified, 46 U.S.C. 1177 and 46 U.S.C. 53701 *et seq.*, the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.*, and provisions of the Debt Collection Improvement Act as codified at 31 U.S.C. 7701.

PURPOSE(S):

This information will allow NMFS to identify applicants and program participants and evaluate them for Financial Services Division financial assistance.

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, these records or information contained therein may specifically be disclosed outside of the Department. These records or information contained therein may specifically be disclosed as a routine use as stated below. The Department will, when so authorized, make the determination as to the relevancy of a record prior to its decision to disclose a document.

1. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute or contract, rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, contract or rule, regulation or order issued pursuant thereto, or protecting the interests of the Department.

2. A record from this system of records may be disclosed in the course

of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed to the Department of Justice in connection with determining whether the Freedom of Information Act (5 U.S.C. 552) requires disclosure thereof.

4. A record from this system of records may be disclosed, as a routine use, to a Federal, state, local, or international agency, in response to its request, in connection with the assignment, hiring or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

5. A record in this system will be disclosed to the Department of Treasury for the purpose of reporting and recouping delinquent debts owed to the United States pursuant to the Debt Collection Improvement Act of 1996.

6. A record in this system of records may be disclosed to a contractor of the Department having need for the information in the performance of the contract but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

7. A record in this system of records may be disclosed to appropriate agencies, entities, and persons when: (1) It is suspected or confirmed that the security of confidentiality of information in the system of records has been compromised; (2) the Department has determined that, as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

8. A record or information in this system of records may be disclosed to private sector appraisers, marine architects, attorneys, accountants, banks, lending institutions, real estate agents, brokers, title companies, state or local agencies, commercial registries,

credit bureaus, rating agencies, and/or other persons and entities for the purpose of making credit and eligibility evaluations; lender due diligence investigations; CCF account validations; FCF claim adjustments; and/or the creation, attachment, perfection, maintenance, realization, or foreclosure of security interests.

9. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

10. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

11. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services Administration (GSA), or his designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.* GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) and the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

Storage: Financial Services Divisions applications and related information are stored in a computerized database; CDs or DVDs; paper records stored in file folders in locked metal cabinets and/or locked rooms.

Retrievability: Records are organized and retrieved by an NMFS internal identification number, name of entity, case number, vessel name or identification number, plant name, processor number, or claim number. Records can be accessed by any file element or any combination thereof.

Safeguards: The system of records is stored in a building with doors that are locked during and after business hours. Visitors to the facility must register with security guards and must be accompanied by Federal personnel at all times. Paper records are stored in a locked room and/or a locked file cabinet. Electronic records containing Privacy Act information are protected by a user identification/password, and reside on an internal computer system protected by an electronic "firewall" to prevent access from outside the Federal facility. The user identification/password is issued to individuals by authorized personnel.

All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, Security of Automated Information Resources, OMB Circular A-130; the Computer Security Act (15 U.S.C. 278g-3 and 278g-4); and the Government Information Security Reform Act, Public Law 106-398; and follows NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems; NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems; and NITS SP 800-53, Recommended Security Controls for Federal Information Systems.

Retention and Disposal: All records are retained and disposed of in accordance with National Archives and Records Administration regulations (35 CFR chapter XII, subchapter B—Records Management); Departmental directives and comprehensive records schedules; NOAA Administrative Order 205-01; and the NMFS Records Disposition Schedule, Chapter 1500.

SYSTEM MANAGERS AND ADDRESSES:

For records at location a.: Chief, Northeast Financial Services Branch, 55 Great Republic Drive, Suite 02-700, Gloucester, MA 01930-2209.

For records at location b.: Chief, Southeast Financial Services Branch, 263 13th Avenue, South, St. Petersburg, FL 33702-2432.

For records at location c.: Chief, Northwest Financial Services Branch, 7600 Sand Point Way NW., (Bin C15700) Bldg. #1, Seattle, WA 98115.

For records at location d.: Chief, Financial Services Division, 1315 East West Highway, Silver Spring, MD 20910.

NOTIFICATION PROCEDURE:

Individuals or businesses seeking to determine whether information about themselves is contained in this system should address written inquiries to the NOAA Privacy Act Officer: Privacy Act Officer, NOAA, 1315 East West

Highway, Room 10641, Silver Spring, MD 20910.

Written requests must be signed by the requesting individual. Requestor must make the request in writing and provide his/her name, address, and date of the request and the nature of the record sought. All such requests must comply with the inquiry provisions of the Department's Privacy Act rules which appear at 15 CFR part 4, Appendix A.

RECORD ACCESS PROCEDURES:

Requests for access to records maintained in this system of records should be addressed to the same address given in the Notification section above.

CONTESTING RECORD PROCEDURES:

The Department's rules for access, for contesting content, and for appealing initial determinations by the individual or business concerned are provided for in 15 CFR part 4, Appendix A.

RECORD SOURCE CATEGORIES:

Information in this system will be collected from individuals and businesses applying for Financial Systems Division financial assistance.

EXEMPTION CLAIMS FOR SYSTEM:

None.

Dated: July 5, 2016.

Michael J. Toland,

Department of Commerce, Freedom of Information/Privacy Act Officer.

[FR Doc. 2016-16171 Filed 7-7-16; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds 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 services from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* August 7, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703)

603-7740, Fax: (703) 603-0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 3/25/2016 (81 FR 16145-16146) and 6/3/2016 (81 FR 35749-35750), 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 service and impact of the additions on the current or most recent contractors, the Committee has determined that the products and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. 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. 8501-8506) in connection with the products and service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and service are added to the Procurement List:

Products

NSN(s)—Product Name(s):

MR 10739—Herb Stripper, Includes Shipper 20739

MR 10732—Hershey's Lava Cake Maker, Shipper 20732

MR 10733—Reese's Lava Cake Maker, Shipper 20732

Mandatory for: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51-6.4

Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC

Contracting Activity: Defense Commissary Agency

Distribution: C-List

NSN(s)—Product Name(s):

7220-00-NSH-0022—Mat, Floor, Chair, 45" x 53" x .110", w/20" x 12" Lip

7220-00-NSH-0023—Mat, Floor, Chair, 45" x 53" x .110", w/25" x 12" Lip

7220-00-NSH-0024—Mat, Floor, Chair, 46" x 60" x .110", w/25" x 12" Lip

7220-00-NSH-0025—Mat, Floor, Chair, 46" x 60" x .110", Without Lip

7220-00-NSH-0026—Mat, Floor, Chair, 60" x 60" x .110", Without Lip

7220-00-NSH-0030—Mat, Floor, Chair, 36" x 48" x .150", w/20" x 12" Lip

7220-00-NSH-0031—Mat, Floor, Chair, 45" x 53" x .150", w/25" x 12" Lip

7220-00-NSH-0032—Mat, Floor, Chair, 45" x 53" x .150", w/20" x 12" Lip

7220-00-NSH-0033—Mat, Floor, Chair, 45" x 53" x .220", w/20" x 12" Lip

7220-00-NSH-0035—Mat, Floor, Chair, 46" x 60" x .150", Without Lip

7220-00-NSH-0036—Mat, Floor, Chair, 46" x 60" x .150", w/25" x 12" Lip

7220-00-NSH-0038—Mat, Floor, Chair, 46" x 60" x .220", w/25" x 12" Lip

7220-00-NSH-0039—Mat, Floor, Chair, 46" x 60" x .220", Without Lip

7220-00-NSH-0040—Mat, Floor, Chair, 60" x 60" x .150", Without Lip

Mandatory for: Total Government Requirement

Mandatory Source(s) of Supply: Northeastern Michigan Rehabilitation and Opportunity Center (NEMROC), Alpena, MI

Contracting Activity: General Services Administration, Fort Worth, TX

Distribution: A-List

Service

Service Type: Base Supply Center

Mandatory for: US Army, Walter Reed Army Institute of Research, Silver Spring, MD

Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI

Contracting Activity: Dept of the Army, W4PZ USA MED RSCH ACQUIS ACT

Deletions

On 6/3/2016 (81 FR 35749-35750), 6/10/2016 (81 FR 37581-37582), and 6/17/2016 (81 FR 39630), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and/or service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):

MR 305—Melamine Dinner Plate
 MR 306—Melamine Fruit Plate
 MR 307—21oz Melamine Tumbler
 MR 308—Bamboo Placemat
 MR 1121—Bag, Storage, Vacuum Sealed, Club Pack
 MR 1130—4-Section Tray, Holiday, Melamine
 MR 1131—Serving Tray, Holiday, Melamine 18" x 13"
 MR 1132—Serving Bowl, Holiday, Melamine
 MR 1135—Set, Spreader, 4Pc
 MR 1150—Set, Mold, Cupcake, Red, Giant Cupcake, 3pc
 MR 1151—Set, Pan, Bake, Perfect Brownie Pan, 3pc
 MR 1152—Set, Pasta Cooker, Blue, Pasta Express, 7pc
 MR 1153—Basket, Cooking, Steel, Multipurpose
 MR 1155—Glove, Oven, Flexi
 MR 1156—Device, Cutting, Multi-Use, Green, Snip It
 MR 1157—Set, Knife and Peeler, Ceramic, Kitchen Samurai
 MR 1158—Set, Meatloaf Pan and Aerated Tray
 MR 1168—Carrier, Cake and Cupcake, Collapsible
 MR 1169—Set, Bowl and Lid, Blue, 4 Piece
Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI

Contracting Activity: Defense Commissary Agency

NSN(s)—Product Name(s):

MR 1053—Mop, Sponge, Triple Action
 MR 1083—Mop, Ratchet, Twist Action, Cotton
 MR 1084—Refill, Mop, Ratchet, Twist Action, Cotton

Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC

Contracting Activity: Defense Commissary Agency

NSN(s)—Product Name(s): 7045–01–599–5293—Privacy Filter, Netbooks, 10.1 Widescreen

Mandatory Source(s) of Supply: Wiscraft, Inc., Milwaukee, WI

Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7045–01–570–8906—Privacy Filter, Notebook, 12.1"
Mandatory Source(s) of Supply: Wiscraft,

Inc., Milwaukee, WI
Contracting Activities: Department of Veterans Affairs, National Acquisition Center, General Services Administration, New York, NY

NSN(s)—Product Name(s): 2510–01–063–3893—Floorboard, Wood

Mandatory Source(s) of Supply: UNKNOWN
Contracting Activity: Defense Logistics Agency Land and Maritime

NSN(s)—Product Name(s): 6530–01–505–0214—Bottle, Prescription, 200cc

Mandatory Source(s) of Supply: Alphapointe, Kansas City, MO

Contracting Activity: Department of Veterans Affairs

Services

Service Type: Switchboard Operation Service
Mandatory for: US Air Force, Patrick Air Force Base, Patrick AFB, FL

Mandatory Source(s) of Supply: Brevard Achievement Center, Inc., Rockledge, FL

Contracting Activity: Dept of the Air Force, FA2521 45 CONS LGC

Service Type: Switchboard Operation Service
Mandatory for: Keesler Air Force Base, Keesler AFB, MS

Mandatory Source(s) of Supply: Mississippi Goodworks, Inc., Gulfport, MS

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–16230 Filed 7–7–16; 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 a product and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete services previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: 8/7/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.
FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41

U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product

NSN(s)—Product Name(s): MR 753—Pillow, Jumbo.

Mandatory for: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4.

Mandatory Source(s) of Supply: Georgia Industries for the Blind, Bainbridge, GA.

Contracting Activity: Defense Commissary Agency.

Distribution: C-List.

Services

Service Type: Mailroom Operation Service.
Mandatory for: US Air Force, Postal Service Center, Tyndall Air Force Base, Tyndall Air Force, FL.

Mandatory Source(s) of Supply: VersAbility, Resources, Inc., Hampton, VA.

Contracting Activity: Dept of the Air Force, FA4890 ACC AMIC, Newport News, VA.

Service Type: Janitorial Service.

Mandatory for: USDA APHIS, Luis Munoz Marin Airport, Terminal A & D, Building C–2, Warehouse #3, 150 Central Sector, Carolina, PR.

Mandatory Source(s) of Supply: The Corporate Source, Inc., New York, NY.

Contracting Activity: Dept of Agriculture, USDA APHIS MRPBS, Animal and Plant Health Inspection Service, Minneapolis, MN.

Mandatory Source(s) of Supply: The Corporate Source, Inc., New York, NY.

Contracting Activity: Dept of Agriculture, USDA APHIS MRPBS, Animal and Plant Health Inspection Service, Minneapolis, MN.

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type: Order Processing Service.
Mandatory for: McGuire Air Force Base, McGuire AFB, NJ.

Mandatory Source(s) of Supply: Bestwork Industries for the Blind, Inc., Cherry Hill, NJ.

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK.

Service Type: Operation of Postal Service Center Service.

Mandatory for: Luke Air Force Base, Glendale, AZ.

Mandatory Source(s) of Supply: Arizona Industries for the Blind, Phoenix, AZ.

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK.

Service Type: Telephone Switchboard Operations Service.

Mandatory for: Barksdale Air Force Base, Shreveport, LA.

Mandatory Source(s) of Supply: Louisiana Association for the Blind, Shreveport, LA.

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK.

Service Type: Embroidery of USAF Service/ Name Tapes & Emboss of Plastic Name Tags.

Mandatory for: Lackland Air Force Base, TX.

Mandatory Source(s) of Supply: Delaware Division for the Visually Impaired, New Castle, DE.

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016-16229 Filed 7-7-16; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Draft Environmental Impact Statement for the East Campus Integration Program, Fort Meade, Maryland

AGENCY: Department of Defense.

ACTION: Notice of availability; notice of public meeting; request for comments.

SUMMARY: The Department of Defense (DoD) announces the availability of the Draft Environmental Impact Statement (EIS) as part of the environmental planning process for the East Campus Integration Program at Fort George G. Meade, Maryland (hereafter referred to as Fort Meade). The DoD proposes to continue to develop operational complex and headquarters space at the National Security Agency's (NSA) East Campus on Fort Meade for use by NSA and the Intelligence Community. The purpose of the Proposed Action is to provide facilities that are fully supportive of the Intelligence Community's function and to continue to integrate the East Campus with the NSA Main Campus. The need for the action is to meet mission requirements, both internally at the NSA and within the Intelligence Community.

This notice announces a 45-day comment period and provides information on how to participate in the public review process. The public comment period for the Draft EIS will officially end 45 days after publication of the Notice of Availability in the **Federal Register**.

DATES: There will be an open house at 4:30 p.m. followed by a public meeting from 5:00 p.m. to 7:00 p.m. on August 3, 2016. The public meeting may end

earlier or later than the stated time depending on the number of persons wishing to speak. All materials that are submitted in response to the Draft EIS should be received by August 22, 2016 to provide sufficient time to be considered in preparation of the Final EIS.

ADDRESSES: Copies of the Draft EIS are available for your review at the Medal of Honor Memorial Library, 4418 Llewellyn Avenue, Fort Meade, MD 20755; the Glen Burnie Regional Library, 1010 Eastway, Glen Burnie, MD 21060; the Odenton Regional Library, 1325 Annapolis Road, Odenton, MD 21113; and the Severn Library, 2624 Annapolis Road, Severn, Maryland 21144. You may also call 301-688-2970 or send an email to ECIPEIS@hdrinc.com to request a copy of the Draft EIS.

The open house and public meeting will be held at the Severn Library, 2624 Annapolis Road, Severn, Maryland 21144. Verbal and written comments will be accepted at the public meeting. You can also submit written comments to "East Campus Integration Program EIS" c/o HDR, 2600 Park Tower Drive, Suite 100, Vienna, VA 22180 or submit by email to ECIPEIS@hdrinc.com.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey Williams at 301-688-2970, or email jdwill2@nsa.gov.

SUPPLEMENTARY INFORMATION:

Background: The NSA is a tenant DoD agency on Fort Meade. NSA is a high-technology communications and data processing organization. In order to meet mission requirements, both at the NSA and within the Intelligence Community, continued integration of the East Campus with the NSA Main Campus on Fort Meade through development of office, operational, and headquarters space is needed. In 2010, NSA completed an EIS that addressed development of facilities on the East Campus. The Record of Decision for the 2010 EIS allowed for initiation of construction currently occurring in the southern portion of the East Campus. This East Campus Integration Program Draft EIS addresses build-out of the northern portion of the East Campus and the adjacent 9800 Troop Support Area, and integration of the East Campus with the NSA Main Campus.

Proposed Action and Alternatives: The East Campus Integration Program was initiated to provide a modern office, operational, and headquarters complex to meet the growth requirements of the NSA and Intelligence Community. Development is proposed along the East Campus central core extending through the NSA Main Campus at Fort Meade.

The Proposed Action consists of the construction of approximately 2,880,000 square feet of office, operational, and headquarters space supporting an increase of 7,200 people with the majority from local leases and government-owned buildings to the NSA Main Campus. The program also includes the demolition of approximately 1,900,000 square feet of buildings and infrastructure. Development would include associated infrastructure (e.g., electrical substation, emergency generator capacity providing 121 megawatts of electricity, life-safety generators, building heating systems, utilities, roads, sidewalks, stormwater management facilities, and parking facilities).

Alternatives identified include four options for emergency power generation and various pollution control systems, two options for building heating systems, four options for locations of parking facilities, and acquisition of additional space at two existing, offsite leased locations. Emergency power generation alternatives are generators and combined generators and combustion turbines. Building heating system alternatives are packaged boilers and a hybrid building heating system consisting of packaged boilers and ground source heat pumps. Parking facility alternatives consist of at least three of the following locations: East Campus Parking Structure 2, Bravo parking lot, N8/N9 parking lot, and Building 9817. Use of multi-level parking facilities were considered in lieu of surface parking. In conjunction with some construction and demolition on the East Campus, lease of space outside of Fort Meade at National Business Park and Annapolis Junction Business Park (Alternatives 1 and 2, respectively) were considered. The No Action Alternative (not undertaking the East Campus Integration Program) is also analyzed in detail.

Summary of Environmental Impacts: The level of environmental impacts potentially resulting from the Proposed Action and alternatives would primarily be dependent on the alternative ultimately selected. Environmental impacts would generally be slightly more adverse for the Proposed Action than for Alternatives 1 and 2 due to the larger building footprints and number of additional personnel associated with the Proposed Action, although facilities and personnel would be consolidated in one location under the Proposed Action.

Generally, construction and demolition would result in some ground disturbance and increased traffic congestion at intersections near the installation and proximal to the build

sites, which would be expected regardless of the alternative selected. Operation of the East Campus Integration Program would be expected to result in long-term, negligible to moderate impacts on land use, noise, air quality, geological resources, water resources, biological resources, infrastructure, sustainability, hazardous materials and waste, and socioeconomic resources. Major impacts on transportation (levels of service) would occur during operation; however, traffic impacts are considered major under the existing conditions as levels of service are already degraded.

Best Management Practices and Mitigation Measures: The Proposed Action has the potential to result in adverse environmental impacts. The Proposed Action includes best management practices, mitigation measures, and design concepts to avoid adverse impacts to the extent practicable. Unavoidable impacts would be minimized or compensated for to the extent practicable. In accordance with Council on Environmental Quality regulations, mitigation measures are considered for adverse environmental impacts.

Copies of the Draft EIS are available for public review at local repositories and by request (see **ADDRESSES**). The DoD invites public and agency input on the Draft EIS. Please submit comments and materials during the 45-day public review period to allow sufficient time for consideration in development of the Final EIS (see **DATES**).

The DoD will consider all comments received and then prepare the Final EIS. As with the Draft EIS, DoD will announce the availability of the Final EIS and once again give you an opportunity for review and comment.

Dated: July 5, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016-16175 Filed 7-7-16; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare an Integrated Feasibility/Environmental Impact Statement for the Proposed Tinian Harbor Modifications Project, Island of Tinian, Commonwealth of the Northern Mariana Islands

AGENCY: Department of the Army, U.S. Army Corps of Engineers (USACE), DoD.

ACTION: Notice of Intent.

SUMMARY: Pursuant to the section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969; the U.S. Army Corps of Engineers and the Commonwealth of the Northern Mariana Islands (CNMI), Municipality of Tinian (Municipality)/Commonwealth Ports Authority (CPA) gives notice that an Integrated Feasibility/Environmental Impact Statement (F/EIS) is being prepared for the Proposed Tinian Harbor Modifications Project, Island of Tinian, CNMI. This project is authorized under section 209 of the Rivers and Harbors Act of 1962 (Pub. L. 87-874) and will consider the implementation of navigation improvements at Tinian Harbor.

DATES: In order to be considered in the Draft F/EIS, comments and suggestions should be received within 30 days after the last public scoping meeting. Two public scoping meetings will be held in Saipan and Tinian in mid/late July 2016. A separate notice will be published for meeting times and places.

ADDRESSES: Mail written comments concerning this notice to: Mr. Milton Yoshimoto, Project Manager, Civil and Public Works Branch, Honolulu District, U.S. Army Corps of Engineers, Civil and Public Works Branch, Bldg 230, Fort Shafter, Hawaii 96858. Comment letters should include the commenter's physical mailing address and the project title in the subject line.

FOR FURTHER INFORMATION CONTACT: Mr. Milton Yoshimoto, Civil and Public Works Branch, Honolulu District, U.S. Army Corps of Engineers, Bldg 230, Fort Shafter, Hawaii 96858, (808) 835-4034, Email: milton.t.yoshimoto@usace.army.mil.

SUPPLEMENTARY INFORMATION: In accordance with NEPA, the Corps intends to prepare an F/EIS report. The primary Federal actions under consideration are: (1) Navigation improvement measures that expand the turning basin; (2) surge reduction measures by constructing protective structures at both harbors; and (3) dredging harbor sediments to allow larger vessels access to the harbor. The F/EIS reports shall meet the requirements of NEPA, including all applicable federal regulations implementing those statutes.

Evaluation will examine the costs and benefits of this project, as well as the environmental impacts of modifying the maintained dimensions of the existing harbor. The purpose of this effort is to conduct a study to assess the technical, environmental and economic feasibility

in the implementation of navigation improvement at Tinian Harbor.

Project Site and Background

Information: Tinian Harbor is the sole commercial harbor servicing the island of Tinian, CNMI and is owned and maintained by the CPA. Due to its isolation, the harbor is extremely important for the continual flow and transit of goods and materials for the small island community. The CNMI is threatened annually by typhoons and tropical storms which has resulted in the deterioration of the protective breakwater and harbor facilities. Failure of the breakwater would result in complete closure of the harbor, requiring costly air transport as the only remaining option to deliver essential commodities to the island. The project will focus on the repair/reconfiguration of the breakwater and an incremental analysis of the harbor depth to assure safe and efficient operation of commercial vessels.

Proposed Action(s): The study reports will assess the technical, environmental and economic feasibility in the implementation of navigation improvement. These include: (1) Navigation improvement measures that expand the federal turning basin; (2) surge reduction measures by constructing protective structures; and (3) expand and deepen the harbor basin and entrance channel to accommodate larger vessels by dredging.

Issues: Potentially significant issues associated with the project may include: aesthetics/visual impacts, air quality emissions, biological resource impacts, environmental justice, hazards and hazardous materials, hydrology and water quality, noise, traffic and transportation, and cumulative impacts from past, present, and reasonably foreseeable future projects.

Scoping Process: The U.S. Army Corps of Engineers is seeking participation and input of all interested federal, state, and local agencies, Native American groups, and other concerned private organizations or individuals on the scope of the F/EIS through this public notice. The purpose of the public scoping meeting is to solicit comments regarding the potential impacts, environmental issues, and alternatives associated with the proposed action to be considered in the study report. The meeting place, date, and time will be advertised in advance in local newspapers, and meeting announcement letters will be sent to interested parties. The draft F/EIS is expected to be available for public review and comment in the summer of 2017 and a public meeting will be held after its publication.

Dated: July 1, 2016.

Christopher W. Crary,
Lieutenant Colonel, U.S. Army, District
Engineer.

[FR Doc. 2016-16188 Filed 7-7-16; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare an Integrated Feasibility/Environmental Impact Statement for the Proposed Rota Harbor Modifications Project, Island of Rota, Commonwealth of the Northern Mariana Islands

AGENCY: Department of the Army, U.S. Army Corps of Engineers (USACE), DoD.

ACTION: Notice of intent.

SUMMARY: Pursuant to the section 102(2)(C) of National Environmental Policy Act (NEPA) of 1969; the U.S. Army Corps of Engineers and the Commonwealth of the Northern Mariana Islands (CMNI), Municipality of Rota (Municipality)/Commonwealth Ports Authority (CPA) gives notice that an Integrated Feasibility/Environmental Impact Statement (F/EIS) report is being prepared for the Proposed Rota Harbor Modifications Project, Island of Rota, CNMI. This project is authorized under section 209 of the Rivers and Harbors Act of 1962 (Pub. L. 87-874) and will consider the implementation of navigation improvements at Rota Harbor.

DATES: In order to be considered in the Draft F/EIS, comments and suggestions should be received within 30 days after the last public scoping meeting. Two public scoping meetings will be held in Saipan and Rota in mid/late July 2016. A separate notice will be published for meeting times and places.

ADDRESSES: Mail written comments concerning this notice to: Mr. Milton Yoshimoto, Project Manager, Civil and Public Works Branch, Honolulu District, U.S. Army Corps of Engineers, Bldg. 230, Fort Shafter, Hawaii 96858. Comment letters should include the commenter's physical mailing address and the project title in the subject line.

FOR FURTHER INFORMATION CONTACT: Mr. Milton Yoshimoto, Project Manager, Civil and Public Works Branch, Honolulu District, U.S. Army Corps of Engineers, Bldg. 230, Fort Shafter, Hawaii 96858, (808) 835-4034, E-Mail: milton.t.yoshimoto@usace.army.mil.

SUPPLEMENTARY INFORMATION: In accordance with NEPA, the Corps

intends to prepare an F/EIS report. The primary Federal actions under consideration are: (1) Navigation improvement measures that expand the federal turning basin; (2) surge reduction measures by constructing protective structures at both harbors; and (3) expand and deepen the harbor basin and entrance channel to accommodate larger vessels by dredging. The F/EIS reports shall meet the requirements of NEPA, including all applicable federal regulations implementing those statutes.

Evaluation will examine the costs and benefits of this project, as well as the environmental impacts of modifying the maintained dimensions of the existing Federal project within its authorized limits. The purpose of this effort is to conduct a study to assess the technical, environmental, and economic feasibility in the implementation of navigation improvement at Rota Harbor.

Project Site and Background Information: Since its construction in 1985, users of the Rota West Harbor have experienced problems with navigation within the entrance channel and with vessels docked at the piers attributable to adverse wave conditions and the current harbor configuration. As recently as late 2013, there have been periods when the harbor has shut down and cargo flown to the island at a considerable cost to the island residents. The project will evaluate wave action within the harbor and identify modifications to general navigations features to improve operating inefficiency and safe navigation and address the need to expand the harbor basin to accommodate larger vessels.

Proposed Action(s): The study reports will assess the technical, environmental and economic feasibility in the implementation of navigation improvement. These include: (1) Navigation improvement measures that expand the federal turning basin; (2) surge reduction measures by constructing protective structures; and (3) dredging harbor sediments to allow larger vessels access to the harbor.

Issues: Potentially significant issues associated with the project may include: aesthetics/visual impacts, air quality emissions, biological resource impacts, environmental justice, hazards and hazardous materials, hydrology and water quality, noise, traffic and transportation, and cumulative impacts from past, present and reasonably foreseeable future projects.

Scoping Process: The U.S. Army Corps of Engineers is seeking participation and input of all interested federal, state, and local agencies, Native American groups, and other concerned

private organizations or individuals on the scope of the F/EIS through this public notice. The purpose of the public scoping meeting is to solicit comments regarding the potential impacts, environmental issues, and alternatives associated with the proposed action to be considered in the study report. The meeting place, date, and time will be advertised in advance in local newspapers, and meeting announcement letters will be sent to interested parties. The draft F/EIS report is expected to be available for public review and comment in the summer of 2017 and a public meeting will be held after its publication.

Dated: July 1, 2016.

Christopher W. Crary,
Lieutenant Colonel, U.S. Army, District
Engineer.

[FR Doc. 2016-16189 Filed 7-7-16; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0081]

Agency Information Collection Activities; Comment Request; Program for the International Assessment of Adult Competencies (PIAAC) 2017 National Supplement

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0081. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the

Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-347, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at NCES.Information.Collections@ed.gov.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Program for the International Assessment of Adult Competencies (PIAAC) 2017 National Supplement.

OMB Control Number: 1850-0870.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Responses: 12,626.

Total Estimated Number of Annual Burden Hours: 3,960.

Abstract: The Program for the International Assessment of Adult Competencies (PIAAC) is a cyclical, large-scale study of adult skills and life experiences focusing on education and employment, designed internationally to assess adults in different countries over a broad range of abilities, from simple reading to complex problem-

solving skills, and to collect information on individuals' skill use and background. In the United States, PIAAC is conducted by the National Center for Education Statistics (NCES). PIAAC defines four core competency domains of adult cognitive skills seen as key to facilitating the social and economic participation of adults in advanced economies: Literacy, reading components, numeracy, and problem solving in technology-rich environments. PIAAC also surveys adults on their education background, work history, the skills they use on the job and at home, their civic engagement, and sense of their health and well-being. The results are used to compare participating countries on the skills capacities of their workforce-aged adults and to learn more about relationships between educational background, employment, and other outcomes. PIAAC is coordinated by the Organization for Economic Cooperation and Development (OECD) and developed by participating countries with the support of the OECD. U.S. participated in the PIAAC Main Study data collection in 2012, conducted a national supplement in 2014, and in this submission requests to conduct the PIAAC 2017 National Supplement data collection from February to September 2017 with a nationally representative sample of 3,800 adults ages 16-74, in a new sample of 80 primary sampling units (PSUs).

Dated: July 5, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016-16224 Filed 7-7-16; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0034]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Study of the Title III Native American and Alaska Native Children in School (NAM) Program

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before August 8, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0034. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-347, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Joanne Bogart, 202-205-7855.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Study of the title III Native American and Alaska Native Children in School (NAM) Program.

OMB Control Number: 1875—New.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 499.

Total Estimated Number of Annual Burden Hours: 505.

Abstract: The NAM Program seeks to improve academic outcomes in English for Native American and Alaska Native (NA/AN) students, providing funding for programs that support language instruction educational programs, including NA/AN language and culture revitalization. The goal of this study is to describe how 22 current grantees have used the NAM Program to support NA/AN students. Results will help the Department structure future funding rounds and better support current and future grantees.

Dated: July 5, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016-16223 Filed 7-7-16; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0083]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Magnet Schools Assistance Program Application for Grants (1894-0001)

AGENCY: Office of Innovation and Improvement (OII), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 8, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0083. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the

Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-349, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Justis Tuia, 202-453-6654.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Magnet Schools Assistance Program Application for Grants (1894-0001).

OMB Control Number: 1855-0011.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 150.

Total Estimated Number of Annual Burden Hours: 6,000.

Abstract: The Magnet Schools Assistance program provides grants to eligible local educational agencies to

establish and operate magnet schools that are operated under a court-ordered or federally approved voluntary desegregation plan. These grants assist in the desegregation of public schools by supporting the elimination, reduction, and prevention of minority group isolation in elementary and secondary schools with substantial numbers of minority group students. In order to meet the statutory purposes of the program under title V of the Elementary and Secondary Education Act, projects also must support the development and implementation of magnet schools that assist in the achievement of systemic reforms and provide all students with the opportunity to meet challenging academic content and student academic achievement standards. Projects support the development and design of innovative education methods and practices that promote diversity and increase choices in public education programs. The program supports capacity development the ability of a school to help all its students meet more challenging standards through professional development and other activities that will enable the continued operation of the magnet schools at a high performance level after funding ends. Finally, the program supports the implementation of courses of instruction in magnet schools that strengthen students knowledge of academic subjects and their grasp of tangible and marketable vocational skills.

Dated: July 5, 2016.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016-16217 Filed 7-7-16; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0080]

Agency Information Collection Activities; Comment Request; IES Research Training Program Surveys

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0080. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-347, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Meredith Larson, 202-219-2025.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: IES Research Training Program Surveys.
OMB Control Number: 1850-0873.
Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Responses: 580.

Total Estimated Number of Annual Burden Hours: 547.

Abstract: The surveys are for participants in the fellowship research training programs and the non-fellowship research training programs funded by Institute of Education Sciences (IES). IES's fellowship programs include predoctoral training under the National Center for Education Research (NCER) and postdoctoral training under NCER and the National Center for Special Education Research (NCSEER). These programs provide universities support to provide training in education research and special education research to graduate students (predoctoral program) and postdoctoral fellows. IES also supports non-fellowship research training through its current programs, e.g., NCER's Methods Research Training program and NCER's Undergraduate Pathways program. IES would like to collect satisfaction information from the participants in these programs and other similar training programs funded through NCER or NCSEER grant programs. The results of the surveys will be used both to improve the training programs as well as to provide information on the programs to the participants, policymakers, practitioners, and the general public. All information released to the public will be in aggregate so that no one program or training group can be distinguished.

Dated: July 5, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016-16180 Filed 7-7-16; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0082]

Agency Information Collection Activities; Comment Request; Native American Career and Technical Education Program (NACTEP) Performance Reports

AGENCY: Office of Career, Technical, and Adult Education (OCTAE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0082. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-349, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Braden Goetz, 202-245-7405.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Native American Career and Technical Education

Program (NACTEP) Performance Reports.

OMB Control Number: 1830–0573.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 30.

Total Estimated Number of Annual Burden Hours: 1,200.

Abstract: The Native American Career and Technical Education Program (NACTEP) is requesting an extension to collect semi-annual, annual/continuation reports, and final performance reports from currently funded NACTEP grantees. This information is necessary to (1) manage and monitor the current NACTEP grantees, and (2) award continuation grants for years four and five of the grantees' performance periods. The continuation performance reports will include budgets, performance/statistical reports, GPRA reports, and evaluation reports. The data, collected from the performance reports, will be used to determine if the grantees successfully met their project goals and objectives, so that NACTEP staff can award continuation grants. Final performance reports are required to determine whether or not the grant can be closed out in compliance with the grant's requirements.

Dated: July 5, 2016.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–16218 Filed 7–7–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14786–000]

Owyhee Hydro LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 30, 2016, Owyhee Hydro LLC filed a revised application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Owyhee Pumped Storage Project (Owyhee Project or project) to be located on Lake Owyhee near Adrian in Malheur County, Oregon. The sole purpose of a preliminary permit, if issued, is to grant the permit holder

priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A new 1,200-foot-long zoned earth and rockfill or concrete-face rockfill dam forming a lined upper reservoir with a surface area of 109 acres and a storage capacity of 4,035 acre-feet at a maximum surface elevation of 4,320 feet mean sea level (msl); (2) an existing 833 foot-long concrete arch dam forming the existing Lake Owyhee (lower reservoir) with a surface area of 13,900 acres and a storage capacity of 1,120,000 acre-feet at a maximum surface elevation of 2,650 msl; (3) a new 14,100 foot-long conduit connecting the upper and lower reservoirs consisting of a 2,200 foot-long, 17.1 foot-diameter concrete lined low-pressure tunnel, a 7,100 foot-long, 17.1 foot-diameter concrete and steel-lined pressure shaft, and a 4,800-foot-long, 20.5 foot-diameter concrete-lined tailrace; (4) a new 80 feet long by 280 feet wide by 120 feet high powerhouse containing four reversible pump-turbine units rated at 125 megawatts (MW) each for a total capacity of 500 MW; (5) either 2.6 or 8 miles of 500-kilovolt transmission line interconnecting with the Boardman-Hemingway Line, depending on design of infrastructure; and (6) appurtenant facilities. The estimated annual generation of the Owyhee Project would be 1,533,000 megawatt-hours.

Applicant Contact: Mr. Matthew Shapiro, CEO, Gridflex Energy, LLC, 1210 W. Franklin St., Ste. 2, Boise, Idaho 83702; phone: (208) 246–9925.

FERC Contact: Julia Kolberg; phone: (202) 502–8261.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at

FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14786–000.

More information about this project, including a copy of the application, can be viewed or printed on the “eLibrary” link of Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P–14786) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: July 1, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016–16166 Filed 7–7–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at the Southwest Power Pool Markets and Operations Policy Committee Meeting

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meeting of the Southwest Power Pool, Inc. Markets and Operations Policy Committee as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

The meeting will be held on July 12, 2016 from 8:00 a.m. to 5:00 p.m. and July 13, 2016 from 8:00 a.m. to 3:00 p.m. Mountain Time. The location of the meeting is at the Rushmore Plaza Holiday Inn, 505 North Fifth St., Rapid City, SD 57701. The hotel phone number is (605) 348–4000.

The discussions may address matters at issue in the following proceedings:

- Docket No. ER11–1844, *Midcontinent Independent System Operator, Inc.*
- Docket No. EL12–60, *Southwest Power Pool, Inc., et al.*
- Docket No. ER12–959, *Southwest Power Pool, Inc.*
- Docket No. ER12–1179, *Southwest Power Pool, Inc.*
- Docket No. ER12–1586, *Southwest Power Pool, Inc.*
- Docket No. EL15–66, *Southern Company Services, et al. v. Midcontinent Independent System Operator, Inc.*
- Docket No. EL15–77, *Morgan Stanley Capital Group Inc. v. Midcontinent Independent System Operator, Inc.*

Docket No. ER14-1183, *Southwestern Electric Power Company*

Docket No. ER14-2445, *Midcontinent Independent System Operator, Inc.*

Docket No. ER14-2850, *Southwest Power Pool, Inc.*

Docket No. ER15-1499, *Southwest Power Pool, Inc.*

Docket No. ER15-1775, *Southwest Power Pool, Inc.*

Docket No. ER15-1777, *Southwest Power Pool, Inc.*

Docket No. ER15-1943, *Southwest Power Pool, Inc.*

Docket No. ER15-1976, *Southwest Power Pool, Inc.*

Docket No. ER15-2028, *Southwest Power Pool, Inc.*

Docket No. ER15-2069, *Northwestern Corporation*

Docket No. ER15-2115, *Southwest Power Pool, Inc.*

Docket No. ER15-2265, *Southwest Power Pool, Inc.*

Docket No. ER15-2324, *Southwest Power Pool, Inc.*

Docket No. ER15-2347, *Southwest Power Pool, Inc.*

Docket No. ER15-2351, *Southwest Power Pool, Inc.*

Docket No. ER15-2356, *Southwest Power Pool, Inc.*

Docket No. EC16-53, *South Central MCN, LLC*

Docket No. EL16-20, *Grid Assurance LLC*

Docket No. EL16-70, *Cottonwood Wind Project, LLC v. Nebraska Public Power District*

Docket No. ER16-13, *Southwest Power Pool, Inc.*

Docket No. ER16-204, *Southwest Power Pool, Inc.*

Docket No. ER16-209, *Southwest Power Pool, Inc.*

Docket No. ER16-228, *Southwest Power Pool, Inc.*

Docket No. ER16-791, *Southwest Power Pool, Inc.*

Docket No. ER16-829, *Southwest Power Pool, Inc.*

Docket No. ER16-846, *Southwest Power Pool, Inc.*

Docket No. ER16-862, *Southwest Power Pool, Inc.*

Docket No. ER16-863, *Southwest Power Pool, Inc.*

Docket No. ER16-932, *Southwest Power Pool, Inc.*

Docket No. ER16-1086, *Southwest Power Pool, Inc.*

Docket No. ER16-1211, *Midcontinent Independent System Operator, Inc.*

Docket No. ER16-1286, *Southwest Power Pool, Inc.*

Docket No. ER16-1305, *Southwest Power Pool, Inc.*

Docket No. ER16-1351, *Westar Energy, Inc.*

Docket No. ER16-1355, *Westar Energy, Inc.*

Docket No. ER16-1314, *Southwest Power Pool, Inc.*

Docket No. ER16-1341, *Southwest Power Pool, Inc.*

Docket No. ER16-1544, *Southwest Power Pool, Inc.*

Docket No. ER16-1546, *Southwest Power Pool, Inc.*

Docket No. ER16-1605, *Southwestern Electric Power Company*

Docket No. ER16-1618, *Southwest Power Pool, Inc.*

Docket No. ER16-1676, *Southwest Power Pool, Inc.*

Docket No. ER16-1709, *Southwest Power Pool, Inc.*

Docket No. ER16-1710, *Southwest Power Pool, Inc.*

Docket No. ER16-1711, *Southwest Power Pool, Inc.*

Docket No. ER16-1712, *Southwest Power Pool, Inc.*

Docket No. ER16-1713, *Southwest Power Pool, Inc.*

Docket No. ER16-1715, *Southwest Power Pool, Inc.*

Docket No. ER16-1772, *Public Service Company of Colorado*

Docket No. ER16-1774, *Southwest Power Pool, Inc.*

Docket No. ER16-1797, *Midcontinent Independent System Operator, Inc.*

Docket No. ER16-1799, *Southwest Power Pool, Inc.*

Docket No. ER16-1812, *Southwestern Electric Power Company*

Docket No. ER16-1814, *Southwest Power Pool, Inc.*

Docket No. ER16-1826, *Southwest Power Pool, Inc.*

Docket No. ER16-1905, *Southwest Power Pool, Inc.*

Docket No. ER16-1912, *Southwest Power Pool, Inc.*

Docket No. ER16-1945, *Southwest Power Pool, Inc.*

Docket No. ER16-1951, *Southwest Power Pool, Inc.*

Docket No. ER16-1959, *Southwest Power Pool, Inc.*

Docket No. ER16-1989, *Southwest Power Pool, Inc.*

These meetings are open to the public. For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249-5937 or patrick.clarey@ferc.gov.

Dated: July 1, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016-16164 Filed 7-7-16; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Notice of Commission Staff Attendance**

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the New York Independent System Operator, Inc.

The New York Independent System Operator, Inc. Electric System Planning Working Group Meeting

July 5, 2016, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2016-07-05.

The New York Independent System Operator, Inc. Business Issues Committee Meeting

July 13, 2016, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: <http://www.nyiso.com/public/committees/documents.jsp?com=bic&directory=2016-07-13>.

The New York Independent System Operator, Inc. Operating Committee Meeting

July 14, 2016, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: <http://www.nyiso.com/public/committees/documents.jsp?com=oc&directory=2016-07-14>.

The New York Independent System Operator, Inc. Electric System Planning Working Group Meeting

July 26, 2016, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2016-07-26.

The New York Independent System Operator, Inc. Management Committee Meeting

July 27, 2016, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: <http://www.nyiso.com/public/committees/documents.jsp?com=mc&directory=2016-07-27>.

The discussions at the meetings described above may address matters at issue in the following proceedings:

New York Independent System Operator, Inc., Docket No. ER13–102.

New York Independent System Operator, Inc., Docket No. ER15–2059.

New York Independent System Operator, Inc., Docket No. ER13–1942.

New York Transco, LLC, Docket No. ER15–572.

New York Independent System Operator, Inc., Docket No. ER16–966.

New York Independent System Operator, Inc., Docket No. ER16–1968.

Boundless Energy NE, LLC, CityGreen Transmission, Inc., and Miller Bros. v. New York Independent System Operator, Inc., Docket No. EL16–84.

New York Independent System Operator, Inc., Docket No. ER16–1785.

For more information, contact James Eason, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–8622 or James.Eason@ferc.gov.

Dated: June 30, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016–16163 Filed 7–7–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14787–000]

Black Canyon Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 13, 2016, the Black Canyon Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Seminole Pumped Storage Project (project) to be located at the U.S. Bureau of Reclamation's (Reclamation) Seminole Reservoir on the North Platte River, near Rawlins, Carbon County, Wyoming. The project would occupy lands managed by the U.S. Bureau of Reclamation and the U.S. Bureau of Land Management. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) Two new intake structures located in Reclamation's 20,291-acre Seminole Reservoir; (2) two new concrete-faced, rock-fill upper reservoirs—one 85 acres and one 63 acres—located on either side of, and about 1,000 feet above, Seminole Reservoir; (3) a 3,000-foot-long, 18.8-foot diameter, low pressure tunnel and 1,250-foot-long, 18.8-foot-diameter, pressure shaft leading to a 250-foot-long, 65-foot-wide, 170-foot-high powerhouse located 1,300 feet east of Seminole Reservoir in an underground cavern with a 2,800-foot-long access tunnel and a 1,300-foot-long, 22.6-foot wide tailrace; (5) a 1,300-foot-long, 22.6-foot-diameter, low pressure tunnel and 1,800-foot-long, 16.1-foot-diameter pressure shaft leading to a 220-foot-long, 55-foot-wide, 120-foot-high powerhouse located 2,800 feet north-northwest of Seminole reservoir in an underground cavern with a 800-foot-long access tunnel and a 2,800-foot-long, 19.3-foot-diameter tailrace; (6) three 133.3-megawatt (MW) adjustable-speed, reversible pump turbines in the east powerhouse; and (7) three 100-MW adjustable-speed reversible pump-turbines in the west powerhouse. The project would also include a double-circuit, 230-kilovolt (kV) transmission line connecting either at PacifiCorp's

planned Aeolus Substation located northwest of Medicine Bow, Wyoming, or the planned northern terminal for the TransWest Express DC Line near Sinclair, Wyoming. If the Aeolus interconnection alternative is built, the line would parallel the existing Western Area Power Administration's (WAPA) Miracle Mile-Cheyenne-Ault 230-kV transmission line. If the TransWest interconnection alternative is built, the line would parallel or consist of a rebuild of the existing WAPA Miracle Mile-Sinclair, 115 kV transmission line. The estimated annual generation would be 1,839,600 MW-hours.

Applicant Contact: Mr. Matthew Shapiro, Chief Executive Officer, Gridflex Energy, LLC, 1210 W. Franklin Street, Suite 2, Boise, ID 83702, phone: (208) 246–9925.

FERC Contact: Suzanne Novak; phone: (202) 502–6665.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14787–000.

More information about this project, including a copy of the application, can be viewed or printed on the “eLibrary” link of Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P–14787) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: June 30, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016–16167 Filed 7–7–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. ER16-2071-000]

Innovative Solar 43, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Innovative Solar 43, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 20, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC

Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: June 30, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016-16241 Filed 7-7-16; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 13755-002]

FFP Missouri 12, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 Code of Federal Regulations part 380, Office of Energy Projects staff has reviewed the application for original license for the Allegheny Lock and Dam 2 Hydroelectric Project (FERC No. 13755-002) on the Allegheny River.

The Allegheny Lock and Dam 2 Hydroelectric Project would be located at an existing lock and dam owned by the U.S. Army Corps of Engineers on the Allegheny River between the boroughs of Sharpsburg and Aspinwall, Pennsylvania, in Allegheny County at river mile 6.7. The project would occupy 3.23 acres of federal land.

Staff has prepared this environmental assessment (EA) that analyzes the potential environmental effects of the project and concludes that constructing and operating the project, with appropriate environmental protection measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at www.ferc.gov using the "eLibrary" link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects.

For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, 202-502-8659. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include: "Allegheny Lock and Dam 2 Hydroelectric Project No. 13755-002."

For further information, contact Nicholas Ettema at (202) 502-6565 or by email at nicholas.ettema@ferc.gov.

Dated: June 30, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016-16165 Filed 7-7-16; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP16-4-000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Schedule for Environmental Review of the Orion Project

On October 9, 2015, Tennessee Gas Pipeline Company, L.L.C. (Tennessee) filed an application in Docket No. CP16-4-000 requesting a Certificate of Public Convenience and Necessity pursuant to section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed project is known as the Orion Project (Project), and would deliver an additional 135,000 dekatherms per day of natural gas to meet needs of three contracted shippers in the northeast United States.

On October 26, 2015, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's

planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA—August 23, 2016.

90-day Federal Authorization Decision Deadline—November 21, 2016.

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Tennessee proposes to construct and operate pipeline facilities, modify existing aboveground facilities, and add new tie-in facilities in Wayne and Pike Counties, Pennsylvania.

The Project would consist of the following facilities:

- Approximately 12.9 miles of new 36-inch-diameter looping¹ pipeline in Wayne and Pike Counties, Pennsylvania;
- a new internal pipeline inspection ("pig")² launcher, crossover, and connecting facilities at the beginning of the proposed pipeline loop in Wayne County;
- a new pig receiver, crossover, and connecting facilities at the end of the proposed pipeline loop in Pike County; and
- modifications at Tennessee's existing Compressor Station 323, including rewheeling/restaging of an existing compressor and other piping and appurtenant modifications.

Background

On November 23, 2015, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Orion Project and Request for Comments on Environmental Issues* (NOI). On December 3, 2015, the Commission issued a supplemental NOI extending the scoping period for the Project. The NOI and supplemental NOI were sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOIs, the Commission received comments from the National Park Service and several individuals. The comments primarily concerned impacts on water resources, land use, recreation, air quality, and reliability and safety.

¹ A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

² A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

The U.S. Army Corps of Engineers is a cooperating agency in the preparation of the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to www.ferc.gov/docs-filing/esubscription.asp.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208-FERC or on the FERC Web site (www.ferc.gov). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (*i.e.*, CP16-4), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208-3676, TTY (202) 502-8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: June 30, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016-16168 Filed 7-7-16; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9027-9]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7146 or <http://www.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EISs) Filed 06/27/2016 Through 07/01/2016 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <http://www.epa.gov/compliance/nepa/eisdata.html>.

EIS No. 20160148, Final, USACE, NC, Figure Eight Island Shoreline

Management Project, Review Period Ends: 08/08/2016, Contact: Mickey Sugg 910-251-4811.

EIS No. 20160149, Final, BIA, FL, Seminole Tribe of Florida Fee to Trust, Review Period Ends: 08/08/2016, Contact: Chester McGhee 615-564-6830.

EIS No. 20160150, Final Supplement, NIGC, CA, Jamul Indian Village, Review Period Ends: 08/08/2016, Contact: Andrew Mendoza 202-634-0012.

EIS No. 20160151, Final, BLM, CO, Bull Mountain Unit Master Development Plan, Review Period Ends: 08/08/2016, Contact: Gina Jones 970-240-5300.

EIS No. 20160152, Draft, USFS, NM, Santa Fe National Forest Geothermal Leasing, Comment Period Ends: 08/22/2016, Contact: Larry Gore 575-289-3264.

Amended Notices

EIS No. 20160128, Final, USACE, NC, Morehead City Harbor Integrated Dredged Material Management Plan, Review Period Ends: 08/11/2016, Contact: Jennifer Owens 910-251-4757.

Revision to FR Notice Published 06/10/2016; Extending Review Period from 07/11/2016 to 08/11/2016.

Dated: July 1, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016-16310 Filed 7-7-16; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2016-0289; FRL-9948-75-OAR]

Draft Guidance on Progress Tracking Metrics, Long-Term Strategies, Reasonable Progress Goals and Other Requirements for Regional Haze State Implementation Plans for the Second Implementation Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and public comment period.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has posted on its Web site a draft guidance document titled, "Draft Guidance on Progress Tracking Metrics, Long-Term Strategies, Reasonable Progress Goals and Other Requirements for Regional Haze State Implementation Plans for the Second Implementation

Period.” The EPA invites the public to review and provide input on its draft guidance document during the comment period specified in the **DATES** section.

DATES: Comments must be received on or before August 22, 2016. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2016-0289, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this draft guidance document, please contact Phil Lorang, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539-04, Research Triangle Park, NC 27711, telephone (919) 541-5463, email at lorang.phil@epa.gov. For questions about section 5 of this draft guidance document, please contact Melinda Beaver, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539-04, Research Triangle Park, NC 27711, telephone (919) 541-1062, email at beaver.melinda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose

The purpose of the draft document on which the EPA is inviting public comment is to provide useful background information and guidance to states on how to develop and submit regional haze state implementation plans (SIPs) for the second implementation period (2018–2028), which under a proposed revision to the

Regional Haze Rule published on May 4, 2016,¹ would be due by July 31, 2021. The required content of these SIPs is specified in 40 CFR 51.308(f), which has also been proposed for revision.²

II. Instructions for Submitting Public Comments and Internet Web Site for Guidance Document Information

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

1. *Submitting CBI.* Do not submit this information to the EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Tiffany Purifoy, OAQPS CBI Officer, U.S. EPA, Office of Air Quality Planning and Standards, Mail Code C404-02, Research Triangle Park, NC 27711, telephone (919) 541-0878, email at purifoy.tiffany@epa.gov, Attention Docket ID No. EPA-HQ-OAR-2016-0289.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the draft guidance by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

B. Where can I find additional information for this draft guidance?

The EPA has also established a Web site for this draft guidance at <https://www.epa.gov/visibility>. From this page, please click on “Guidance Documents.”

¹ Protection of Visibility: Amendments to Requirements for State Plans: Proposed Rule, May 4, 2016, 81 FR 26942.

² For clarity for purposes of comment, the draft guidance document available for public comment is written as if the revisions of the Regional Haze Rule proposed in May 2016 have been finalized as proposed. If the final revisions to the Regional Haze Rule differ from this assumption, corresponding changes will be made in the final guidance document.

The Web site provides related information that the public may find useful.

Dated: June 30, 2016.

Stephen Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2016-16131 Filed 7-7-16; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination; 10293, Haven Trust Bank Florida, Ponte Vedra Beach, Florida

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10293, Haven Trust Bank Florida, Ponte Vedra Beach, Florida (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Haven Trust Bank Florida (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective July 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: July 5, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016-16202 Filed 7-7-16; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATES AND TIMES: Tuesday, July 12, 2016 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 52 U.S.C. 30109. Matters concerning participation in civil actions or proceeding, or arbitration. Information the premature disclosure of

which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

PERSON TO CONTACT FOR INFORMATION:

Judith Ingram, Press Officer; Telephone: (202) 694-1220.

Shawn Woodhead Werth,

Commission Secretary and Clerk.

[FR Doc. 2016-16268 Filed 7-6-16; 11:15 am]

BILLING CODE 6715-01-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 applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 4, 2016.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528. Comments can also be sent electronically to

Comments.applications@rich.frb.org:

1. *BNC Bancorp*, High Point, North Carolina; to acquire 100 percent of the voting shares of High Point Bank Corporation, High Point, North Carolina, and thereby indirectly acquire High

Point Bank and Trust Company, High Point, North Carolina.

Board of Governors of the Federal Reserve System, July 5, 2016.

Margaret Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016-16255 Filed 7-7-16; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10137, CMS-10237 and CMS-379]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 6, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10137 Solicitation for Applications for Medicare Prescription Drug Plan 2018 Contracts
 CMS-10237 Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits
 CMS-379 Financial Statement of Debtor

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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Solicitation for Applications for Medicare Prescription Drug Plan 2018 Contracts; **Use:** Coverage for the prescription drug benefit is provided through contracted prescription drug (PD) plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under section 1876 of the Social Security Act, and Employer Group Waiver Plans may also provide a part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing part D Sponsors may also expand their contracted service area by completing the Service Area Expansion application. **Form Number:** CMS-10137 (OMB control number: 0938-0936); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other For-profits and Not-for-profit institutions); **Number of Respondents:** 463; **Total Annual Responses:** 160; **Total Annual Hours:** 1,565. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715.)

2. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Applications for part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide part C Benefits; **Use:** This information collection includes the process for organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application annually, file a bid, and receive final approval from CMS. The application process has two options for applicants that include: Request for new MA product or request for expanding the service area of an existing product. This collection process is the only mechanism for MA and/or MA-PD organizations to complete the required application process. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the Medicare Advantage program and to make a decision related to contract award. **Form Number:** CMS-10237 (OMB control number: 0938-0935); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other For-

profits and Not-for-profit institutions); **Number of Respondents:** 310; **Total Annual Responses:** 310; **Total Annual Hours:** 10,941. (For policy questions regarding this collection contact Marcella Watts at 410-786-5724.)

3. Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** Financial Statement of Debtor; **Use:** Section 1893(f)(1) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. In addition, the DOJ Final Rule, the Federal Claims Collection Standards, which was published as 32 CFR parts 900-904, on November 22, 2000, in the **Federal Register**, section 32 CFR 900.1 stipulates that, standards for Federal agency use in the administrative collection, offset, compromise, and the suspension or termination of collection activity. Section 32 CFR 901.8(a) states that, Agencies should obtain financial statements from debtors who represent that they are unable to pay the debt in one lump sum. **Form Number:** CMS-379 (OMB control number: 0938-0270); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other for-profits); **Number of Respondents:** 500; **Total Annual Responses:** 500; **Total Annual Hours:** 1,000. (For policy questions regarding this collection contact Anita Crosier at 410-786-0217.)

Dated: July 5, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-16220 Filed 7-7-16; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1233]

Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing-Based In Vitro Diagnostics; Draft Guidance for Stakeholders and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of the draft guidance entitled “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics.” This draft guidance document describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA’s regulatory review of next generation sequencing (NGS)-based tests. This draft guidance further outlines the process by which administrators of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 6, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-1233 for “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Personalized Medicine Staff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4546, Silver Spring, MD 20993-0002, 301-796-7561, pmi@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document describes one part of FDA’s effort to create a flexible regulatory approach to the oversight of NGS-based tests as part of the White House’s Precision Medicine Initiative (PMI). FDA held two workshops on this issue: “Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants” on November 13, 2015, and “Patient and Medical Professional Perspectives on the Return of Genetic Test Results” on March 2, 2016. The goal of this effort is to help ensure patients receive accurate and meaningful results, while

promoting innovation in test development. This draft guidance document describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA’s regulatory review of NGS-based tests. FDA is also issuing a draft guidance entitled “Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases” which is being released concurrently elsewhere in this issue of the **Federal Register**.

NGS can enable rapid, broad, and deep sequencing of a portion of a gene, entire exome(s), or a whole genome and may be used clinically for a variety of diagnostic purposes, including risk prediction, diagnosis, and treatment selection for a disease or condition. The rapid adoption of NGS-based tests in both research and clinical practice is leading to identification of an increasing number of genetic variants (e.g., pathogenic, benign, and of unknown significance), including rare variants that may be unique to a single individual or family. This draft guidance document describes FDA’s considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. This draft guidance further outlines the process by which administrators of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> and for Center for Biologics Evaluation and Research guidance documents is available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16008 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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.

Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics OMB Control Number 0910—NEW

The draft guidance document “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-

Based In Vitro Diagnostics” describes FDA’s considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. This draft guidance further outlines the process by which administrators¹ of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. The draft guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database’s Web site.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the Web site.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application for recognition of genetic database	5	1	5	80	400

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of recognition activities	5	1	5	20	100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

¹ FDA acknowledges that many databases may not use the term “administrator” or may have a

committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a

genetic variant database administrator is the entity or entities that oversee database operations.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Public disclosure of policies, procedures, and conflicts of interest	5	1	5	1	5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756. The collections of information regarding premarket submissions have been approved as follows: The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231.

V. Other Issues for Consideration

The Agency invites comments on the draft guidance document entitled “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics,” in general, and on the following questions, in particular:

1. Should the quality recommendations outlined in the guidance apply equally to databases of somatic variants and to germline variants?

2. While this document applies to NGS-based tests, FDA expects that it may also be relevant to genetic tests that use other technologies (e.g., polymerase chain reaction, Sanger sequencing, etc.). Are any additional considerations necessary to support the use of these databases in the premarket review of tests using technologies other than NGS, should FDA decide to apply this approach more broadly in the future?

3. FDA recognizes that the evidence linking specific variants to diseases or conditions will change over time, and as such, assertions about those variants may also change. If an assertion regarding a variant changes over time, how should FDA assess what regulatory

actions may be appropriate with respect to in IVDs supported by such assertions? How often should FDA conduct ongoing review of an FDA-recognized database?

4. FDA notes that databases may have “discordant calls” with other databases, where the assertions for a variant in each database vary. While FDA believes that these discordant calls often arise because one database has information the other does not and our proposed policy will mitigate these issues over time; what, if any, action should FDA take when it learns about discordant calls between two databases with respect to database recognition or IVDs supported by such calls in FDA-recognized databases?

5. FDA has requested information regarding conflicts of interest for curators and personnel of databases seeking FDA recognition. FDA acknowledges that many personnel involved with variant curation and interpretation may have some connection to NGS test developers. What type of information should FDA collect and what policies should it implement to mitigate such potential conflicts of interest in FDA-recognized databases?

Dated: July 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16200 Filed 7–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1270]

Use of Standards in the Food and Drug Administration’s Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases; Draft Guidance for Stakeholders and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases.” As part of the White House’s Precision Medicine Initiative (PMI),¹ FDA is issuing this draft guidance to provide FDA’s proposed approach on the content and possible use of standards in providing oversight for targeted and whole exome human DNA sequencing (WES) NGS-based tests intended to aid in the diagnosis of individuals with suspected germline diseases or other conditions. This document provides recommendations for designing, developing, and validating NGS-based tests for germline diseases, and also discusses possible use of FDA-recognized standards for regulatory oversight of these tests. These recommendations are based on FDA’s understanding of the tools and processes needed to run an NGS-based test along with the design and analytical validation considerations appropriate for such tests. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 6, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to

¹ The Precision Medicine Initiative found on the White House’s Web site at: <https://www.whitehouse.gov/precision-medicine>.

the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1270 for "Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Personalized Medicine Staff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4544, Silver Spring, MD 20993-0002, 301-796-6206; or PMI@fda.hhs.gov; or Stephen Ripley, Center for Biologics

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the PMI, FDA is committed to implementing a flexible and adaptive regulatory oversight approach, which fosters innovation and simultaneously assures that patients have access to accurate and meaningful test results. FDA held two public workshops on this issue: "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests Public Workshop" held on February 20, 2015, and "Standards Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests" held on November 12, 2016. This guidance document, when finalized, provides recommendations for designing, developing, and validating for targeted and whole exome human DNA sequencing (WES) NGS-based tests intended to aid in the diagnosis of individuals with suspected germline diseases or other conditions (hereinafter referred to as "NGS-based tests for germline diseases" or "NGS-based tests"). It also outlines considerations for possibly classifying certain NGS-based tests for germline diseases in class II and exempting them from premarket notification requirements. Upon finalization of this guidance, these recommendations should be used as guidelines for test developers for premarket submissions. However, the longer-term goal is for these recommendations to form the basis for standards that FDA could recognize or for special controls and/or conditions for premarket notification (510(k)) exemption. FDA is also issuing a draft guidance entitled "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics" which is being issued concurrently elsewhere in this issue of the **Federal Register**.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on use of standards in FDA regulatory oversight of NGS-based IVDs used for diagnosing germline diseases. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if

it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, and for Center for Biologics Evaluation and Research guidance documents is available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16009 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 and 21 CFR 809.10, regarding labeling, have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910–0756.

V. Other Issues for Consideration

The Agency invites comments on the draft guidance document entitled "Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases," in general, and on the following questions, in particular:

1. Does the draft guidance content adequately address the analytical performance of targeted and whole exome human DNA sequencing (WES) NGS-based tests intended to aid in the diagnosis of individuals with suspected germline diseases or other conditions (referred to as "NGS-based tests for germline diseases" or "NGS-based tests" in the guidance)? For example, do the recommendations outlined in the draft guidance adequately address the analytical performance of NGS-based tests used as an aid in diagnosis of patients with signs and symptoms of developmental delay or intellectual disability, undiagnosed diseases, or hereditary cancer syndromes? If not, what additional test design, development, or validation activities are necessary for analytical validation of such tests? Are there specific indications within this broad intended use that require different or additional test design, development, or validation activities from those described in the draft guidance?

2. Do the recommendations in the draft guidance adequately address the analytical validation of NGS-based tests that use targeted panels or WES? Targeted sequencing panels? Are there differences between the use of targeted panels and WES that were not adequately distinguished in the recommendations described in the draft guidance?

3. The recommendations in this document focus on WES and targeted NGS-based tests for germline diseases. Are the recommendations outlined in the guidance sufficient to address analytical validation for whole genome sequencing (WGS) NGS-based tests for germline diseases? If not, what additional test design, development, and validation activities are needed to address the analytical validation of such tests?

4. Accuracy is generally described using an agreement, typically positive and negative percent agreement (PPA and NPA), between a new test and an accepted reference method. For NGS-based tests, positive predictive value (PPV) may be a more meaningful metric than NPA when calculating the likelihood that a variant call detected by the test is a true positive. If PPV is

calculated using only analytical results without taking into account prevalence in a population, it is sometimes called "technical" PPV (TPPV) to distinguish it from prevalence-based PPV. What are the benefits and weaknesses to assessing NGS-based test accuracy using TPPV in addition to PPA and NPA, or instead of NPA?

5. Are the minimum performance thresholds presented in this draft guidance appropriate, or are alternative thresholds more appropriate? Are there "best ways" to determine acceptable thresholds for each metric? Are there performance metrics that do not require minimum thresholds? Are there test scenarios where minimum thresholds are not useful or relevant?

6. How can bias and over-fitting be minimized or accounted for if known "reference" samples are used as comparators in accuracy studies?

Dated: July 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16201 Filed 7–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1206]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Ebola Zaire Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Ebola Zaire virus in response to the Ebola virus outbreak in West Africa. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Biocartis NV. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the September 22, 2006, determination by then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security. On the basis of such determination, the Secretary of Health

and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices for detection of Ebola virus, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of May 26, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT:

Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant

potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA¹ concludes: (1) That an agent

referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Request for an In Vitro Diagnostic Device for Detection of the Ebola Zaire Virus

On September 22, 2006, then-Secretary of DHS, Michael Chertoff, determined that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security². On August 5, 2014, under section 564(b)(1) of the FD&C Act and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices for detection of Ebola virus, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** on

² Under section 564(b)(1) of the FD&C Act, the HHS Secretary's declaration that supports the EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat under section 319F-2 of the PHS Act sufficient to affect national security or the health and security of U.S. citizens living abroad (section 564(b)(1)(D) of the FD&C Act.

¹ The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

August 12, 2014 (79 FR 47141). On May 2, 2016, Biocartis NV submitted a complete request for, and on May 26, 2016, FDA issued, an EUA for the Idylla™ Ebola Virus Triage Test, subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the

Authorization are available on the Internet at <http://www.regulations.gov>.

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of Ebola Zaire virus (detected

in the West Africa outbreak in 2014) subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164-01-P



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

May 26, 2016

Luc Van Hove, M.D., Ph.D.
Chief Medical Officer
Biocartis NV
Generaal De Wittelaan 11 B3
2800 Mechelen
Belgium

Dear Dr. Van Hove:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Idylla™ Ebola Virus Triage Test for the presumptive detection of Ebola Zaire virus¹ (detected in the West Africa outbreak in 2014) on the Idylla™ Instrument System (Idylla™ System) in EDTA venous whole blood specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors, by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests and by laboratories in the U.S. certified under CLIA to perform high complexity tests,² or in similarly qualified non-U.S. laboratories, by clinical laboratory personnel who have received specific training on the use of the Idylla™ Ebola Virus Triage Test on the Idylla™ System, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus presents a material threat against the United States population sufficient to affect national security.³ Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of the Department of Health and Human Services (HHS) declared on August 5, 2014, that

¹ This assay is authorized for the presumptive detection of RNA from Ebola Zaire virus (detected in the West Africa outbreak in 2014). It may also detect RNA from *Sudan ebolavirus*; however, it does not distinguish between these different Ebola virus species.

² For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests and by laboratories in the U.S. certified under CLIA to perform high complexity tests, or in similarly qualified non-U.S. laboratories" together as "authorized laboratories."

³ Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat pursuant to section 319F-2 of the PHS Act sufficient to affect national security or the health and security of United States citizens living abroad (section 564(b)(1)(D) of the Act).

Page 2 – Dr. Luc Van Hove, Biocartis NV

circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)).⁴

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Idylla™ Ebola Virus Triage Test (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (as described in the Scope of Authorization section of this letter (section II)) for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Idylla™ Ebola Virus Triage Test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Ebola Zaire virus (detected in the West Africa outbreak in 2014) can cause Ebola virus disease, a serious or life-threatening disease or condition to humans infected with this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Idylla™ Ebola Virus Triage Test may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, and that the known and potential benefits of the Idylla™ Ebola Virus Triage Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the Idylla™ Ebola Virus Triage Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.⁵

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Idylla™ Ebola Virus Triage Test by authorized laboratories for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

⁴ U.S. Department of Health and Human Services. *Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus*. 79 Fed. Reg. 47141 (August 12, 2014).

⁵ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The Authorized Idylla™ Ebola Virus Triage Test

The Idylla™ Ebola Virus Triage Test is an automated test intended for the *in vitro* qualitative detection of Ebola Zaire virus RNA from EDTA venous whole blood specimens. The assay is performed on the Idylla™ System. A quick reference guide and Instructions for Use are included in the test kit.

The Idylla™ System consists of an instrument, a console, and a single-use test-specific cartridge. The Idylla™ Console is connected to one or more Idylla™ Instruments. Samples are inserted into the Idylla™ Cartridges which are processed, fully automated, on the Idylla™ System using application specific, encrypted software, called Test Type Packages (TTP). Driven by the Idylla™ Ebola specific software (Ebola TTP), the Idylla™ System covers the entire process from sample-to-result with fully integrated sample preparation (homogenization, cell lysis and RNA extraction) followed by real-time reverse transcription polymerase chain reaction (rRT-PCR) amplification, detection of target sequences, analysis of the obtained PCR data, and reporting of the results.

The Idylla™ Ebola Virus Triage Test is an rRT-PCR assay using TaqMan® probes for detection of Ebola virus in the Idylla™ Cartridge. Two hundred microliters (200 µl) of EDTA venous whole blood is dispensed into the Idylla™ Cartridge. All the reagents and controls required to perform the testing are contained within the Idylla™ Cartridge.

The user identifies the sample identifier and then initiates the Idylla™ Ebola Virus Triage Test request through the Idylla™ Console. The Idylla™ Cartridge containing the sample is inserted into an Idylla™ Instrument and the Idylla™ Instrument processes the specific assay test following the Ebola TTP.

The Idylla™ Cartridge contains five PCR chambers in which the rRT-PCR takes place. In four chambers, PCRs for the detection of Ebola RNA and a Sample Process Control take place; in the fifth chamber an Endogenous Control (RNase P) is amplified. Fluorescent labeled reporter dyes generated upon amplification are analyzed in each of the chambers and a software algorithm converts the data to a final reportable result. The Idylla™ Instrument executes the Ebola TTP. Test results are uploaded to the Idylla™ Console making the test report available to the user. The Idylla™ Cartridge can be safely disposed as biological waste after test completion.

To prevent erroneous reporting, each Idylla™ Cartridge contains the following controls:

- **Sample Process Control (SPC):** The SPC is an armored RNA that is dried onto the lysis pad of the Idylla™ Cartridge to verify adequate processing of the sample. The SPC is used as an internal process control for both the nucleic acid extraction and rRT-PCR reaction of the Ebola PCR. Additionally, this control detects specimen-associated inhibition of the RT-PCR reaction. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. In the presence of high Ebola virus concentrations, the RT-PCR of the SPC may be competitively inhibited and can provide a negative or a positive result. In the absence of Ebola, the SPC must be positive to produce a valid negative result. The SPC is interpreted by the Ebola TTP software included data interpretation algorithm. A result will be provided only if the SPC passes the systems acceptance criteria; otherwise, the sample will be called invalid.

- Endogenous Control (EC): The EC amplifies the sample inherent RNase P gene and ensures that a human sample was correctly added to the test cartridge. The EC is interpreted by the Ebola TTP software included data interpretation algorithm. The EC passes if an RNase P signal is detected; otherwise, the sample will be called invalid.

The above described Idylla™ Ebola Virus Triage Test, when labeled consistently with the labeling authorized by FDA entitled “Idylla™ Ebola Virus Triage Test Instructions for Use” (available at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), which may be revised by Biocartis NV in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Idylla™ Ebola Virus Triage Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care providers and patients:

- Fact Sheet for Health Care Providers: Interpreting Idylla™ Ebola Virus Triage Test Results
- Fact Sheet for Patients: Understanding Results from the Idylla™ Ebola Virus Triage Test

As described in section IV below, Biocartis NV and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized Idylla™ Ebola Virus Triage Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Idylla™ Ebola Virus Triage Test in the specified population, when used for presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Idylla™ Ebola Virus Triage Test may be effective in the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available to FDA including the information supporting the conclusions described in section I above, and concludes that the authorized Idylla™ Ebola Virus Triage Test, when used to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Idylla™ Ebola Virus Triage Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (section II) and the Conditions of Authorization (section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Idylla™ Ebola Virus Triage Test described above is authorized to diagnose Ebola Zaire virus

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(detected in the West Africa outbreak in 2014) infection in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Idylla™ Ebola Virus Triage Test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Idylla™ Ebola Virus Triage Test.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Biocartis NV and Any Authorized Distributor(s)

- A. Biocartis NV and any authorized distributor(s) will distribute the authorized Idylla™ Ebola Virus Triage Test with the authorized labeling, as may be revised only by Biocartis NV in consultation with DMD/OIR/CDRH, to authorized laboratories.
- B. Biocartis NV and any authorized distributor(s) will provide to authorized laboratories the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Health Care Providers and the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Patients.
- C. Biocartis NV and any authorized distributor(s) will make available on their websites the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Health Care Providers and the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Patients.
- D. Biocartis NV and any authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.
- E. Biocartis NV and any authorized distributor(s) will ensure that authorized laboratories using the authorized Idylla™ Ebola Virus Triage Test have a process in place for

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reporting test results to health care providers and relevant public health authorities, as appropriate.⁶

- F. Through a process of inventory control, Biocartis NV and any authorized distributor(s) will maintain records of device usage.
- G. Biocartis NV and any authorized distributor(s) will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Biocartis NV and any authorized distributor(s) become aware.
- H. Biocartis NV and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Idylla™ Ebola Virus Triage Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Biocartis NV

- I. Biocartis NV will notify FDA of any authorized distributor(s) of the Idylla™ Ebola Virus Triage Test, including the name, address, and phone number of any authorized distributor(s).
- J. Biocartis NV will provide any authorized distributor(s) with a copy of this EUA, and communicate to any authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).
- K. Biocartis NV may request changes to the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Health Care Providers or the authorized Idylla™ Ebola Virus Triage Test Fact Sheet for Patients. Such requests will be made by Biocartis NV in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Biocartis NV may request the addition of other specimen types for use with the authorized Idylla™ Ebola Virus Triage Test. Such requests will be made by Biocartis NV in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Biocartis NV may request that the Idylla™ Ebola Virus Triage Test be used for the presumptive detection of other species of the Ebola virus, including the Ebola Sudan virus. Such requests will be made by Biocartis NV upon submission of acceptable analytical and clinical data, and will be made in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Biocartis NV will track adverse events and report to FDA under 21 CFR part 803.

⁶ For questions related to reporting Ebola test results to relevant public health authorities, it is recommended that Biocartis NV and authorized laboratories consult with the applicable country, state or territory health department(s). According to the U.S. Centers for Disease Control and Prevention (CDC), Ebola is a nationally notifiable condition. <http://www.cdc.gov/vhf/ebola/>.

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Authorized Laboratories

- O. Authorized laboratories will include with reports of the results of the Idylla™ Ebola Virus Triage Test the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- P. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.⁷
- Q. Authorized laboratories will collect information on the performance of the assay, and report to Biocartis NV and any authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.
- R. All laboratory personnel using the assay will be appropriately trained on the use of the Idylla™ Ebola Virus Triage Test on the Idylla™ System and use appropriate laboratory and personal protective equipment when handling this test.

Biocartis NV, Any Authorized Distributors and Authorized Laboratories

- S. Biocartis NV, any authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

- T. All advertising and promotional descriptive printed matter relating to the use of the authorized Idylla™ Ebola Virus Triage Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

⁷ For questions related to reporting Ebola test results to relevant public health authorities, it is recommended that Biocartis NV and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Ebola is a nationally notifiable condition. <http://www.cdc.gov/vhf/ebola/>.

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- U. All advertising and promotional descriptive printed matter relating to the use of the authorized Idylla™ Ebola Virus Triage Test shall clearly and conspicuously state that:
- This test has not been FDA cleared or approved;
 - This test has been authorized by FDA under an EUA for use by authorized laboratories;
 - This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), and any other Ebola virus species if so authorized; and
 - This test is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Idylla™ Ebola Virus Triage Test may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.

The emergency use of the authorized Idylla™ Ebola Virus Triage Test described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Luciana Borio, M.D.
Acting Chief Scientist
Food and Drug Administration

Enclosures

Dated: July 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-16176 Filed 7-7-16; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0795]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with medical devices third-party review under the Food and Drug Administration Modernization Act.

DATES: Submit either electronic or written comments on the collection of information by September 6, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0795 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@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.

Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act—OMB Control Number 0910-0375—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit

a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the

efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

FDA receives an average of one application for accreditation for third-party review per year. According to FDA's data, the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers. Third-party reviewers are required to keep records of their review of each submission.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	10	26	260	40	10,400
Total					10,424

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews	10	26	260	10	2,600

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 1, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-16158 Filed 7-7-16; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2016-N-0001]

Regional Public Workshop on the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Q3D Implementation of Guideline for Elemental Impurities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: Regional Public Workshop on ICH Q3D Implementation of Guideline for

Elemental Impurities. The purpose of the public workshop is to elaborate key aspects of the ICH Guideline Q3D: Guideline on Elemental Impurities in order facilitate a harmonized interpretation and implementation by industry and regulators. It is not intended to provide additional guidance beyond the scope of Q3D. The meeting will take place on the FDA campus and also be broadcast on the Web allowing participants to join in person or via the Web.

DATES: The public workshop will be held on August 22 and 23, from 9 a.m. to 5 p.m., EST. See the **SUPPLEMENTARY INFORMATION** section for information on how to register.

ADDRESSES: The public workshop will be held at 10903 New Hampshire Ave., Bldg. 31, Rm. 1503B/C, Silver Spring, MD 20993. The entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/>

WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993, 301-796-4548, email: Amanda.Roache@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The ICH brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. The ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. The ICH Q3D Guideline was developed by the ICH to provide a global policy for limiting elemental impurities qualitatively and quantitatively in drug products and ingredients. Following finalization of this Guideline, an Implementation Working Group was established to develop a comprehensive training program and supporting documents sponsored by ICH to ensure the proper interpretation and effective utilization

by industry and regulators alike to enable a harmonized and smooth implementation of Q3D on a global basis.

The U.S. regional workshop is intended to clarify key aspects of ICH Q3D: Guideline on Elemental Impurities by elaborating on those key topics. It will include: (1) A discussion of how to apply Q3D concepts to routes of administration, not addressed in Q3D, (2) justification for elemental impurity levels higher than an established permissible daily exposure (PDE) (3) application of Q3D concepts to determine safe levels of elements not included in Q3D, (4) discussion of the rationale for limits on large volume parenterals, (5) elaboration of the concepts outlined in the Q3D Sections on Risk Assessment and Control of Elemental Impurities and (6) options for converting between PDEs and concentrations.

In addition, case studies may be presented to illustrate the concepts described previously, and frequently asked questions will be discussed. The presentation of the material will follow the modules that are available on the ICH Web site, www.ich.org, and will include time for questions and discussion. Breakout sessions will be provided to discuss key topics and provide feedback to participants. Material will be presented by members of the ICH Q3D Implementation Working Group. The agenda for the workshop will be made available on the internet at <http://www.fda.gov/Drugs/NewsEvents/ucm498553.htm>.

Registration: If you wish to attend this meeting, visit the following Web site to register: <https://www.eventbrite.com/e/regional-public-workshop-on-ich-q3d-implementation-of-guideline-for-elemental-impurities-tickets-25492458630>. Please register by August 15, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast on the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special

accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Dated: July 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-16152 Filed 7-7-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1486]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Hologic, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of June 17, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT:

Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad,

and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances),

FDA¹ concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Request for an In Vitro Diagnostic Device for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a

¹ The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On June 15, 2016, Hologic, Inc. requested, and on June 17, 2016, FDA issued, an EUA for the Aptima® Zika Virus assay, subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at <http://www.regulations.gov>.

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of Zika virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164-01-P



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

June 17, 2016

Ken Hood, MBA
Senior Director, Regulatory Affairs
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Dear Mr. Hood:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Hologic, Inc.'s Aptima[®] Zika Virus assay for the qualitative detection of RNA from Zika virus in human serum and plasma specimens from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).¹ Assay results are for the identification of Zika viral RNA. Zika viral RNA is generally detectable in serum during the acute phase of infection (approximately 7 days following onset of symptoms, if present). Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus.² Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).³

¹ For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."

² As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

³ HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

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Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Aptima[®] Zika Virus assay (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Aptima[®] Zika Virus assay for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Aptima[®] Zika Virus assay, when used with the specified instrument and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Aptima[®] Zika Virus assay for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the Aptima[®] Zika Virus assay for detecting Zika virus and diagnosing Zika virus infection.⁴

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Aptima[®] Zika Virus assay by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

The Authorized Aptima[®] Zika Virus Assay

Hologic, Inc.'s Aptima[®] Zika Virus assay is a transcription-based nucleic acid amplification test for the *in vitro* qualitative detection of Zika virus RNA in serum and plasma specimens collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g.,

⁴ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

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history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). The Aptima[®] Zika Virus assay can also be used with other authorized specimen types. The Aptima[®] Zika Virus assay involves three main steps, which take place in a single tube: sample preparation, Zika virus RNA target amplification by transcription-mediated amplification, and detection of the amplification products (amplicon) by the Hybridization Protection Assay. The Aptima[®] Zika Virus assay is performed using the Panther System or other authorized instruments. The Panther System automates the processing, interpretation, and management of nucleic acid testing. The assay incorporates an internal control, or other authorized control materials, to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error.

The Aptima[®] Zika Virus assay kit includes the following materials or other authorized materials: Internal Control Reagent, Target Capture Reagent, Amplification Reagent, Enzyme Reagent, Probe Reagent, Selection Reagent, and Aptima[®] Zika Virus assay positive and negative calibrators. The following ancillary kits or other authorized ancillary reagents are required for Aptima[®] Zika Virus assay, but not included with the test: Aptima[®] Auto Detect Reagents kit and Aptima[®] Assay Fluids kit.

The above described Aptima[®] Zika Virus assay, when labeled consistently with the labeling authorized by FDA entitled "Aptima[®] Zika Virus assay Instructions for Use" (available at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), which may be revised by Hologic, Inc. in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Aptima[®] Zika Virus assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care providers, pregnant women, and other patients:

- Fact Sheet for Health Care Providers: Interpreting Aptima[®] Zika Virus Assay Test Results
- Fact Sheet for Pregnant Women: Understanding Results from the Aptima[®] Zika Virus Assay Test
- Fact Sheet for Patients: Understanding Results from the Aptima[®] Zika Virus Assay

As described in Section IV below, Hologic, Inc. is also authorized to make available additional information relating to the emergency use of the authorized Aptima[®] Zika Virus assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Aptima[®] Zika Virus assay in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific

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evidence available to FDA, that it is reasonable to believe that the authorized Aptima[®] Zika Virus assay may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in section I above, and concludes that the authorized Aptima[®] Zika Virus assay, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Aptima[®] Zika Virus assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Aptima[®] Zika Virus assay described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to geographic regions during a period of active Zika virus transmissions at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Aptima[®] Zika Virus assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Aptima[®] Zika Virus assay.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

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Hologic, Inc. and Its Authorized Distributor(s)

- A. Hologic, Inc. and its authorized distributor(s) will distribute the authorized Aptima[®] Zika Virus assay with the authorized labeling, as may be revised by Hologic, Inc. in consultation with DMD/OIR/CDRH, only to authorized laboratories.
- B. Hologic, Inc. and its authorized distributor(s) will provide to authorized laboratories the authorized Aptima[®] Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima[®] Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima[®] Zika Virus Assay Fact Sheet for Patients.
- C. Hologic, Inc. and its authorized distributor(s) will make available on their website(s) the authorized Aptima[®] Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima[®] Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima[®] Zika Virus Assay Fact Sheet for Patients.
- D. Hologic, Inc. and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.
- E. Hologic, Inc. and its authorized distributor(s) will ensure that authorized laboratories using the authorized Aptima[®] Zika Virus assay have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.⁵
- F. Through a process of inventory control, Hologic, Inc. and its authorized distributor(s) will maintain records of device usage.
- G. Hologic, Inc. and its authorized distributor(s) will collect information on the performance of the test. Hologic, Inc. will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Hologic, Inc. becomes aware.
- H. Hologic, Inc. and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Aptima[®] Zika Virus assay that is consistent with, and does not exceed, the terms of this letter of authorization.

Hologic, Inc.

- I. Hologic, Inc. will notify FDA of any authorized distributor(s) of the Aptima[®] Zika Virus assay, including the name, address, and phone number of any authorized distributor(s).
- J. Hologic, Inc. will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be

⁵ For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Hologic, Inc. and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition. <http://www.cdc.gov/zika/>.

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made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

- K. Hologic, Inc. may request changes to the authorized Aptima[®] Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima[®] Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima[®] Zika Virus Assay Fact Sheet for Patients. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- K. Hologic, Inc. may request the addition of other instruments for use with the authorized Aptima[®] Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Hologic, Inc. may request the addition of other ancillary reagents for use with the authorized Aptima[®] Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Hologic, Inc. may request the addition of other specimen types for use with the authorized Aptima[®] Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Hologic, Inc. may request the addition of other control materials for use with the authorized Aptima[®] Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Hologic, Inc. will assess traceability⁶ of the Aptima[®] Zika Virus assay with an FDA-recommended reference material. After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Hologic, Inc. will update its labeling to reflect the additional testing.
- P. Hologic, Inc. will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

- Q. Authorized laboratories will include with reports of the results of the Aptima[®] Zika Virus assay the authorized Fact Sheet for Health Care Providers, the authorized Fact Sheet for Pregnant Women, and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- R. Authorized laboratories will perform the Aptima[®] Zika Virus assay on the Panther System or other authorized instruments.
- S. Authorized laboratories will perform the Aptima[®] Zika Virus assay using the Aptima[®] Auto Detect Reagents kit and Aptima[®] Assay Fluids kit or other authorized ancillary reagents.

⁶ Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

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- T. Authorized laboratories will perform the Aptima[®] Zika Virus assay on serum, plasma, or other authorized specimen types.
- U. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.⁷
- V. Authorized laboratories will collect information on the performance of the test and report to Hologic, Inc., any suspected occurrence of false positive or false negative results of which they become aware.
- W. All laboratory personnel using the test should be appropriately trained in nucleic acid amplification techniques and use appropriate laboratory and personal protective equipment when handling this kit.

Hologic, Inc., Its Authorized Distributor(s) and Authorized Laboratories

- X. Hologic, Inc., its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

- Y. All advertising and promotional descriptive printed matter relating to the use of the authorized Aptima[®] Zika Virus assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- Z. All advertising and promotional descriptive printed matter relating to the use of the authorized Aptima[®] Zika Virus assay shall clearly and conspicuously state that:
 - This test has not been FDA cleared or approved;
 - This test has been authorized by FDA under an EUA for use by authorized laboratories;
 - This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
 - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

⁷ For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Hologic, Inc. and authorized laboratories consult with the applicable, country, state or territory health department(s) and/or CDC. According to CDC, Zika is a nationally notifiable condition. <http://www.cdc.gov/zika/>.

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No advertising or promotional descriptive printed matter relating to the use of the authorized Aptima® Zika Virus assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Aptima® Zika Virus assay as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: July 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-16177 Filed 7-7-16; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for “Blockchain and Its Emerging Role in Healthcare and Health-related Research”

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

Award Approving Official: Karen DeSalvo, National Coordinator for Health Information Technology.

ACTION: Notice.

SUMMARY: The “Blockchain and Its Emerging Role in Healthcare and Health-related Research.” Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use for Healthcare. Winners will be invited to present their submission at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

DATES:

- Submission period begins: June 20.
- Submission period ends: July 29.
- Evaluation begins: August 1.
- Evaluation ends: August 16.
- Winners notified: August 17.
- Winners Announced: August 20.
- Winner Presentation: September 26th–27th.

FOR FURTHER INFORMATION CONTACT:

Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690-0213.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

A blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

Proponents of blockchain suggest that it could be used to address concerns

regarding the privacy, security and the scalability of health records. Critics ascertain that it would take enormous processing power and specialized equipment that far exceeds the benefits. Although most would acknowledge blockchain’s potential it is still evolving and maturing, especially with respect to its applicability to the health care.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data.

This nationwide call may be addressed by an individual investigator or a investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may participate in no more than three submissions. A limited number of these submissions will be selected. The selection of a White Paper will result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th at NIST Headquarters in Gaithersburg, MD.

Objective

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of blockchain technology, examine how the use of blockchain can advance industry interoperability needs expressed in the Nationwide Interoperability Roadmap, patient centered outcomes research (PCOR), precision medicine, and other health care delivery needs, as well as provide recommendations for blockchain’s implementation.

In lieu of a monetary award, challenge winners will be provided the opportunity to present their White Papers at an industry-wide “Blockchain & Healthcare Workshop” co-hosted by ONC and NIST.

Submission Requirements

Include a White Paper, not longer than ten (10) pages in length, that:

- Educates its audience on the technology; and
- Can be used to determine whether there is a place in Health IT and/or Healthcare related Research for the technology.
- The paper should:
 - Describe the value of blockchain to the health-care system;
 - Identify potential gaps;
 - Discuss the effectiveness of the solution and the solutions ability to function in the “real world.” This

discussion may include information regarding meeting privacy and security standards, implementation and potential performance issues, and cost implications. Risk analysis and mitigation would be appropriate to include here as well.

- Discuss the solution’s link to the stated objectives in the Nationwide Interoperability Roadmap, PCOR, precision medicine and other national health care delivery priorities.

How To Enter

Challenge participants will have five (5) weeks from the date of the posting of this Notice. Those submissions must comply with the requirements provided above. Up to eight submissions may be selected as winners. The names of the winners will be posted on the *Challenge.gov* Web site, as well as the names of any participants receiving an honorary mention. Honorary mentions may be given to highly ranked submissions.

Eligibility Rules for Participating in the Challenge

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge.
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.
4. May not be a Federal entity or Federal employee acting within the scope of their employment.
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge Submission.

An individual or entity shall not be deemed ineligible because the

individual or entity used Federal facilities or consulted with Federal employees during a Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

General Submission Requirements

In order for a Submission to be eligible to win this Challenge, it must meet the following requirements:

1. No HHS or ONC logo—The Solution must not use HHS' or ONC's logos or official seals and must not claim endorsement.
2. Functionality/Accuracy—A Solution may be disqualified if it fails to function as expressed in the description provided by the participant, or if it provides inaccurate or incomplete information.

Registration Process for Participants

To register for this Challenge, participants can access <http://www.challenge.gov> and search for "Blockchain and Its Emerging Role in Healthcare and Health-related Research."

Prize

Winners will be provided the following:

- Opportunity to present their paper at a Blockchain & Healthcare Workshop Hosted at NIST
- Paid travel to the Workshop;
- Paid room and board for the Workshop; and
- Paid Per Diem.

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

The evaluation process will begin by removing those that are not responsive to this Challenge or not in compliance with all rules for eligibility. Judges will examine all responsive and compliant submissions, and rate the entries. Judges will determine the most meritorious submissions, based on these ratings and select up to eight (8) finalists. Honorable Mentions may be included and announced, along with the winners on Challenge.gov.

The judging panel will rate each submission based upon the effectiveness of the overall concept to help foster transformative change in the HealthIT culture, the viability of the proposed recommendations, the innovativeness of the approach, and its potential for achieving the objectives of ONC.

Up to eight (8) submissions will be selected as winners. Winners will be

awarded with the opportunity to present their White Paper at a two-day Blockchain & Healthcare Workshop. In lieu of a monetary prize, finalists will be provided with full expenses for travel to the Workshop, which will be held at the NIST Headquarters in Gaithersburg, MD.

At the end of the submission period, Submissions will be posted on the challenge Web site and will be reviewed, graded, and voted on by a steering committee.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the Challenge. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

- (a) Participant is the sole author, creator, and owner of the Submission;
- (b) The Submission is not the subject of any actual or threatened litigation or claim;
- (c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party;

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal Agency sponsors reserve the right to disqualify any Submission that, in their discretion,

deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo,

National Coordinator for Health Information Technology.

[FR Doc. 2016-16133 Filed 7-6-16; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Opioid Analgesic Prescriber Education and Training Opportunities To Prevent Opioid Overdose and Opioid Use Disorder

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for information.

SUMMARY: Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain—have been increasingly implicated in drug overdose deaths over the last decade. Alarming, deaths related to opioid analgesic overdose have quadrupled since 1999, and this increase in deaths has been linked to parallel increases in opioid prescribing. As part of its comprehensive response to the opioid epidemic, HHS is actively working to stem overprescribing of opioids in a number of ways, including by providing clinicians with the tools and education they need to make informed prescribing decisions. In particular, HHS has developed a number of activities that support opioid analgesic prescriber education. This Request for Information (RFI) seeks comment on the most promising approaches in prescriber education and training programs and effective ways to leverage HHS programs to implement/expand them.

DATES: Comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2016.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the

instructions for submitting electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.

- *Regular, Express, or Overnight Mail:*

You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

• *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 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 mail drop slots located in the main lobby of the building.)

• *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

• *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Office of the Assistant Secretary for Planning and Evaluation, 202-690-7858.

SUPPLEMENTARY INFORMATION:

I. Background

Education and training in pain management and appropriate opioid analgesic prescribing, including how to identify patients who may be at risk for opioid misuse and ensuring patients treated with opioids receive the appropriate dose and quantity of medication for their condition, are key elements of the response to the opioid epidemic. Surveys of healthcare providers indicate that they receive inadequate training on pain management, and many feel uncomfortable managing patients with pain. In addition, research has identified significant gaps and fragmentation in pain education in

health professional schools, and the National Pain Strategy indicates that health professional education is a central component of advancing a system of care in which all people receive high quality and evidence-based pain care.

To improve education and training on pain management and appropriate opioid prescribing, HHS has developed programs that engage prescribers throughout their training and professional career. For example, in an effort to educate health professional students, the National Institutes on Drug Abuse (NIDA) coordinates the National Institutes of Health Pain Consortium's Centers of Excellence in Pain Education that develop and distribute pain management curriculum resources for medical, dental, nursing, and pharmacy schools.

Many HHS training initiatives target practicing clinicians throughout their learning and practice lifecycles. Some programs, such as NIDA's NIDAMED program, offer opioid and pain management training as continuing education credit opportunities. Additionally, the Food and Drug Administration (FDA) has put in place a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications. The ER/LA Opioid Analgesic REMS requires manufacturers to make prescriber training available through accredited continuing education (CE) programs funded by the ER/LA sponsors. To assure that the training is balanced and to protect from industry influence, the training is based upon the FDA blueprint for Prescriber Education for ER/LA opioids and is made available through third-party CE providers.

Other programs utilize a peer-to-peer mentoring model. The Substance Abuse and Mental Health Services Administration's Providers' Clinical Support System for Opioid Therapies (PCSS-O) is one such model that offers colleague support and mentoring as well as evidence-based educational resources on how to effectively utilize opioid analgesics for patients with pain and patients with opioid use disorders. And, other resources are intended to support decision making during an active patient encounter. The Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain facilitates providers' decision-making regarding appropriate pain treatment for patients 18 years and older in the primary care setting.

II. Solicitation of Comments

This RFI is seeking comment on the range of approaches to educating and

training providers on pain management and appropriate opioid analgesic prescribing, including identifying patients at risk for abuse and prescribing the appropriate dose and quantity of medication for their condition. As noted above HHS has undertaken several programs to engage providers on these topics, and this RFI is meant to solicit input not only on those but also on other approaches. For example, HHS seeks comment on the impact of non-federal prescriber training policies or programs on opioid analgesic prescriber competency:

- How states have developed, promoted, and made pain management and opioid analgesic prescriber education available,

- whether state requirements for mandatory pain management and opioid prescribing training have led to any changes in prescriber behavior and/or other outcomes as a result of these programs,

- the challenges opioid education providers have faced in implementing opioid prescriber education initiatives,

- which measures education providers use to evaluate the success of their interventions, or

- how health information technology has been implemented to assist the prescriber in appropriate opioid prescribing and pain management.

HHS also is soliciting suggestions for additional activities the Department could implement to ensure universal prescriber education on appropriate pain management and opioid prescribing. For example, additional HHS activities could include:

- Adding new opioid prescriber education to Medicare Conditions of Participation and/or to Medicare enrollment requirements,

- adding quality measures around safe opioid use to the specialty core measures that clinicians may choose to report under the Merit-based Incentive Payment System (MIPS), or

- revising the ER/LA Opioid Analgesic REMS to require that prescribers of opioids receive appropriate training on pain management and safe opioid use before being able to prescribe specific opioids.

Finally, HHS seeks feedback through this RFI on the ability of existing HHS education and training programs to educate all opioid analgesic prescribers on appropriate pain management and opioid prescribing including comments on the development and delivery of the content and on efforts to assess the impact of the training initiatives.

III. 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.

Dated: June 29, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016-16067 Filed 7-6-16; 8:45 am]

BILLING CODE 4150-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Workshop—Iron Screening and Supplementation of Iron-Replete Pregnant Women and Young Children

SUMMARY: The Office of Dietary Supplements at the National Institutes of Health (NIH) is sponsoring an open public workshop titled, “Iron Screening and Supplementation of Iron-replete Pregnant Women and Young Children,” September 28–29, 2016, on the NIH main campus in Bethesda, Maryland. It will also be available to be viewed live or later on-demand as a videocast. The workshop discussions will focus on the U.S. and developed countries and will serve to specify data gaps and research needs by (1) exploring current understanding of iron homeostasis in pregnant women and in young children (6-24 months); (2) identifying the challenges associated with measuring iron status and with screening practices; and (3) considering emerging issues associated with routine supplementation of iron-replete individuals. All persons are invited to attend, especially clinical educators, those who develop clinical recommendations, health care providers and researchers. Persons wishing to attend are required to register in advance of the conference.

DATES: September 28–29, 2016; 8:30 to 5:15 p.m. (Eastern Time) on the first day and 8:00 to 12:30 p.m. on the second day.

ADDRESSES: National Institutes of Health, William H. Natcher Building; Natcher Conference Center, Building 45, Bethesda, Maryland, 20892.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Rooney, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard,

Room 3B01, Bethesda, MD 20892-7523, Email: rooneyc@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The conference is sponsored by the NIH Office of Dietary Supplements along with co-sponsors from other federal agencies. Information about the conference agenda, registration procedures, and videocast arrangements can be found at: https://events-suport.com/events/NIH_Iron_Workshop.

Through its Iron Initiative, the National Institutes of Health (NIH) Office of Dietary Supplements leads efforts to advance scientific understanding of iron and health: <https://ods.od.nih.gov/Research/Iron.aspx>.

Dated: July 1, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016-16254 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request National Institutes of Health (NIH) Loan Repayment Programs; Office of the Director (OD)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Division of Loan Repayment (DLR), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2016, and page numbers 8514–8516, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Steve Boehlert, Director of Operations, Division of Loan Repayment, National Institutes of Health, 6011 Executive Blvd., Room 206 (MSC 7650), Bethesda, Maryland 20892-7650. Mr. Boehlert may be contacted via email at BoehlerS@od.nih.gov or by calling 301-451-4465. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: National Institutes of Health (NIH) Loan Repayment Programs (LRP). *Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925-0361, expiration date 06/30/17). Form Numbers: NIH 2674-1, NIH 2674-2, NIH 2674-3, NIH 2674-4, NIH 2674-5, NIH 2674-6, NIH 2674-7, NIH 2674-8, NIH 2674-9, NIH 2674-10, NIH 2674-11, NIH 2674-12, NIH 2674-13, NIH 2674-14, NIH 2674-15, NIH 2674-16, NIH 2674-17, NIH 2674-18, NIH 2674-19, and NIH 2674-20 (new).

Need and Use of Information Collection: The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., D.C., N.D., O.D., D.V.M., or equivalent degree holders who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees or scientists funded by domestic non-profit organizations for a minimum of two years (three years for the General Research LRP) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS-LRP) is authorized by section 487A of the Public Health Service Act (42 U.S.C. 288-1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) is authorized by section 487E (42 U.S.C. 288-5); the General Research Loan Repayment Program (GR-LRP) is authorized by section 487C of the Public Health Service Act (42 U.S.C. 288-3); the Clinical Research Loan Repayment Program (LRP-CR) is authorized by section 487F (42 U.S.C. 288-5a); the Pediatric Research Loan Repayment Program (PR-LRP) is authorized by

section 487F (42 U.S.C. 288–6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR–LRP) is authorized by an amendment to section 487E (42 U.S.C. 288–5); the Contraception and Infertility Research LRP (CIR–LRP) is authorized by section 487B (42 U.S.C. 288–2); and the Health Disparities Research Loan Repayment Program (HD–LRP) is authorized by section 485G (42 U.S.C. 287c–33).

The Loan Repayment Programs can repay up to \$35,000 per year toward a participant’s extant eligible educational loans, directly to financial institutions. The information proposed for collection

will be used by the Division of Loan Repayment to determine an applicant’s eligibility for participation in the program.

Frequency of Response: Initial application and one- or two-year renewal application.

Affected Public: Individuals or households; Nonprofits; and Businesses or other for-profit.

Type of Respondents: Physicians, other scientific or medical personnel, and institutional representatives.

Questions, required information, and requested documents remain largely unchanged. Improvements were made to the structure and appearance of online forms to provide applicants with a

better user experience. Recommenders will no longer be asked to complete a recommendation form, but to write a reference letter that comments on the research skills and the abilities of the applicant. A general eligibility checklist (NIH 2674–20) was added at the start of the application to reduce the likelihood of ineligible individuals working through the application only to learn of their disqualification after submitting the application. Redundant questions or statements were eliminated. OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 33,242.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
<i>Intramural LRPs</i>				
Initial Applicants	40	1	10	400
Advisors/Supervisors	40	1	1	40
Recommenders	120	1	30/60	60
Financial Institutions	8	1	15/60	2
Subtotal	208			502
<i>Extramural LRPs</i>				
Initial Applicants	1,650	1	11	18,150
Advisors/Supervisors	1,480	1	1	1,480
Recommenders	4,950	1	30/60	2,475
Financial Institutions	100	1	15/60	25
Subtotal	8,180			22,130
<i>Intramural LRPs</i>				
Renewal Applicants	40	1	7	280
Advisors/Supervisors	40	1	2	80
Subtotal	80			360
<i>Extramural LRPs</i>				
Renewal Applicants	1,000	1	8	8,000
Advisors/Supervisors	750	1	1	750
Recommenders	3,000	1	30/60	1,500
Subtotal	4,750			10,250
Total	13,218			33,242

Dated: July 1, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–16227 Filed 7–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Training Grants Review.

Date: July 26, 2016.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: CAROL J. GOTER-ROBINSON, PH.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, NATIONAL INSTITUTES OF HEALTH, ROOM 7347, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892–5452, (301) 594–7791, goterrobinsonc@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Program Project on Gut Microbial Host Interactions.

Date: August 5, 2016.

Time: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: MARIA E. DAVILA-BLOOM, PH.D., SCIENTIFIC REVIEW OFFICER, REVIEW BRANCH, DEA, NIDDK, ROOM 7017, 6707 DEMOCRACY BOULEVARD, BETHESDA, MD 20892, (301) 594-7637, davila-bloomm@extra.nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 1, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-16142 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: National Institute of Neurological Disorders and Stroke Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Access Request

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 Neurological Disorders and Stroke (NINDS), 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.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sophia Jeon, Health Science Policy Analyst, Office of Science Policy and Planning (OSPP), NINDS, NIH, 31 Center Drive, Building 31, Room 8A03, Bethesda, MD 20892, or call non-toll-free number (301) 435-7571, or Email your request, including your address to: sophia.jeon@nih.gov Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: National Institute of Neurological Disorders and Stroke Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Access Request, 0925-0677, Expiration Date 08/31/2016—Reinstatement without change, National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH).

Need and Use of Information Collection: The FITBIR Informatics System Data Access Request form is necessary for "Recipient" Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the FITBIR Informatics System for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. Type of respondents affected by this information collection are researchers, such as Principal Investigators (PI), who are interested in obtaining access to study data and images from the FITBIR Informatics System for research purposes.

There are two scenarios for completing the form. The first is where the Principal Investigator (PI) completes the entire FITBIR Informatics System Data Access Request form, and the second where the PI has the Research Assistant begins filling out the form and PI provides the final reviews and signs it. The estimated annual burden hours to complete the data request form are listed below.

OMB approval reinstatement is requested for 3 years. The total estimated annualized burden hours are 63.

ESTIMATED ANNUALIZED BURDEN

Estimated annual burden hours for respondents

Form	Type of respondent	Number of respondents	Annual frequency per response	Hours per response	Total hours
FITBIR Informatics System Data Access Request.	Individuals (Principal Investigators)	40	1	95/60	63
Total	40	40	63

Dated: July 1, 2016.

Paul Scott,

Project Clearance Liaison Officer, National Institute of Neurological Disorders and Stroke, NIH.

[FR Doc. 2016-16256 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Interventions and Mechanisms for Addictions.

Date: July 19, 2016.

Time: 10:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300-6541, boulaymg@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR15-287: Opportunities for Collaborative Research at the NIH Clinical Center (U01).

Date: July 20, 2016.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, (301) 408-9436, fungai.chanetsa@nih.hhs.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: Biology of Development and Aging Integrated Review Group; International and Cooperative Projects—1 Study Section.

Date: August 8, 2016.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Hilary D. Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594-6377, sigmonh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-16140 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Risk, Prevention and Health Behavior.

Date: July 11, 2016.

Time: 1:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Stacey C. FitzSimmons, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 451-9956, fitzsimmons@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-16141 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2584-16; DHS Docket No. USCIS-2007-0028]

RIN 1615-ZB53

Extension of the Designation of El Salvador for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of El Salvador for Temporary Protected Status (TPS) for 18 months from September 10, 2016 through March 9, 2018.

The extension allows currently eligible TPS beneficiaries to retain TPS through March 9, 2018, so long as they otherwise continue to meet the eligibility requirements for TPS. The Secretary has determined that an extension is warranted because the conditions in El Salvador supporting the TPS designation continue to be met. There continues to be a substantial, but temporary, disruption of living conditions in El Salvador resulting from a series of earthquakes in 2001, and El Salvador remains unable, temporarily, to handle adequately the return of its nationals.

Through this Notice, DHS also sets forth procedures necessary for nationals of El Salvador (or aliens having no nationality who last habitually resided in El Salvador) to re-register for TPS and to apply for renewal of their Employment Authorization Documents (EAD) with U.S. Citizenship and Immigration Services (USCIS). Re-registration is limited to persons who have previously registered for TPS under the designation of El Salvador and whose applications have been granted. Certain nationals of El Salvador

(or aliens having no nationality who last habitually resided in El Salvador) who have not previously applied for TPS may be eligible to apply under the late initial registration provisions, if they meet: (1) At least one of the late initial filing criteria; and, (2) all TPS eligibility criteria (including continuous residence in the United States since February 13, 2001, and continuous physical presence in the United States since March 9, 2001).

For individuals who have already been granted TPS under the El Salvador designation, the 60-day re-registration period runs from July 8, 2016 through September 6, 2016. USCIS will issue new EADs with a March 9, 2018 expiration date to eligible El Salvador TPS beneficiaries who timely re-register and apply for EADs under this extension. Given the timeframes involved with processing TPS re-registration applications, DHS recognizes that not all re-registrants will receive new EADs before their current EADs expire on September 9, 2016. Accordingly, through this Notice, DHS automatically extends the validity of EADs issued under the TPS designation of El Salvador for 6 months, through March 9, 2017, and explains how TPS beneficiaries and their employers may determine which EADs are automatically extended and their impact on Employment Eligibility Verification (Form I-9) and the E-Verify processes.

DATES: The 18-month extension of the TPS designation of El Salvador is effective September 10, 2016, and will remain in effect through March 9, 2018. The 60-day re-registration period runs from July 8, 2016 through September 6, 2016. (**Note:** It is important for re-registrants to timely re-register during this 60-day re-registration period and not to wait until their EADs expire.)

FOR FURTHER INFORMATION CONTACT:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. You can find specific information about this extension of El Salvador for TPS by selecting “El Salvador” from the menu on the left of the TPS Web page.

- You can also contact Jerry Rigdon, Chief of the Waivers and Temporary Services Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529-2060; or by phone at 202-272-1533 (this is not a toll-free number). **Note:** The phone number provided here is solely for questions regarding this TPS Notice.

It is not for individual case status inquires.

- Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833). Service is available in English and Spanish.

- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
 DHS—Department of Homeland Security
 DOS—Department of State
 EAD—Employment Authorization Document
 FNC—Final Nonconfirmation
 GDP—Gross Domestic Product
 Government—U.S. Government
 IJ—Immigration Judge
 INA—Immigration and Nationality Act
 OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
 SAVE—USCIS Systematic Alien Verification for Entitlements Program
 Secretary—Secretary of Homeland Security
 TNC—Tentative Nonconfirmation
 TPS—Temporary Protected Status
 TTY—Text Telephone
 USCIS—U.S. Citizenship and Immigration Services

What is Temporary Protected Status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the Immigration and Nationality Act (INA), or to persons without nationality who last habitually resided in the designated country.

- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and obtain EADs, so long as they continue to meet the requirements of TPS.

- TPS beneficiaries may also be granted travel authorization as a matter of discretion.

- The granting of TPS does not result in or lead to permanent resident status.

- When the Secretary terminates a country’s TPS designation through a separate **Federal Register** Notice, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

When was El Salvador designated for TPS?

On March 9, 2001, the Attorney General designated El Salvador for TPS based on an environmental disaster within that country, specifically the devastation resulting from a series of earthquakes that occurred in 2001. See *Designation of El Salvador Under Temporary Protected Status*, 66 FR 14214 (Mar. 9, 2001). The Secretary last announced an extension of TPS for El Salvador on January 7, 2015, based on his determination that the conditions warranting the designation continued to be met. See *Extension of the Designation of El Salvador for Temporary Protected Status*, 80 FR 893 (January 7, 2015). This announcement is the eleventh extension of TPS for El Salvador since the original designation in 2001.

What authority does the Secretary of Homeland Security have to extend the designation of El Salvador for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate U.S. Government agencies, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.¹ The Secretary may then grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state). See INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a country’s TPS designation or extension, the Secretary, after consultation with appropriate Government agencies, must review the conditions in a foreign state designated for TPS and determine whether the conditions for the TPS designation continue to be met. See INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that a foreign state continues to meet the conditions for TPS designation, the designation may be extended for an additional period of 6, 12, or 18 months. See INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C). If the Secretary determines that the foreign state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. See INA section 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

¹ As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107-296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS “shall be deemed to refer to the Secretary” of Homeland Security. See 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

Why is the Secretary extending the TPS designation for El Salvador through March 9, 2018?

DHS and the Department of State (DOS) have reviewed conditions in El Salvador. Based on these reviews and after consulting with DOS, the Secretary has determined that an 18-month extension is warranted because the conditions supporting El Salvador's 2001 designation for TPS persist.

El Salvador was originally designated for TPS following two separate earthquakes in 2001. The first earthquake, on January 13, registered 7.6 in magnitude on the standard seismic scale; the second, on February 13, measured 6.6 in magnitude. Over 3,000 aftershocks hit El Salvador in the aftermath of the earthquakes, including those with 5.1 and 5.6 magnitudes in late February 2001.

Together, the earthquakes killed over 1,000 people, caused approximately 8,000 injuries, and affected approximately 1.5 million people. Of 262 municipalities in El Salvador, 165 suffered serious damage in the first quake. The earthquakes caused significant damage to transportation infrastructure, housing, education and health services, small and medium businesses, and the environment.

Recovery from the earthquakes has been slow and encumbered by subsequent natural disasters and environmental challenges, including hurricanes and tropical storms, heavy rains and flooding, volcanic and seismic activity, an ongoing coffee rust epidemic, and a prolonged regional drought that is impacting food security. The regional drought currently affecting El Salvador has made the country the driest it has been in 35 years. The drought is projected to cause more than \$400 million in losses from corn, beans, coffee, sugar cane, livestock, and vegetables, resulting in subsistence farmers facing malnutrition and pressure to migrate. Due to the drought and a regional coffee rust epidemic, coffee production for the 2015–2016 harvest is projected to be 30-percent lower than the previous season, and the U.S. Department of Agriculture expects next year's harvests to be the smallest in 80 years. Further, environmental and social conditions have contributed to an outbreak of mosquito borne illnesses, including chikungunya and dengue.

Although progress has been made in repairing physical damage caused by the 2001 earthquakes, infrastructure challenges remain. El Salvador faces a housing deficit of approximately 630,000 houses, created in part because 340,000 homes destroyed in the 2001

earthquakes still have not been rebuilt. A lack of potable water and electricity remain serious problems; more than 10 percent of El Salvador's total population lacks access to potable water. Water contamination and shortages are of particular concern in the San Salvador metropolitan area, where they have affected the day-to-day activities of the population and have reportedly led to conflicts over water. In March 2016, extortion demands from gangs caused an almost weeklong temporary bottled water shortage and halting of some water deliveries in San Salvador. Insecurity and water shortages have contributed to increased inflation, which is generally low due to El Salvador's dollarized economy.

Increasing violence and insecurity is also a major constraint to economic growth. According to a study released in April 2016 by El Salvador's Central Bank and the United Nations Development Program, Salvadoran citizens paid \$756 million in extortion payments to gangs in 2014, representing about three percent of Gross Domestic Product (GDP). The study estimates the total cost of violence, including the amount households spend on extra security and the lost income from people deterred from working, is nearly 16 percent of GDP, the highest level in Central America. Hampered by limited financial resources, the government continues to struggle to respond adequately to increasing levels of crime, and there is little confidence the security situation will improve in the short term.

The fiscal, unemployment, and security situations in El Salvador also remain poor. El Salvador's economy is experiencing significant challenges. Around a third of the country's work force is underemployed or unable to find full-time work. In 2014, almost a third of all Salvadorans (31.9 percent) lived in poverty. Murder, extortion, and robbery rates are high, and the government struggles to respond adequately to crime, including significant criminal gang activity. The police suffer from insufficient staffing, corruption, and inadequate training. The judicial system is also weak, with a low criminal conviction rate and high levels of corruption, creating an environment of impunity.

Based upon this review and after consultation with appropriate U.S. Government agencies, the Secretary finds that:

- The conditions supporting the March 9, 2001 designation of El Salvador for TPS continue to be met. See INA sections 244(b)(1)(B), (b)(3)(A)

and (C), 8 U.S.C. 1254a(b)(1)(B), (b)(3)(A) and (C).

- There continues to be a substantial, but temporary, disruption of living conditions in El Salvador as a result of an environmental disaster. See INA section 244(b)(1)(B)(i), 8 U.S.C. 1254a(b)(1)(B)(i).

- El Salvador continues to be unable, temporarily, to handle adequately the return of its nationals (or aliens having no nationality who last habitually resided in El Salvador). See INA section 244(b)(1)(B)(ii), 8 U.S.C. 1254a(b)(1)(B)(ii).

- The designation of El Salvador for TPS should be extended for an additional 18-month period from September 10, 2016 through March 9, 2018. See INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).

- There are approximately 195,000 current El Salvador TPS beneficiaries who are expected to file for re-registration and may be eligible to retain their TPS under the extension.

Notice of Extension of the TPS Designation of El Salvador

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate U.S. Government agencies, that the conditions that prompted the designation of El Salvador for TPS in 2001 continue to be met. See INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). On the basis of this determination, I am extending the designation of El Salvador for TPS for 18 months from September 10, 2016, through March 9, 2018. See INA sections 244(b)(2) and (b)(3), 8 U.S.C. 1254a(b)(2) and (b)(3).

Jeh Charles Johnson,
Secretary.

Required Application Forms and Application Fees To Register or Re-Register for TPS

To register or re-register for TPS based on the designation of El Salvador, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I-821).

- If you are filing an application for late initial registration, you must pay the fee for the Application for Temporary Protected Status (Form I-821). See 8 CFR 244.2(f)(2) and 244.6 and information on late initial filing on the USCIS TPS Web page at <http://www.uscis.gov/tps>.

- If you are filing an application for re-registration, you do not need to pay the fee for the Application for

Temporary Protected Status (Form I-821). See 8 CFR 244.17. and

2. Application for Employment Authorization (Form I-765).

- If you are applying for late initial registration and want an EAD, you must pay the fee for the Application for Employment Authorization (Form I-765) only if you are age 14 through 65. No fee for the Application for Employment Authorization (Form I-765) is required if you are under the age of 14 or are 66 and older and applying for late initial registration.

- If you are applying for re-registration, you must pay the fee for the Application for Employment Authorization (Form I-765) only if you want an EAD, regardless of age.

- You do not pay the fee for the Application for Employment Authorization (Form I-765) if you are not requesting an EAD, regardless of whether you are applying for late initial registration or re-registration.

You must submit both completed application forms together. If you are unable to pay for the Application for Employment Authorization (Form I-765) and/or biometrics fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I-912) or submitting a personal letter requesting a fee waiver, and by providing satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. Fees for the Application for

Temporary Protected Status (Form I-821), the Application for Employment Authorization (Form I-765), and biometric services are also described in 8 CFR 103.7(b)(1)(i).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I-912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at <http://www.uscis.gov>. If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

Re-Filing a Re-Registration TPS Application After Receiving a Denial of a Fee Waiver Request

USCIS urges all re-registering applicants to file as soon as possible within the 60-day re-registration period so that USCIS can process the applications and issue EADs promptly. Filing early will also allow those applicants who may receive denials of their fee waiver requests to have time to re-file their applications before the re-registration deadline. If, however, an

applicant receives a denial of his or her fee waiver request and is unable to re-file by the re-registration deadline, the applicant may still re-file his or her application. This situation will be reviewed to determine whether the applicant has established good cause for late re-registration. However, applicants are urged to re-file within 45 days of the date on their USCIS fee waiver denial notice, if at all possible. See INA section 244(c)(3)(C); 8 U.S.C. 1254a(c)(3)(C); 8 CFR 244.17(c). For more information on good cause for late re-registration, visit the USCIS TPS Web page at <http://www.uscis.gov/tps>. **Note:** As previously stated, although a re-registering TPS beneficiary age 14 and older must pay the biometric services fee (but not the initial TPS application fee) when filing a TPS re-registration application, the applicant may decide to wait to request an EAD, and therefore not pay the Application for Employment Authorization (Form I-765) fee, until after USCIS has approved the individual's TPS re-registration, if he or she is eligible. If you choose to do this, you would file the Application for Temporary Protected Status (Form I-821) with the fee and the Application for Employment Authorization (Form I-765) without the fee and without requesting an EAD.

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If . . .	Mail to . . .
Are applying for re-registration and you live in the following states/territories: Alabama, Alaska, American Samoa, Arkansas, Colorado, Guam, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, New York, North Dakota, Northern Mariana Islands, Oklahoma, Puerto Rico, South Dakota, Tennessee, Texas, Utah, Virgin Islands, Wisconsin, Wyoming.	U.S. Postal Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, P.O. Box 660864, Dallas, TX 75266. Non-U.S. Postal Delivery Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, 2501 S. State Highway, 121 Business Suite 400, Lewisville, TX 75067.
Are applying for re-registration and you live in the following states/territories: Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, Washington D.C., West Virginia.	U.S. Postal Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, P.O. Box 8635, Chicago, IL 60680-8635. Non-U.S. Postal Delivery Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, 131 S. Dearborn—3rd Floor, Chicago, IL 60603-5517.
Are applying for re-registration and you live in the following states: Arizona, California, Nevada, Oregon, Washington	U.S. Postal Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, P.O. Box 21800, Phoenix, AZ 85036. Non-U.S. Postal Delivery Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, 1820 E. Skyharbor Circle S, Suite 100, Phoenix, AZ 85034.
Are applying for the first time as a late initial registration (this is for all states/territories)	U.S. Postal Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, P.O. Box 8635, Chicago, IL 60680-8635. Non-U.S. Postal Delivery Service: U.S. Citizenship and Immigration Services, Attn: TPS El Salvador, 131 S. Dearborn—3rd Floor, Chicago, IL 60603-5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, or are re-registering for the first time following a grant of TPS by an IJ or the BIA, please mail your application to the appropriate address in Table 1. When submitting a re-registration application and/or requesting an EAD based on an IJ/BIA grant of TPS, please include a copy of the IJ or BIA order granting you TPS with your application. This will aid in the verification of your grant of TPS and processing of your application, as USCIS may not have received records of your grant of TPS by either the IJ or the BIA.

E-Filing

You cannot electronically file your application when re-registering or submitting an initial registration for El Salvador TPS. Please mail your application to the mailing address listed in Table 1.

Supporting Documents

The filing instructions on the Application for Temporary Protected Status (Form I-821) list all the documents needed to establish basic eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying or registering for TPS on the USCIS Web site at www.uscis.gov/tps under "El Salvador."

Do I need to submit additional supporting documentation?

If one or more of the questions listed in Part 4, Question 2 of the Application for Temporary Protected Status (Form I-821) applies to you, then you must submit an explanation on a separate sheet(s) of paper and/or additional documentation.

Employment Authorization Document (EAD)

How can I obtain information on the status of my EAD request?

To get case status information about your TPS application, including the status of a request for an EAD, you can check Case Status Online at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833). If your Application for Employment Authorization (Form I-765) has been pending for more than 90 days and you still need assistance, you may request an EAD inquiry appointment with USCIS by using the InfoPass system at <https://infopass.uscis.gov>. However, we strongly encourage you first to check Case Status Online or call the USCIS

National Customer Service Center for assistance before making an InfoPass appointment.

Am I eligible to receive an automatic 6-month extension of my current EAD through March 9, 2017?

Provided that you currently have TPS under the designation of El Salvador, this Notice automatically extends your EAD by 6 months if you:

- Are a national of El Salvador (or an alien having no nationality who last habitually resided in El Salvador);
- Received an EAD under the last extension of TPS for El Salvador; and
- Have an EAD with a marked expiration date of September 9, 2016, bearing the notation "A-12" or "C-19" on the face of the card under "Category."

Although this Notice automatically extends your EAD through March 9, 2017, you must re-register timely for TPS in accordance with the procedures described in this Notice if you would like to maintain your TPS.

When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Employment Eligibility Verification (Form I-9)?

You can find a list of acceptable document choices on the "Lists of Acceptable Documents" for Employment Eligibility Verification (Form I-9). You can find additional detailed information on the USCIS I-9 Central Web page at <http://www.uscis.gov/I-9Central>. Employers are required to verify the identity and employment authorization of all new employees by using Employment Eligibility Verification (Form I-9). Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization) or one document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). Or you may present an acceptable receipt for List A, List B, or List C documents as described in the Employment Eligibility Verification (Form I-9) Instructions. An EAD is an acceptable document under "List A." Employers may not reject a document based on a future expiration date.

If your EAD has an expiration date of September 9, 2016, and states "A-12" or "C-19" under "Category," it has been extended automatically for 6 months by virtue of this **Federal Register** Notice, and you may choose to present your

EAD to your employer as proof of identity and employment authorization for Employment Eligibility Verification (Form I-9) through March 9, 2017 (see the subsection titled "How do my employer and I complete the Employment Eligibility Verification (Form I-9) using an automatically extended EAD for a new job?" for further information). To minimize confusion over this extension at the time of hire, you should explain to your employer that USCIS has automatically extended your EAD through March 9, 2017. You may also show your employer a copy of this **Federal Register** Notice confirming the automatic extension of employment authorization through March 9, 2017. As an alternative to presenting your automatically extended EAD, you may choose to present any other acceptable document from List A, a combination of one selection from List B and one selection from List C, or a valid receipt.

What documentation may I show my employer if I am already employed but my current TPS-related EAD is set to expire?

Even though EADs with an expiration date of September 9, 2016, that state "A-12" or "C-19" under "Category" have been automatically extended for 6 months by this **Federal Register** Notice, your employer will need to ask you about your continued employment authorization once September 9, 2016, is reached to meet its responsibilities for Employment Eligibility Verification (Form I-9). Your employer may need to reinspect your automatically extended EAD to check the expiration date and code to record the updated expiration date on your Form I-9 if he or she did not keep a copy of this EAD when you initially presented it. However, your employer does not need a new document to reverify your employment authorization until March 9, 2017, the expiration date of the automatic extension. Instead, you and your employer must make corrections to the employment authorization expiration dates in Section 1 and Section 2 of Employment Eligibility Verification (Form I-9) (see the subsection titled "What corrections should my current employer and I make to Employment Eligibility Verification (Form I-9) if my EAD has been automatically extended?" for further information). In addition, you may also show this **Federal Register** Notice to your employer to explain what to do for Employment Eligibility Verification (Form I-9).

By March 9, 2017, the expiration date of the automatic extension, your employer must reverify your

employment authorization. At that time, you must present any document from List A or any document from List C on Employment Eligibility Verification (Form I-9) to reverify employment authorization, or an acceptable List A or List C receipt described in the Employment Eligibility Verification (Form I-9) Instructions. Your employer should complete either Section 3 of the Employment Eligibility Verification (Form I-9) originally completed for you or, if this Section has already been completed or if the version of Employment Eligibility Verification (Form I-9) has expired (check the date in the upper right-hand corner of the form), complete Section 3 of a new Employment Eligibility Verification (Form I-9) using the most current version. Note that employers may not specify which List A or List C document employees must present, and cannot reject an acceptable receipt.

Can my employer require that I produce any other documentation to prove my status, such as proof of my Salvadoran citizenship?

No. When completing Employment Eligibility Verification (Form I-9), including re-verifying employment authorization, employers must accept any documentation that appears on the "Lists of Acceptable Documents" for Employment Eligibility Verification (Form I-9) that reasonably appears to be genuine and that relates to you or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the "Lists of Acceptable Documents." Therefore, employers may not request proof of Salvadoran citizenship or proof of re-registration for TPS when completing Employment Eligibility Verification (Form I-9) for new hires or reverifying the employment authorization of current employees. If presented with EADs that have been automatically extended, employers should accept such EADs as valid List A documents so long as the EADs reasonably appear to be genuine and to relate to the employee. Refer to the *Note to Employees* section of this Notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

What happens after March 9, 2017, for purposes of employment authorization?

After March 9, 2017, employers may no longer accept the EADs that this **Federal Register** Notice automatically

extended. Before that time, however, USCIS will endeavor to issue new EADs to eligible TPS re-registrants who request them. These new EADs will have an expiration date of March 9, 2018, and can be presented to your employer for completion of Employment Eligibility Verification (Form I-9). Alternatively, you may choose to present any other legally acceptable document or combination of documents listed on the Employment Eligibility Verification (Form I-9).

How do my employer and I complete Employment Eligibility Verification (Form I-9) using an automatically extended EAD for a new job?

When using an automatically extended EAD to complete Employment Eligibility Verification (Form I-9) for a new job prior to March 9, 2017, you and your employer should do the following:

1. For Section 1, you should:
 - a. Check "An alien authorized to work;"
 - b. Write your alien number (USCIS number or A-number) in the first space (your EAD or other document from DHS will have your USCIS number or A-number printed on it; the USCIS number is the same as your A-number without the A prefix); and
 - c. Write the automatically extended EAD expiration date (March 9, 2017) in the second space.
2. For Section 2, employers should record the:
 - a. Document title;
 - b. Document number; and
 - c. Automatically extended EAD expiration date (March 9, 2017).

By March 9, 2017, employers must reverify the employee's employment authorization in Section 3 of the Employment Eligibility Verification (Form I-9).

What corrections should my current employer and I make to Employment Eligibility Verification (Form I-9) if my EAD has been automatically extended?

If you are an existing employee who presented a TPS-related EAD that was valid when you first started your job, but that EAD has now been automatically extended, your employer may need to reinspect your automatically extended EAD if your employer does not have a copy of the EAD on file, and you and your employer should correct your previously completed Employment Eligibility Verification (Form I-9) as follows:

1. For Section 1, you should:
 - a. Draw a line through the expiration date in the second space;
 - b. Write "March 9, 2017" above the previous date;

- c. Write "TPS Ext." in the margin of Section 1; and
- d. Initial and date the correction in the margin of Section 1.

2. For Section 2, employers should:
 - a. Draw a line through the expiration date written in Section 2;

- b. Write "March 9, 2017" above the previous date;
 - c. Write "TPS Ext." in the margin of Section 2; and
 - d. Initial and date the correction in the margin of Section 2.

By March 9, 2017, when the automatic extension of EADs expires, employers must reverify the employee's employment authorization in Section 3.

If I am an employer enrolled in E-Verify, what do I do when I receive a "Work Authorization Documents Expiration" alert for an automatically extended EAD?

E-Verify automated the verification process for employees whose TPS status was automatically extended in a **Federal Register** Notice. If you have an employee who is a TPS beneficiary who provided a TPS-related EAD when he or she first started working for you, you will receive a "Work Authorization Documents Expiring" case alert when the auto-extension period for this EAD is about to expire. By March 9, 2017, you must reverify employment authorization in Section 3. Employers should not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888-464-4218 (TTY 877-875-6028) or email USCIS at I-9Central@dhs.gov. Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process, employers may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Employer Hotline at 800-255-8155 (TTY 800-237-2515), which offers language interpretation in numerous languages, or email OSC at oscrcrt@usdoj.gov.

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888-897-7781 (TTY 877-875-6028) or email at I-9Central@dhs.gov. Calls are accepted in English and many other languages. Employees or applicants may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Worker Information Hotline at 800-255-7688 (TTY 800-237-2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, or for information regarding discrimination related to Employment Eligibility Verification (Form I-9) and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Employment Eligibility Verification (Form I-9) Instructions. Employers may not require extra or additional documentation beyond what is required for Employment Eligibility Verification (Form I-9) completion. Further, employers participating in E-Verify who receive an E-Verify case result of "Tentative Nonconfirmation" (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Employment Eligibility Verification (Form I-9) differs from Federal or State government records.

Employers may not terminate, suspend, delay training, withhold pay, lower pay or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888-897-7781 (TTY 877-875-6028). An employee that believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker

Information Hotline at 800-255-7688 (TTY 800-237-2515). Additional information about proper nondiscriminatory Employment Eligibility Verification (Form I-9) and E-Verify procedures is available on the OSC Web site at <http://www.justice.gov/crt/about/osc/> and the USCIS Web site at <http://www.dhs.gov/E-verify>.

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each State may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS. Examples are:

- (1) Your unexpired EAD that has been automatically extended or your EAD that has not expired;
- (2) A copy of this **Federal Register** Notice if your EAD is automatically extended under this Notice;
- (3) A copy of your Application for Temporary Protected Status Notice of Action (Form I-797) for this re-registration;
- (4) A copy of your past or current Application for Temporary Protected Status Notice of Action (Form I-797), if you received one from USCIS; and/or
- (5) If there is an automatic extension of work authorization, a copy of the fact sheet from the USCIS TPS Web site that provides information on the automatic extension.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to verify the current immigration status of applicants for public benefits. If such an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person

interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at <http://www.uscis.gov/save>, then by choosing "For Benefit Applicants" from the menu on the left and selecting "Questions about your Records?"

[FR Doc. 2016-15802 Filed 7-7-16; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5907-N-28]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 402-3970; TTY number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: June 30, 2016.

Brian P. Fitzmaurice,
Director, Division of Community Assistance,
Office of Special Needs Assistance Programs.

[FR Doc. 2016-16017 Filed 7-7-16; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[LLCOS05000.L13100000.DB0000.16X]

Notice of Availability of the Final Environmental Impact Statement for the Bull Mountain Unit Master Development Plan, Gunnison County, CO**AGENCY:** Bureau of Land Management, Interior.**ACTION:** Notice.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, and the Mineral Leasing Act of 1920 (MLA), as amended, the Bureau of Land Management (BLM) prepared a Final Environmental Impact Statement (EIS) for the Bull Mountain Unit Master Development Plan (MDP) and by this notice is announcing its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days after the date the Environmental Protection Agency publishes its Notice of Availability for the Bull Mountain MDP Final EIS in the **Federal Register**.

ADDRESSES: Copies of the Bull Mountain MDP Final EIS are available for public inspection at the Uncompahgre Field Office, 2465 South Townsend Ave., Montrose, CO 81401. Interested persons may also review the Final EIS on the project Web site at www.blm.gov/co/st/en/BLM_Information/nepa/ufo/Bull_Mountain_EIS.html.

FOR FURTHER INFORMATION CONTACT: Gina Jones, Southwest District NEPA Coordinator; telephone (970) 240-5300; Uncompahgre Field Office, 2465 South Townsend Ave., Montrose, CO 81401; email gmjones@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, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: SG Interests I, Ltd. (SGI) submitted a master development plan proposal, the Bull Mountain MDP, to the BLM's Uncompahgre Field Office for its Bull Mountain Unit. The MDP covers natural gas exploration and development within the Bull Mountain Unit. An MDP provides information common to

multiple planned wells, including drilling plans, Surface Use Plans of Operations, and plans for future production in order to guide that development going forward. The MDP allows SGI to exercise their lease rights, while drilling in a manner that limits the impacts to natural resources in the area.

The Bull Mountain Unit MDP Final EIS analyzed the environmental impacts of the exploration and development of up to 146 natural gas wells, four water disposal wells, and associated infrastructure on Federal and private mineral leases within a federally unitized area known as the Bull Mountain Unit. SGI developed the unit after exploration wells demonstrated the potential for economically viable reserves of natural gas.

The Bull Mountain Unit is located within the Colorado River basin, approximately 30 miles northeast of the town of Paonia, and is bisected by State Highway 133. The boundaries of the unit encompass approximately 19,670 acres of Federal and private oil and gas mineral estate in Gunnison County, CO. The unit consists of 440 acres of federally owned surface lands and mineral estate administered by the BLM; 12,900 acres of split-estate lands, consisting of private surface and BLM-administered Federal mineral estate; and 6,330 acres of fee land, consisting of private surface and private mineral estate.

Work on the MDP began with a preliminary Environmental Assessment (EA) in 2008. In 2012, the BLM determined that an EIS was necessary, due to potential significant impacts to air quality in nearby Class I air sheds, water, socioeconomics, and wildlife. The BLM released the Draft EIS for a 45-day public comment period on January 16, 2015. The comment period was subsequently extended for an additional 45 days and closed on April 16, 2015. The BLM held one public meeting on February 10, 2015, and received 565 unique comment letters and 83 form letters. The BLM carefully reviewed and responded to those comments as part of the development of the Final EIS.

To comply with the Endangered Species Act, the BLM consulted with the U.S. Fish and Wildlife Service (USFWS) for two threatened species—greenback cutthroat trout and the Canada Lynx. The USFWS concurred with the BLM's finding that the proposed action "may affect, but is not likely to adversely affect" the greenback cutthroat trout and the Canada Lynx, or designated habitat for either species. To comply with Section 106 of the National Historic Preservation Act, the BLM

consulted with the Colorado State Historic Preservation Office (SHPO) and interested Indian Tribes. The SHPO concurred with the BLM's finding of no effect on historic properties.

The Final EIS analyzes a reasonable range of alternatives, including a No Action Alternative (Alternative A), the proposed action (Alternative B), and a modified action (Alternative C). Based on the public comment received, additional internal reviews were completed by the BLM; updated information was provided by SGI; the BLM added clarifying text to the Final EIS; and the BLM developed an additional alternative, Alternative D, which was selected as the preferred alternative. Alternative D includes additional design features that specifically address impacts to air resources and air quality-related resource values, water resources, and wildlife.

Alternative D is also the environmentally preferred alternative, because it best achieves the following:

- Satisfies statutory requirements (true for all alternatives);
- Represents what the BLM believes to be the best combination of action alternatives analyzed in the EIS and best meets the purpose and need for action, as described in Chapter 1 of the Final EIS;
- Provides the best approach to address key resource and planning issues;
- Provides resource protection and a viable strategy for development of the mineral resources in the area;
- Responds to the public comments received; and
- Reflects input from cooperating agencies, stakeholders, the public, and BLM resource specialists.

Alternative D is within the scope of the Alternatives analyzed in the Draft EIS.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016-16090 Filed 7-7-16; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-BSD-CONC-20917;
PPWOBSDCO, PPMVSCS1Y.Y00000(166)]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Commercial Use Authorizations

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) 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 IC is scheduled to expire on August 31, 2016. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: You must submit comments on or before August 8, 2016.

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_Submission@omb.eop.gov* (email). Please provide a copy of your comments to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, Room 2C114, Mail Stop 242, Reston, VA 20192 (mail); or *madonna_baucum@nps.gov* (email). Please include “1024-0268 CUA” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Samantha Towery, National Park Service, 12795 West Alameda Parkway, Lakewood, CO 80228; by fax at (303) 987-6901; or via email at *Samantha_Towery@nps.gov*. 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:

I. Abstract

The purpose of this information collection is to assist the NPS in managing the Commercial Use Authorization Program. Conducting commercial operations in a unit of the National Park System without a contract, permit, commercial use authorization, or some other written agreement is prohibited. Section 418, Public Law 105-391 (54 U.S.C. 101925) gives the Secretary of the Interior the authority to authorize a private person, corporation, or other entity to provide

services to visitors in units of the National Park System through a Commercial Use Authorization (CUA). Such authorizations are not considered concession contracts. We authorize commercial operations that originate and operate entirely within a park (in-park); commercial operations that provide services originating and terminating outside of the park boundaries; organized children’s camps, outdoor clubs, and nonprofit institutions; and other uses as the Secretary determines appropriate. The commercial operations include a range of services, such as mountain climbing guides, boat repair services, transportation services and tours, canoe livery operations, hunting guides, retail sales, equipment rentals, catering services, and dozens of other visitor services.

Section 418 limits CUAs to:

- Commercial operations with annual gross receipts of not more than \$25,000 resulting from services originating and provided solely within a unit of the National Park System;
- Incidental use of resources of the unit by commercial operations which provide services originating and terminating outside of the boundaries of the unit; or
- Uses by organized children’s camps, outdoor clubs and nonprofit institutions (including back country use) and such other uses as the Secretary determines appropriate.

The legislative mandate of the NPS, found at 54 U.S.C. 1100101, is to preserve America’s natural wonders unimpaired for future generations, while also making them available for the enjoyment of visitors. Meeting this mandate requires the NPS to balance preservation with use. Maintaining a good balance requires both information and limits. The information requested will allow the unit manager to evaluate requests for a commercial use to determine impact on the resources and the appropriateness of the activity.

We collect information on the CUA Application (Form 10-550), the CUA Annual Report (Form 10-660), and CUA Monthly Report (Form 10-660A). We use the information from these forms to:

- Manage the program and operations.

- Determine the qualifications and abilities of the commercial operators to provide a high quality, safe, and enjoyable experience for park visitors.

- Determine the impact on the parks natural and cultural resources.
- Manage the use and impact of multiple operators.

The information requested will allow the NPS to evaluate requests for a commercial use authorization and determine the suitability of the applicants to safely and effectively provide an appropriate service to the visiting public. It will also enable the NPS to manage the activity in a manner that protects the natural and cultural resources and the park visitor. Management includes, but is not limited to, managing the number of permits issued, determining the location and time that the activity occurs, and requiring the appropriate visitor protections including insurance, equipment, training, and procedures.

Regulations Resulting in Information Collection Required for a Commercial Use Authorization

- 36 CFR 1.6—Permits
- 36 CFR 2—Resource Protection, Public Use and Recreation
- 36 CFR 5—Commercial and Private Operations.
- 36 CFR 7—Special Regulations,
- 36 CFR Sec. 13—National Park System Units in Alaska

II. Data

OMB Number: 1024-0268.

Title: Commercial Use Authorization.

Form(s): 10-550, “Commercial Use Authorization Application and Instructions”, 10-660, “Commercial Use Authorization Annual Report and Instructions”, and 10-660A, “Commercial Use Authorization Monthly Report and Instructions”.

Type of Request: Revision to a Currently Approved Collection.

Description of Respondents: Respondents will be businesses that wish to provide a commercial service to visitors in areas of the National Park System.

Respondent Obligation: Required to Obtain or Retain a Benefit.

	Annual respondents	Total annual responses	Average time per response (hours)	Total annual burden hours
Form 10-550, “Commercial Use Authorization Application and Instructions”				
Private Sector	5,900	5,900	2.5	14,750

	Annual respondents	Total annual responses	Average time per response (hours)	Total annual burden hours
Form 10-660, "Commercial Use Authorization Annual Report and Instructions"				
Private Sector	5,900	5,900	1.25	7,375
Form 10-660A, "Commercial Use Authorization Monthly Report and Instructions"				
Private Sector	5,900	53,100	.75	39,825
Totals	17,700	64,900	61,950

Estimated Annual Nonhour Burden Cost: \$590,000 (\$100 × 5,900 Forms 10-550, "Commercial Use Authorization Application and Instructions" per year).

III. Comments

On January 11, 2016, we published in the **Federal Register** (80 FR 1202) a Notice requesting public comment on this information collection. The comment period ended on March 11, 2016. We received five comments in response to this Notice, all of which concerned the new requirement of form 10-660A, CUA Monthly Reporting at Katmai National Park. Commenters stated that the additional reporting requirement would create excess burden on CUA holders during a very busy and short operating season. They also expressed concern that the requirement to report visitation numbers would result in duplicate reporting since most park visitors utilized the services of more than one CUA holder.

NPS Response/Action Taken: NPS must strictly manage some CUA activities by imposing restrictions such as daily visitor limits to protect sensitive natural and cultural resources. Parks may require the submission of the CUA Monthly Report to more closely track these CUA activities and associated visitor use to ensure that maximum daily limits and seasonal average limits are not exceeded. By closely monitoring this information, the parks can also ensure that commercial operators do not exceed the authorized use before the end of the season and create a gap when prospective visitors cannot be accommodated.

Additionally, in Katmai National Park only, CUA holders that provide transportation are required to submit the CUA Monthly report in addition to the CUA Annual Report. The vast majority of visitors access the park by plane or boat operated by authorized commercial service providers and there are no entrance stations to track the number of visitors. The CUA Monthly reports provide the only means of securing an accurate visitor count and are used to influence short-term resource

management decisions. By requiring only those authorized transportation providers to submit the CUA Monthly report, duplicate reporting is eliminated. The decision to limit the requirement of monthly reporting to only those CUA holders providing transportation was reached after public meetings held with current and prospective CUA holders. The NPS did not make any changes to our information collection based on these comments.

We also received a comment from Jean Public. The commenter did not address the information collection requirements, but stated that the Government should charge CUA holders fees to operate on public lands. NPS is legally required to charge a fee for commercial operations [section 418, Pub. L. 105-391 (54 U.S.C. 101925)]. Parks, at a minimum, charge a fee to recover costs associated with the management and administration of CUAs. We did not make any changes to our information collection based on this comment.

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, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying

information from public review, we cannot guarantee that it will be done.

Dated: July 1, 2016.

Madonna L. Baucum,
Information Collection Clearance Officer,
National Park Service.

[FR Doc. 2016-16208 Filed 7-7-16; 8:45 am]

BILLING CODE 4310-EH-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRSS-EQD-SSB-21470; PPSESERON2, PPMRSNR1N.NM0000 (166)]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Cape Lookout National Seashore Cultural Resource Values and Vulnerabilities Assessment

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) 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. 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: To ensure that your comments on this ICR are considered, OMB must receive them on or before August 8, 2016.

ADDRESSES: Please direct all written comments on this ICR directly to the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of the Interior, to *OIRA_Submission@omb.eop.gov* (email) or 202-395-5806 (fax); and identify your submission as 1024-CALOSURV. Please also send a copy of your comments to Phadrea

Ponds, Information Collection Coordinator, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525 (mail); or phadrea_ponds@nps.gov (email). Please reference Information Collection 1024—CALOSURV in the subject line.

FOR FURTHER INFORMATION CONTACT: Phadrea Ponds, Information Collection Coordinator, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525 (mail); or phadrea_ponds@nps.gov (email). Please reference Information Collection 1024—CALOSURV in the subject line. You may also access this ICR at www.reginfo.gov.

I. Abstract

Managers of Cape Lookout National Seashore (CALO) are interested in identifying ways to reduce the risk of damage to coastal buildings and sensitive species from storm surge, sea level rise, and shoreline erosion anticipated over the next 20 to 30 years. Of specific interest to managers are contemporary cultural resource values and perceptions of cultural resource vulnerability and feasible adaptation strategies to sustain its cultural resources for future generations. The National Park Service will conduct a survey with members of CALO's partner organizations and cultural resource experts from federal and state agencies and nongovernmental organizations.

The collection will be used to understand the values these stakeholders place on cultural resources within the historic districts, and perceptions of strategies to adapt and respond to changes in cultural resource conditions from storms, flooding, and erosion. The information from this collection will provide NPS managers with information that can be used to prepare resource management planning documents.

II. Data

OMB Control Number: 1024—New.

Title: Cape Lookout National Seashore Cultural Resource Values and Vulnerabilities Assessment.

Type of Request: New collection.

Affected Public: Federal, state and local government and nongovernmental, members of partner organizations and academic faculty with cultural resource expertise in historic preservation.

Respondent Obligation: Voluntary.

Frequency of Collection: One time.

Estimated Number of Responses: 260.

Estimated Annual Burden Hours: 65 hours. We estimate the public reporting burden for The Partner Survey to be 15 minutes per response and 45 minutes per response for the Expert Survey. This

includes the time for reviewing instructions and completing the survey.

Estimated Annual Reporting and Recordkeeping "Non-Hour Cost": None.

III. Request for Comments

A notice was published in the **Federal Register** (80 FR 29334) on May 21, 2015 stating that we intended to request OMB approval of our information collection associated with the Cape Lookout National Seashore Cultural Resource Values and Vulnerabilities Assessment project. In this notice, we solicited public comment for 60 days ending June 8, 2015. We did not receive any comments in response to that notice.

We again invite comments concerning this information collection on:

- Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful;
- The accuracy of the agency's estimate of the burden of the proposed collection of information;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: July 1, 2016.

Madonna L. Baucum

*Information Collection Clearance Officer,
National Park Service.*

[FR Doc. 2016-16209 Filed 7-7-16; 8:45 am]

BILLING CODE 4310-EH-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NEO-CACO-21348; PPNECACOS0, PPMPSD1Z.YM0000]

Notice of September 19, 2016, Meeting for Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: This notice sets forth the date of the 303rd Meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The public meeting of the Cape Cod National Seashore Advisory Commission will be held on Monday, September 19, 2016, at 1:00 p.m. (EASTERN).

ADDRESSES: The 303rd meeting of the Cape Cod National Seashore Advisory Commission will take place on Monday, September 19, 2016, at 1:00 p.m., in the conference room at park headquarters, 99 Marconi Site Road, Wellfleet, Massachusetts 02667 to discuss the following:

1. Adoption of Agenda
2. Reports of Officers
3. Reports of Subcommittees
 - Update of Pilgrim Nuclear Plant Emergency Planning Subcommittee
 - Nickerson Fellowship
4. Superintendent's Report
 - Update From U.S. Army Corps of Engineers About Next Steps for FUDS (Formerly Used Defense Sites)
 - Examination of Un-Exploded Ordnance
 - Former Camp Wellfleet Update on Horton's Campground Private Commercial Properties Related to Their Certificates of Suspension From Condemnation
 - Storm Damage/Erosion Update
 - Shorebird Management Plan/Environmental Assessment—Update
 - Seashore Projects
 - Nauset Spit Update
 - National Park Service Centennial Improved Properties/Town Bylaws
 - Herring River Wetland Restoration
 - Highlands Center Update
 - Ocean Stewardship Topics—Shoreline Change
 - Climate Friendly Parks
5. Old Business
 - Live Lightly Campaign Progress Report
6. New Business
7. Date and Agenda for Next Meeting
8. Public Comment
9. Adjournment

FOR FURTHER INFORMATION CONTACT:

Further information concerning the meeting may be obtained from George E. Price, Jr., Superintendent, Cape Cod National Seashore, 99 Marconi Site, Wellfleet, Massachusetts 02667, or via telephone at (508) 771-2144 or by email at george_price@nps.gov.

SUPPLEMENTARY INFORMATION: The Commission was reestablished pursuant to Public Law 87-126, as amended by Public Law 105-280. The purpose of the Commission is to consult with the Secretary of the Interior, or her designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members. Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Alma Rippis,

Chief, Office of Policy.

[FR Doc. 2016–16139 Filed 7–7–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKRO–DENA–21466; PPAKAKROR4; PPMRLE1Y.LS0000]

Notice of an Open Public Meeting for the National Park Service Alaska Region Subsistence Resource Commission Program

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: As required by the Federal Advisory Committee Act (16 U.S.C. Appendix 1–16), the National Park Service (NPS) is hereby giving notice that the Denali National Park Subsistence Resource Commission (SRC) will hold a public meeting to develop and continue work on NPS subsistence program recommendations, and other related regulatory proposals and resource management issues. The NPS SRC program is authorized under title VIII, section 808 of the Alaska National Interest Lands Conservation Act, Public Law 96–487.

DATES: The Denali National Park SRC will meet from 10:30 a.m. to 5:00 p.m. or until business is completed on Tuesday, August 2, 2016.

ADDRESSES: The Denali National Park SRC will meet at Friday Creek at the Kantishna Yurt in Denali National Park, AK.

For more detailed information regarding this meeting, or if you are interested in applying for SRC

membership, contact Designated Federal Official Donald Striker, Superintendent, at (907) 683–9581, or via email at don_striker@nps.gov or Amy Craver, Subsistence Manager at (907) 644–3604 or by email at amy_craver@nps.gov or Clarence Summers, Subsistence Manager, at (907) 644–3603 or via email at clarence_summers@nps.gov.

Proposed Meeting Agenda: The agenda may change to accommodate SRC business. The proposed meeting agenda includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introductions
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Superintendent's Welcome and Review of the SRC Purpose
6. SRC Membership Status
7. SRC Chair and Members' Reports
8. Superintendent's Report
9. Old Business
10. New Business
11. Federal Subsistence Board Update
12. Alaska Boards of Fish and Game Update
13. National Park Service Reports
 - a. Ranger Update
 - b. Resource Manager's Report
 - c. Subsistence Manager's Report
14. Public and Other Agency Comments
15. Work Session
16. Set Tentative Date and Location for Next SRC Meeting
17. Adjourn Meeting

SRC meeting locations and dates may change based on inclement weather or exceptional circumstances. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and radio stations to announce the rescheduled meeting.

SUPPLEMENTARY INFORMATION: The meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we

cannot guarantee that we will be able to do so.

Alma Rippis,

Chief, Office of Policy.

[FR Doc. 2016–16138 Filed 7–7–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02013000, 16XR0680G3, RX178511101000000]

Notice of Availability for the Final Environmental Impact Statement/Environmental Impact Report for the Mendota Pool Bypass and Reach 2B Improvements Project

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation and the California State Lands Commission have prepared the Mendota Pool Bypass and Reach 2B Improvements Project Final Environmental Impact Statement/Environmental Impact Report (EIS/EIR). The Mendota Pool Bypass and Reach 2B Improvements Project is a component of Phase 1 of the San Joaquin River Restoration Program which seeks to restore flows to the San Joaquin River from Friant Dam to the confluence of the Merced River, and restore a self-sustaining Chinook salmon fishery in the river while reducing or avoiding adverse water supply impacts associated with restoration flows. The Project includes the construction, operation, and maintenance of the Mendota Pool Bypass and improvements in the San Joaquin River channel in Reach 2B to contribute to achieving the San Joaquin River Restoration Program's Restoration Goal.

DATES: The Bureau of Reclamation (Reclamation) will not issue a final decision on the proposed action until at least 30 days after the date that the Environmental Protection Agency releases the Final EIS/EIR. After the EIS/EIR has been available for 30 days, Reclamation will complete a Record of Decision. The Record of Decision will state the action that Reclamation will implement and will discuss all factors considered in the decision.

ADDRESSES: Send written correspondence or requests for copies or a compact disc of the Final EIS/EIR to Ms. Becky Victorine, Bureau of Reclamation, San Joaquin River Restoration Program, 2800 Cottage Way, Room W–1727, Sacramento, California

95825, via email to rvictorine@usbr.gov, or by calling (916) 978-4624.

The Final EIS/EIR may be viewed on Reclamation's Web site at http://www.usbr.gov/mp/nepa/nepa_projdetails.cfm?Project_ID=4032. See the Supplementary Information section for locations where copies of the Final EIS are available for public review.

FOR FURTHER INFORMATION CONTACT: Ms. Katrina Harrison, Program Engineer, Bureau of Reclamation, via email at kharrison@usbr.gov, or at (916) 978-5465; or Chris Huitt, California State Lands Commission, via email at christopher.huitt@slc.ca.gov, or at (916) 574-2080.

SUPPLEMENTARY INFORMATION: The San Joaquin River Restoration Program (SJRRP) was established in late 2006 to implement the Stipulation of Settlement (Settlement) in *Natural Resources Defense Council, et al. v. Kirk Rodgers, et al.* The Mendota Pool Bypass and Reach 2B Improvements Project (Project) consists of establishing a floodplain width which would be capable of conveying at least 4,500 cubic feet per second (cfs), a method to bypass restoration flows around Mendota Pool, and a method to deliver water to Mendota Pool. The Project footprint extends from approximately 0.3 mile above the Chowchilla Bypass Bifurcation Structure to approximately one mile below the Mendota Dam in the area of Fresno and Madera counties, near the town of Mendota, California. This Final EIS/EIR has been prepared in coordination with the parties to the Settlement and the SJRRP Implementing Agencies, including the U.S. Fish and Wildlife Service, National Marine Fisheries Service, State of California Department of Water Resources, and State of California Department of Fish and Wildlife. National Marine Fisheries Service, U.S. Environmental Protection Agency, and the U.S. Army Corps of Engineers have been cooperating agencies in preparation of the Final EIS/EIR.

The EIS/EIR analyzes five alternatives. Under the No-Action Alternative, the Project would not be implemented. Although future conditions would not include the components described below in the Action Alternatives, other components of the SJRRP would be implemented following completion and receipt of appropriate environmental reviews and approvals, as necessary. Likely future conditions include implementation of the other components of the SJRRP selected alternative, as described in the 2012 Record of Decision and analyzed in the SJRRP Program EIS/EIR,

including Restoration Flows similar to those that started January 2014, and other reasonably foreseeable actions expected to occur in the Project area.

Four Action Alternatives are analyzed in the EIS/EIR: Alternative A (Compact Bypass with Narrow Floodplain and South Canal), Alternative B (Compact Bypass with Consensus-Based Floodplain and Bifurcation Structure), Alternative C (Fresno Slough Dam with Narrow Floodplain and Short Canal), and Alternative D (Fresno Slough Dam with Wide Floodplain and North Canal). All four Action Alternatives are designed to provide conveyance of at least 4,500 cfs in Reach 2B and through the Mendota Pool Bypass, and diversion and screening of up to 2,500 cfs from Reach 2B into Mendota Pool. Constructed elements common to the Action Alternatives include the provision of fish habitat and passage, seepage control measures, removal of existing levees and structures, and levee and structure construction and modification, among other activities.

Alternative B (Compact Bypass with Consensus-Based Floodplain and Bifurcation Structure) [PREFERRED ALTERNATIVE], would construct the Compact Bypass Channel between Reach 2B and Reach 3 to bypass the Mendota Pool. Restoration Flows would enter Reach 2B at the Chowchilla Bifurcation Structure, flow through Reach 2B, then downstream to Reach 3 via the Compact Bypass Channel. The existing Chowchilla Bifurcation Structure would continue to divert San Joaquin River flows into the Chowchilla Bypass during flood operations, and a fish passage facility and control structure modifications would be included at the San Joaquin River control structure at the Chowchilla Bypass. A bifurcation structure would be built at the head of the Compact Bypass Channel to control diversions into Mendota Pool. Fish passage facilities would be built at the Compact Bypass bifurcation structure to provide passage around the structure and prevent fish being entrained in the diversion. The San Mateo Avenue crossing would be removed.

A Notice of Availability for the Draft EIS/EIR was published in the **Federal Register** on June 9, 2015 (80 FR 32604). The comment period for the Draft EIS/EIR ended on August 10, 2015. Public meetings on the Draft EIS/EIR were held on Wednesday, July 8, 2015, from 6 to 9 p.m., in Fresno, CA; Thursday, July 9, 2015, from 6 to 9 p.m., in Los Banos, CA; and Friday, July 10, 2015, from 9 a.m. to 12 noon, in Sacramento, CA. The Final EIS/EIR contains responses to all comments received and reflects

comments and any additional information received during the review period.

Copies of the Final EIS/EIR are available for public review at the following locations:

1. Bureau of Reclamation, Mid-Pacific Region, Regional Library, 2800 Cottage Way, Sacramento, CA 95825.
2. Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW., Main Interior Building, Washington, DC 20240-0001.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in any communication, you should be aware that your entire communication—including your personal identifying information—may be made publicly available at any time. While you can ask us in your communication to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: April 13, 2016.

Pablo R. Arroyave,

Deputy Regional Director, Mid-Pacific Region.

[FR Doc. 2016-15891 Filed 7-7-16; 8:45 am]

BILLING CODE 4332-90-P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE-2016-0008; OMB Control Number 1014-0001 164E1700D2 EEEE50000 ET1SF0000.DAQ000]

Information Collection Activities: Oil and Gas Well-Workover Operations; Proposed Collection; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Safety and Environmental Enforcement (BSEE) is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns renewal to the paperwork requirements in the regulations under Subpart F, *Oil and Gas Well-Workover Operations*.

DATES: You must submit comments by September 6, 2016.

ADDRESSES: You may submit comments by either of the following methods listed below.

- *Electronically:* go to www.regulations.gov and search for

BSEE–2016–0008. Follow the instructions to submit public comments and view all related materials. We will post all comments.

- *Email: regs@bsee.gov.* You may also hand-carry comments to the Department of the Interior; BSEE; Regulations and Standards Branch; Attention: Kelly Odom; 45600 Woodland Road, Sterling, Virginia 20166. Please reference ICR 1014–0001 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Kelly Odom, Regulations and Standards Branch at (703) 787–1775 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR part 250, subpart F, Oil and Gas Well-Workover Operations.

OMB Control Number: 1014–0001.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations necessary for the administration of the leasing provisions of the Act related to the mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop mineral resources in a manner that is consistent with the need to make such resources available to meet the Nation’s energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

Section 5(a) of the OCS Lands Act requires the Secretary to prescribe rules and regulations “to provide for the prevention of waste, and conservation of the natural resources of the Outer Continental Shelf, and the protection of correlative rights therein” and to include provisions “for the prompt and efficient exploration and development of a lease area.” These authorities and responsibilities are among those

delegated to BSEE to ensure that operations in the OCS will meet statutory requirements; provide for safety and protection of the environment; and result in diligent exploration, development, and production of OCS leases. This information collection (IC) request addresses the regulations at 30 CFR 250, subpart F, Oil and Gas Well-Workover Operations, and any associated supplementary Notices to Lessees and Operators (NTLs) intended to provide clarification, description, or explanation of these regulations.

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA’s provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

The regulations at 30 CFR 250, Subpart F, Oil and Gas Well-Workover Operations are the subject of this collection. Specifically, BSEE uses the information collected to:

- Review log entries of crew meetings to verify that safety procedures have been properly reviewed.

- Review well-workover procedures relating to hydrogen sulfide (H2S) to ensure the safety of the crew in the event of encountering H2S.

- Review well-workover diagrams and procedures to ensure the safety of well-workover operations.

- Verify that the crown block safety device is operating and can be expected to function and avoid accidents.

- Assure that the well-workover operations are conducted on well casing that is structurally competent.

The BSEE will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2); 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection*; and 30 CFR part 252, *OCS Oil and Gas Information Program*. No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion, weekly, monthly, annually, and varies by section.

Description of Respondents: Potential respondents include Federal OCS oil, gas, and sulphur lessees and holders of pipeline rights-of-way.

Estimated Reporting and Recordkeeping Hour Burden: The current OMB inventory includes 53,156 burden hours for this collection of information. This submission requests 2,941 burden hours. The adjustment decrease of 50,215 hours is due to the publication of the final blowout preventer regulations which moved many of the requirements of Subpart F into the new Subpart G regulations, *Well Operations and Equipment*. There is no non-hour cost burden associated with this collection. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

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BURDEN BREAKDOWN

Citation 30 CFR 250, Subpart F and NTL	Reporting requirement	Hour burden	Average number of annual reponses	Annual burden hours (rounded)
600–620	General departure and alternative compliance requests not specifically covered elsewhere in Subpart F regulations.	Burden covered under 1014–0022.		0
611	Document results weekly of traveling-block safety device in the operations log.	1.5	351 workovers × 3 results = 1,053.	1,580
612	Request establishment/amendment/cancellation of field well-workover rules.	5	23 requests	115

BURDEN BREAKDOWN—Continued

Citation 30 CFR 250, Subpart F and NTL	Reporting requirement	Hour burden	Average number of annual reponses	Annual burden hours (rounded)
613; 616(a)(4); 619(f)	These sections contain references to information, approvals, requests, payments, etc., which are submitted with an APM, the burdens for which are covered under its own information collection.	Burden covered under 1014–0026.		0
613(d)	Submit to District Manager on Form BSEE–0125, End of Operations Report, an operation resulting in the initial recompletion of a well into a new zone, include a new schematic of the tubing sub-surface equipment if subsurface equipment has been changed.	Burden covered under 1014–0018.		0
614(b)	Post number of stands of drill pipe or workover string and drill collars that may be pulled prior to filling the hole and equivalent well-control fluid volume.	0.75	306 postings.	230
NTL	Notify BSEE if sustained casing pressure is observed on a well.	2	508 notifications	1,016
Total Burden	1,890 Responses		2,941

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified no non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency “. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .”. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the

Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

BSEE Information Collection Clearance Officer: Nicole Mason (703) 787–1607.

Dated: June 30, 2016.

Robert W. Middleton,
Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2016–16206 Filed 7–7–16; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–16–024]

Sunshine Act Meeting

AGENCY: United States International Trade Commission.

TIME AND DATE: July 12, 2016 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731–TA–298 (Fourth Review) (Porcelain-on-Steel Cooking Ware from China). The Commission is currently scheduled to complete and file its determination and views of the Commission on July 22, 2016.

5. Outstanding action jackets: None. In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: July 5, 2016.

William R. Bishop,
Supervisory Hearings and Information Officer.

[FR Doc. 2016–16296 Filed 7–6–16; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1058 (Second Review)]

Wooden Bedroom Furniture From China; Scheduling of a Full Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of a full review pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty order on wooden bedroom furniture from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: *Effective Date:* July 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Amy Sherman (202–205–3289), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<http://www.usitc.gov>). The public record for this review may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On February 5, 2016, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review should proceed (81 FR 8991, February 23, 2016); accordingly, a full review is being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners’ votes, the Commission’s statement on adequacy, and any individual Commissioner’s statements are available from the Office of the Secretary and at the Commission’s Web site.

Participation in the review and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission’s rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission’s notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses

of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission’s rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission’s notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the review will be placed in the nonpublic record on October 20, 2016, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission’s rules.

Hearing.—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on Thursday, November 10, 2016, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before November 7, 2016. A nonparty who has testimony that may aid the Commission’s deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on November 8, 2016, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission’s rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the review may submit a prehearing brief to the Commission. Prehearing

briefs must conform with the provisions of section 207.65 of the Commission’s rules; the deadline for filing is October 31, 2016. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission’s rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission’s rules. The deadline for filing posthearing briefs is November 22, 2016. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before November 22, 2016. On December 21, 2016, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before December 23, 2016, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission’s rules. All written submissions must conform with the provisions of section 201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on E-Filing, available on the Commission’s Web site at <http://edis.usitc.gov>, elaborates upon the Commission’s rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission’s rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission’s rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission’s rules.

By order of the Commission.

Issued: July 1, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016-16148 Filed 7-7-16; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Access Control Systems and Components Thereof, DN 3162*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,¹ and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.² The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.³ Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf

of The Chamberlain Group, Inc. ("CGI") on July 5, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain access control systems and components thereof. The complaint names as respondents Techtronic Industries Co. Ltd of Hong Kong; Techtronic Industries North America, Inc. of Hunt Valley, MD; One World Technologies Inc. of Anderson, SC; OWT Industries Inc. of Pickens, SC; Ryobi Technologies, Inc. of Anderson, SC; and Et Technology (Wuxi) Co., Ltd. of China. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3162") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures).⁴ Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.⁵

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: July 5, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016-16225 Filed 7-7-16; 8:45 am]

BILLING CODE 7020-02-P

¹ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

² United States International Trade Commission (USITC): <http://edis.usitc.gov>.

³ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

⁴ Handbook for Electronic Filing Procedures: http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.

⁵ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

DEPARTMENT OF LABOR**Employee Benefits Security Administration****Advisory Council on Employee Welfare and Pension Benefit Plans; Nominations for Vacancies**

Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 88 Stat. 895, 29 U.S.C. 1142, provides for the establishment of an Advisory Council on Employee Welfare and Pension Benefit Plans (the Council), which is to consist of 15 members to be appointed by the Secretary of Labor (the Secretary) as follows: Three representatives of employee organizations (at least one of whom shall be a representative of an organization whose members are participants in a multiemployer plan); three representatives of employers (at least one of whom shall be a representative of employers maintaining or contributing to multiemployer plans); one representative each from the fields of insurance, corporate trust, actuarial counseling, investment counseling, investment management, and accounting; and three representatives from the general public (one of whom shall be a person representing those receiving benefits from a pension plan). No more than eight members of the Council shall be members of the same political party.

Council members shall be persons qualified to appraise the programs instituted under ERISA. Appointments are for terms of three years. The prescribed duties of the Council are to advise the Secretary with respect to the carrying out of his or her functions under ERISA, and to submit to the Secretary, or his or her designee, recommendations with respect thereto. The Council will meet at least four times each year.

The terms of five members of the Council expire at the end of this year. The groups or fields they represent are as follows: (1) Employee organizations; (2) employers; (3) insurance; (4) accounting; and (5) the general public. The Department of Labor is committed to equal opportunity in the workplace and seeks a broad-based and diverse Council.

Accordingly, notice is hereby given that any person or organization desiring to nominate one or more individuals for appointment to the Advisory Council on Employee Welfare and Pension Benefit Plans to represent any of the groups or fields specified in the preceding paragraph may submit nominations to Larry Good, Council Executive

Secretary, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue NW., Suite N-5623, Washington, DC 20210, or as email attachments to good.larry@dol.gov. Nominations (including supporting nominations) must be received on or before August 1, 2016. Please allow two weeks for regular mail delivery to the Department of Labor. If sending electronically, please use an attachment in rich text, Word, or pdf format. Nominations may be in the form of a letter, resolution or petition, signed by the person making the nomination or, in the case of a nomination by an organization, by an authorized representative of the organization.

Nominations, including supporting letters, should:

- State the person's qualifications to serve on the Council.
- State that the candidate will accept appointment to the Council if offered.
- Include which of the five positions (representing groups or fields) the candidate is nominated to fill.
- Include the nominee's full name, work affiliation, mailing address, phone number, and email address.
- Include the nominator's full name, mailing address, phone number, and email address.
- Include the nominator's signature, whether sent by email or otherwise.

Please do not include any information that you do not want publicly disclosed.

In selecting Council members, the Secretary of Labor will consider individuals nominated in response to this **Federal Register** notice, as well as other qualified individuals.

Nominees will be contacted to provide information on their political affiliation and their status as registered lobbyists. Anyone currently subject to federal registration requirements as a lobbyist is not eligible for appointment. Nominees should be aware of the time commitment for attending meetings and actively participating in the work of the Council. Historically, this has meant a commitment of at least 20 days per year. The Department of Labor has a process for vetting nominees under consideration for appointment.

Signed at Washington, DC.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2016-16216 Filed 7-7-16; 8:45 am]

BILLING CODE 4510-29-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16-049)]

NASA Advisory Council; Ad Hoc Task Force on STEM Education Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a meeting of the Ad Hoc Task Force on Science, Technology, Engineering and Mathematics (STEM) of the NASA Advisory Council (NAC). This Task Force reports to the NAC.

DATES: Tuesday, July 26, 2016, 10:00 a.m.–5:15 p.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, 3rd Floor Conference Room, 22800 Cedar Point Road, Cleveland, Ohio 44142, from 10:00 a.m. to 3:15 p.m. From 3:15 p.m. to 5:15 p.m., a joint session with the NAC Science Committee will take place in Industry Room B.

FOR FURTHER INFORMATION CONTACT: Dr. Beverly Girten, Executive Secretary for the NAC Ad Hoc Task Force on STEM Education, NASA Headquarters, Washington, DC 20546, (202) 358-0212, or beverly.e.girten@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. From the start of the meeting on July 26 at 10:00 a.m. until 3:15 p.m., please use the following information: The meeting will be held in the 3rd Floor Conference Room. Any person interested in joining the meeting may dial the toll free access number 844-467-6272 or toll access number 720-259-6462, and then the numeric participant passcode: 329152 followed by the # sign. If dialing in, please "mute" your telephone. To join via WebEx, the link is <https://nasa.webex.com/>, the meeting number is 991 407 556 and the password is STEMEdJuly26! (case sensitive). Beginning at 3:15 p.m. on July 26 until the end of the meeting at 5:15 p.m., for the joint session with the NAC Science Committee, please use the following information: The joint session will be held in Industry Room B. Any person interested in joining the meeting may call the USA toll free conference call number 1-888-790-1716, passcode 4101817, or toll number 1-212-287-

1654, passcode 4101817 followed by the # sign. If dialing in, please “mute” your telephone. The WebEx link is <https://nasa.webex.com/>, the meeting number is 992 934 159 and the password is SC@July2016 (case sensitive).

The agenda for the July 26 meeting will include the following:

- Opening Remarks by Chair
- Interagency Collaborations in Education
- Formulating Findings and Recommendations
- Joint Session with NAC Science Committee
- Other Related Topics

Attendees will be required to sign a register. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016–16184 Filed 7–7–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–047)]

NASA Advisory Council; Institutional Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the Institutional Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Tuesday, July 26, 2016, 8:30 a.m.–5:00 p.m., Local Time; and Wednesday, July 27, 2016, 8:15 a.m.–10:00 a.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, NASA Safety Center (NSC) Conference Room, 22800 Cedar Point Road, Cleveland, Ohio 44142.

FOR FURTHER INFORMATION CONTACT: Mr. Todd Mullins, Executive Secretary for the NAC Institutional Committee, NASA Headquarters, Washington, DC 20546; (202) 358–3831, or todd.mullins@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-

tone phone to participate in this meeting. Any person interested in joining the meeting may dial the toll free access number (844) 467–6272 or toll access number (720) 259–6462, and then the numeric participant passcode: 180093 followed by the # sign. If dialing in, please “mute” your telephone. To join via WebEx on July 26, the web link is <https://nasa.webex.com/>, the meeting number is 991 872 492 and the password is Meeting2016! (case sensitive). To join via WebEx on July 27, the link is <https://nasa.webex.com/>, the meeting number is 991 030 614 and the password is Meeting2016! (case sensitive).

The agenda for the meeting includes the following topics:

- NAC Institutional Committee Work Plan
- Business Systems Assessment Overview Status
- Business Systems Assessment Procurement Implementation Plan
- Business Systems Assessment Human Resources Implementation Plan

Attendees will be required to sign a register. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016–16182 Filed 7–7–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–051)]

NASA Advisory Council; Science Committee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Science Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Monday, July 25, 2016, 1:00 p.m.–5:30 p.m., Local Time; Tuesday, July 26, 2016, 8:45 a.m.—5:15 p.m.;

Local Time; and Wednesday, July 27, 2016, 8:30 a.m.–10:00 a.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, Industry Room B, 22800 Cedar Point Road, Cleveland, Ohio 44142.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779, or ann.b.delo@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting will also be available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any person interested in joining the meeting may call the USA toll free conference call number 1–888–790–1716, passcode 4101817, or toll number 1–212–287–1654, passcode 4101817, for all three days. If dialing in, please “mute” your telephone. The WebEx link is <https://nasa.webex.com/>; the meeting number is 992 934 159 and the password is SC@July2016 (case sensitive) for all three days. The agenda for the meeting includes the following topics:

- Science Mission Directorate Division Updates
- NAC Science Committee Subcommittee Reports
- Planetary Defense Coordination Office
- Harmful Algal Blooms
- Joint Session with the NAC Ad Hoc Task Force on STEM Education

Attendees will be required to sign a register. It is imperative that this meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016–16186 Filed 7–7–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–046)]

NASA Advisory Council; Human Exploration and Operations Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Human Exploration and Operations

(HEO) Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Monday, July 25, 2016, 9:30 a.m.–4:30 p.m.; and Tuesday, July 26, 2016, 8:00 a.m.–2:00 p.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, President's Room, 22800 Cedar Point Road, Cleveland, Ohio 44142.

FOR FURTHER INFORMATION CONTACT: Dr. Bette Siegel, Executive Secretary for the NAC HEO Committee, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2245, or bette.siegel@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person in joining the meeting may dial the toll free access number 1–888–455–6733 or toll access number 1–210–839–8935, and then the numeric participant passcode: 4213809 followed by the #sign. If dialing in, please “mute” your telephone. The WebEx link is <https://nasa.webex.com/>, the meeting number is 990 997 513, and the password is Exploration@2016 (case sensitive).

The agenda for the meeting includes the following topics:

- Status of Human Exploration and Operations Mission Directorate
- Status of Exploration Systems Development
- Status of International Space Station
- International Space Station Research
- Research Subcommittee Update
- Status of Asteroid Redirect Mission
- System Maturation Teams
- Habitation Module Presentation
- Status of Commercial Crew Program

Attendees will be required to sign a register. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,
*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016–16181 Filed 7–7–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 16–050]

NASA Advisory Council; Technology, Innovation and Engineering Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Technology, Innovation and Engineering (TI&E) Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Tuesday, July 26, 2016, 8:00 a.m.–12:15 p.m.; and 3:30 p.m.–5:00 p.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, Board Room (Second Floor), 22800 Cedar Point Rd, Cleveland, Ohio 44142.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Green, Executive Secretary for the NAC TI&E Committee, Space Technology Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4710, or g.m.green@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any person interested in joining the meeting may call the USA toll-free conference number 1–844–467–6272, passcode 102421 followed by the # sign. If dialing in, please “mute” your telephone. The WebEx link is <https://nasa.webex.com/>, the meeting number is 998 519 793, and the password is “Technology16\$” (case sensitive).

The agenda for the meeting includes the following topics:

- Welcome to NASA Glenn Research Center and Remarks
- Space Technology Mission Directorate Update
- Nuclear Propulsion and Power Overview
- SpaceX Red Dragon Partnership Overview
- Chief Technologist Update

Attendees will be required to sign a register. It is imperative that this meeting be held on this date to

accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,
*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016–16185 Filed 7–7–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–048)]

NASA Advisory Council; Aeronautics Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the Aeronautics Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. The meeting will be held for the purpose of soliciting, from the aeronautics community and other persons, research and technical information relevant to program planning.

DATES: Tuesday, July 26, 2016, 10:00 a.m.–4:30 p.m., Local Time.

ADDRESSES: Ohio Aerospace Institute, Industry Room A, 22800 Cedar Point Road, Cleveland, Ohio 44142

FOR FURTHER INFORMATION CONTACT: Ms. Irma Rodriguez, Executive Secretary for the NAC Aeronautics Committee, NASA Headquarters, Washington, DC 20546, (202) 358–0984, or irma.c.rodriguez@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting will also be available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any person interested in joining the meeting by telephone and WebEx should contact Ms. Irma Rodriguez at (202) 358–0984 for the toll-free number, Web link and passcode. The agenda for the meeting includes the following topics:

- National Research Council-Led Low Carbon Study
- Thrust 4 Roadmaps Out Brief
- New Aviation Horizons Formulation Rationale and Approach

Attendees will be required to sign a register. It is imperative that the meeting be held on this date to accommodate the

scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space
Administration.*

[FR Doc. 2016-16183 Filed 7-7-16; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

[NARA-2016-039]

State, Local, Tribal, and Private Sector Policy Advisory Committee (SLTPS- PAC)

AGENCY: National Archives and Records
Administration (NARA).

ACTION: Notice of Advisory Committee
Meeting.

SUMMARY: In accordance with the
Federal Advisory Committee Act (5
U.S.C. app 2) and implementing
regulation 41 CFR 101-6, NARA
announces the following committee
meeting.

DATES: The meeting will be on July 27,
2016, from 10:00 a.m. to 12:00 p.m.
EDT.

ADDRESSES: National Archives and
Records Administration; 700
Pennsylvania Avenue NW.; Jefferson
Room; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT:
Robert J. Skwirot, Senior Program
Analyst, by mail at ISOO, National
Archives Building; 700 Pennsylvania
Avenue NW.; Washington, DC 20408, by
telephone at (202) 357-5398, or by
email at robert.skwirot@nara.gov.
Contact ISOO at ISOO@nara.gov.

SUPPLEMENTARY INFORMATION: The
purpose of this meeting is to discuss
matters relating to the Classified
National Security Information Program
for State, Local, Tribal, and Private
Sector Entities. The meeting is open to
the public. However, due to space
limitations and access procedures, you
must submit the name and telephone
number of individuals planning to
attend to the Information Security
Oversight Office (ISOO) no later than
Friday, July 22, 2016. ISOO will provide
additional instructions for entering the
building.

Patrice Little Murray,

Committee Management Officer.

[FR Doc. 2016-16231 Filed 7-7-16; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL SCIENCE FOUNDATION

Committee Management; Renewals

The National Science Foundation (NSF) management officials having responsibility for the advisory committees listed below have determined that renewing these groups for another two years is necessary and in the public interest in connection with the performance of duties imposed upon the Director, National Science Foundation (NSF), by 42 U.S.C. 1861 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Committees

Advisory Committee for Computer and
Information Science and Engineering
#1115

Advisory Committee for Mathematical
and Physical Sciences #66

Advisory Committee for Social,
Behavioral, and Economic Sciences
#1171

Business and Operations Advisory
Committee #9556

Committee on Equal Opportunities in
Sciences and Engineering #1173

Proposal Review Panel for Astronomical
Sciences #1186

Proposal Review Panel for Chemical,
Bioengineering, Environmental, and
Transport Systems #1189

Proposal Review Panel for Chemistry
#1191

Proposal Review Panel for Civil,
Mechanical, and Manufacturing
Innovation #1194

Proposal Review Panel for Computer
and Network Systems #1207

Proposal Review Panel for Computing &
Communication Foundations #1192

Proposal Review Panel for
Cyberinfrastructure #1185

Proposal Review Panel for Electrical,
Communications, and Cyber Systems
#1196

Proposal Review Panel for Engineering
Education and Centers #173

Proposal Review Panel for Graduate
Education #57

Proposal Review Panel for Human
Resource Development #1199

Proposal Review Panel for Information
and Intelligent Systems #1200

Proposal Review Panel for Materials
Research #1203

Proposal Review Panel for Mathematical
Sciences #1204

Proposal Review Panel for Physics
#1208

Proposal Review Panel for Polar
Programs #1209

Proposal Review Panel for
Undergraduate Education #1214

Effective date for renewal is July 1,
2016. For more information, please
contact Crystal Robinson, NSF, at (703)
292-8687.

Dated: July 5, 2016.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2016-16172 Filed 7-7-16; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-327 and 50-328; NRC-
2016-0130]

Completion Date of Cyber Security Plan Implementation Milestone 8; Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2

AGENCY: Nuclear Regulatory
Commission.

ACTION: License amendment request;
opportunity to comment, request a
hearing, and petition for leave to
intervene; order.

SUMMARY: The U.S. Nuclear Regulatory
Commission (NRC) is considering
issuance of amendments to Facility
Operating License Nos. DPR-77 and
DPR-79, issued to the Tennessee Valley
Authority, for operation of the Sequoyah
Nuclear Plant (SQN), Units 1 and 2. The
proposed amendments would revise the
SQN, Units 1 and 2, Cyber Security Plan
(CSP) implementation schedule for
Milestone 8 and would revise the
associated license condition in the
Facility Operating Licenses. The
amendment request contains sensitive
unclassified non-safeguards information
(SUNSI).

DATES: Submit comments by August 8,
2016. Requests for a hearing or petition
for leave to intervene must be filed by
September 6, 2016. Any potential party
as defined in § 2.4 of title 10 of the *Code
of Federal Regulations* (10 CFR), who
believes access to SUNSI is necessary to
respond to this notice must request
document access by July 18, 2016.

ADDRESSES: You may submit comments
by any of the following methods (unless
this document describes a different
method for submitting comments on a
specific subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0130. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Andrew Hon, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-8480, email: *Andrew.Hon@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2016-0130 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0130.

• *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to *pdr.resource@nrc.gov*. The License Amendment Request (SQN-TS-16-03) to Change the Completion Date of Cyber Security Plan Implementation Milestone 8 is available in ADAMS under Accession No. ML16138A247.

• *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2016-0130 and “Sequoyah Nuclear Plant, Units 1 and 2, application dated May 16, 2016, license amendment request to change the completion date of Cyber Security Plan Implementation Milestone 8,” in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission.

The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The NRC is considering issuance of amendments to Facility Operating License Nos. DPR-77 and DPR-79, issued to the Tennessee Valley Authority, for operation of the SQN, Units 1 and 2, located in Hamilton County, Tennessee. The proposed amendments would revise the SQN, Units 1 and 2, CSP implementation schedule for Milestone 8 and would revise the associated license condition in the Facility Operating Licenses.

Before any issuance of the proposed license amendments, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC’s regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the NRC’s regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequence of an accident previously evaluated?

Response: No.

The proposed change revises the CSP Milestone 8 implementation date. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in

which systems are operated, maintained, modified, tested, or inspected. The proposed change is an extension to the completion date of implementation Milestone 8, that in itself does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and have no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment revises the CSP Implementation Schedule. This proposed change to extend the completion date of implementation Milestone 8 does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems and components relied upon to mitigate the consequences of postulated accidents. This change also does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change extends the CSP Implementation Schedule. Because there is no change to these established safety margins as result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves a No Significant Hazards Consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendments until the

expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendments before expiration of the 60-day notice period if the Commission concludes the amendments involve no significant hazards consideration. In addition, the Commission may issue the amendments prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendments to the subject facility operating licenses or combined licenses. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition

should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendments under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a

determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)-(iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendments and make them immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendments. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendments unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by September 6, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing

conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by September 6, 2016.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta

System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the license amendment request dated May 16, 2016.

Attorney for licensee: Ms. Sherry A. Quirk, Executive Vice President and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Acting NRC Branch Chief: Tracy J. Orf.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555-0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov*, respectively.¹ The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order² setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the dates the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a

determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.³

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 1st day of July 2016.

For the Nuclear Regulatory Commission,
Rochelle C. Baval,
Acting, Secretary of the Commission.

¹ While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

² Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

³ Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of Federal Register notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2016-16211 Filed 7-7-16; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2016-0133]

Dedication of Commercial-Grade Items for Use in Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants." This DG proposes new guidance that describes methods that the NRC staff considers acceptable in meeting regulatory requirements for dedication of commercial-grade items used in nuclear power plants.

DATES: Submit comments by September 6, 2016. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure

consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specified subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0133. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN-12 H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see "Obtaining Information and

Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Richard Laura, Office of New Reactors, telephone: 301-415-1837, email: Richard.Laura@nrc.gov, and Stephen Burton, Office of Nuclear Regulatory Research, telephone: 301-415-7000, email: Stephen.Burton@nrc.gov. Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2016-0133 when contacting the NRC about the availability of information regarding this action. You may obtain publically-available information related to this action, by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0133.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the

ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The DG is electronically available in ADAMS under Accession No. ML15313A425.

- *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2016-0133 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses. The DG, entitled, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," is a proposed new guide temporarily identified by its task number, DG-1292. It proposes new guidance that describes acceptance methods that the NRC staff considers acceptable in meeting regulatory requirements for dedication

of commercial-grade items used in nuclear power plants.

III. Backfitting and Issue Finality

DG-1292 describes a method that the staff of the NRC considers acceptable for dedication of commercial-grade items for use in nuclear power plants. Issuance of this DG, if finalized, would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the "Implementation" section of this DG, the NRC has no current intention to impose this DG, if finalized, on holders of current operating licenses or combined licenses.

Dated at Rockville, Maryland, this 29th day of June, 2016.

For the Nuclear Regulatory Commission.

Harriett Karagiannis,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016-16215 Filed 7-7-16; 8:45 am]

BILLING CODE 7590-01-P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 8, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202-268-3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 1, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 230 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2016-162, CP2016-235.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016-16162 Filed 7-7-16; 8:45 am]

BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 8, 2016.

FOR FURTHER INFORMATION CONTACT:

Elizabeth A. Reed, 202-268-3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 1, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 231 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2016-163, CP2016-236.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016-16161 Filed 7-7-16; 8:45 am]

BILLING CODE 7710-12-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0528, SEC File No. 270-465]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213.

Extension:

Rule 237.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

In Canada, as in the United States, individuals can invest a portion of their earnings in tax-deferred retirement savings accounts ("Canadian retirement accounts"). These accounts, which operate in a manner similar to

individual retirement accounts in the United States, encourage retirement savings by permitting savings on a tax-deferred basis. Individuals who establish Canadian retirement accounts while living and working in Canada and who later move to the United States (“Canadian-U.S. Participants” or “participants”) often continue to hold their retirement assets in their Canadian retirement accounts rather than prematurely withdrawing (or “cashing out”) those assets, which would result in immediate taxation in Canada.

Once in the United States, however, these participants historically have been unable to manage their Canadian retirement account investments. Most securities that are “qualified investments” for Canadian retirement accounts are not registered under the U.S. securities laws. Those securities, therefore, generally cannot be publicly offered and sold in the United States without violating the registration requirement of the Securities Act of 1933 (“Securities Act”).¹ As a result of this registration requirement, Canadian-U.S. Participants previously were not able to purchase or exchange securities for their Canadian retirement accounts as needed to meet their changing investment goals or income needs.

The Commission issued a rulemaking in 2000 that enabled Canadian-U.S. Participants to manage the assets in their Canadian retirement accounts by providing relief from the U.S. registration requirements for offers of securities of foreign issuers to Canadian-U.S. Participants and sales to Canadian retirement accounts.² Rule 237 under the Securities Act³ permits securities of foreign issuers, including securities of foreign funds, to be offered to Canadian-U.S. Participants and sold to their Canadian retirement accounts without being registered under the Securities Act.

Rule 237 requires written offering documents for securities offered and sold in reliance on the rule to disclose prominently that the securities are not registered with the Commission and are

exempt from registration under the U.S. securities laws. The burden under the rule associated with adding this disclosure to written offering documents is minimal and is non-recurring. The foreign issuer, underwriter, or broker-dealer can redraft an existing prospectus or other written offering material to add this disclosure statement, or may draft a sticker or supplement containing this disclosure to be added to existing offering materials. In either case, based on discussions with representatives of the Canadian fund industry, the staff estimates that it would take an average of 10 minutes per document to draft the requisite disclosure statement.

The Commission understands that there are approximately 3,619 Canadian issuers other than funds that may rely on rule 237 to make an initial public offering of their securities to Canadian-U.S. Participants.⁴ The staff estimates that in any given year approximately 36 (or 1 percent) of those issuers are likely to rely on rule 237 to make a public offering of their securities to participants, and that each of those 36 issuers, on average, distributes 3 different written offering documents concerning those securities, for a total of 108 offering documents.

The staff therefore estimates that during each year that rule 237 is in effect, approximately 36 respondents⁵ would be required to make 108 responses by adding the new disclosure statements to approximately 108 written offering documents. Thus, the staff estimates that the total annual burden associated with the rule 237 disclosure requirement would be approximately 18 hours (108 offering documents × 10 minutes per document). The total annual cost of burden hours is estimated to be \$6,840 (18 hours × \$380 per hour of attorney time).⁶

⁴ This estimate is based on the following calculation: 3,520 equity issuers (as of April 2016) + 99 bond issuers (as of April 2016) = 3,619 total issuers (as of April 2016). See World Federation of Exchanges, Monthly Reports, available at <http://www.world-exchanges.org/home/index.php/statistics/monthly-reports> (providing number of equity issuers listed on Canada’s Toronto Stock Exchange). After 2009, the World Federation of Exchanges ceased reporting the number of fixed-income issuers on Canada’s Toronto Stock Exchange. The number of fixed-income issuers as of April 2016 is based on the ratio of the number of fixed-income issuers listed on Canada’s Toronto Stock Exchange in 2009 (111) relative to the number of bonds listed on that exchange in that year (178) multiplied against the number of bonds listed on that exchange as of April 2016 (159): (111/178) × 159 = 99.

⁵ This estimate of respondents only includes foreign issuers. The number of respondents would be greater if foreign underwriters or broker-dealers draft stickers or supplements to add the required disclosure to existing offering documents.

⁶ The Commission’s estimate concerning the wage rate for attorney time is based on salary information

In addition, issuers from foreign countries other than Canada could rely on rule 237 to offer securities to Canadian-U.S. Participants and sell securities to their accounts without becoming subject to the registration requirements of the Securities Act. However, the staff believes that the number of issuers from other countries that rely on rule 237, and that therefore are required to comply with the offering document disclosure requirements, is negligible.

These burden hour estimates are based upon the Commission staff’s experience and discussions with the fund industry. The estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

Compliance with the collection of information requirements of the rule is mandatory and is necessary to comply with the requirements of the rule in general. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: PRA_Mailbox@sec.gov.

Dated: July 5, 2016.

Brent J. Fields,
Secretary.

[FR Doc. 2016-16193 Filed 7-7-16; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold an Open Meeting on Tuesday, July 12, 2016, at 1:00 p.m.,

for the securities industry compiled by the Securities Industry and Financial Markets Association (“SIFMA”). The \$380 per hour figure for an attorney is from SIFMA’s *Management & Professional Earnings in the Securities Industry 2013*, modified by Commission staff to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

¹ 15 U.S.C. 77. In addition, the offering and selling of securities of investment companies (“funds”) that are not registered pursuant to the Investment Company Act of 1940 (“Investment Company Act”) is generally prohibited by U.S. securities laws. 15 U.S.C. 80a.

² See Offer and Sale of Securities to Canadian Tax-Deferred Retirement Savings Accounts, Release Nos. 33-7860, 34-42905, IC-24491 (June 7, 2000) [65 FR 37672 (June 15, 2000)]. This rulemaking also included new rule 7d-2 under the Investment Company Act, permitting foreign funds to offer securities to Canadian-U.S. Participants and sell securities to Canadian retirement accounts without registering as investment companies under the Investment Company Act. 17 CFR 270.7d-2.

³ 17 CFR 230.237.

in the Auditorium (L-002) at the Commission's headquarters building, to hear oral argument in an appeal by the Respondents John J. Aesoph, CPA and Darren M. Bennett, CPA, and a cross-appeal by the Division of Enforcement, from an initial decision of an administrative law judge.

On June 27, 2014, the law judge found that Aesoph and Bennett engaged in "improper professional conduct" under Commission Rule of Practice 102(e) and Section 4C of the Securities Exchange Act of 1934, during their service as the engagement partner and senior manager of KPMG, LLP's audit of the 2008 financial statements of TierOne Corporation, a holding company for TierOne Bank. The law judge suspended Aesoph from appearing or practicing before the Commission as an accountant for one year, and suspended Bennett from appearing or practicing before the Commission as an accountant for six months.

Respondents appealed the law judge's findings of liability and the sanctions imposed; the Division cross-appealed the sanctions imposed. The issues likely to be considered at oral argument include, among other things, whether Respondents engaged in "improper professional conduct" as alleged and, if so, the extent to which they should be sanctioned. Also likely to be considered at oral argument is whether these administrative proceedings violate the U.S. Constitution.

For further information, please contact Brent J. Fields from the Office of the Secretary at (202) 551-5400.

Dated: July 5, 2016.

Lynn M. Powalski,
Deputy Secretary.

[FR Doc. 2016-16309 Filed 7-6-16; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549-2736.

Extension:

Rule 17a-1; SEC File No. 270-244, OMB Control No. 3235-0208.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information

provided for in Rule 17a-1 (17 CFR 240.17a-1) under the Securities Exchange Act of 1934, as amended (the "Act") (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 17a-1 requires that every national securities exchange, national securities association, registered clearing agency, and the Municipal Securities Rulemaking Board keep on file for a period of not less than five years, the first two years in an easily accessible place, at least one copy of all documents, including all correspondence, memoranda, papers, books, notices, accounts, and other such records made or received by it in the course of its business as such and in the conduct of its self-regulatory activity, and that such documents be available for examination by the Commission.

There are 29 entities required to comply with the rule: 19 national securities exchanges, 1 national securities association, 8 registered clearing agencies, and the Municipal Securities Rulemaking Board. The Commission staff estimates that the average number of hours necessary for compliance with the requirements of Rule 17a-1 is 52 hours per year. In addition, 4 national securities exchanges notice-registered pursuant to Section 6(g) of the Act (15 U.S.C. 78f(g)) are required to preserve records of determinations made under Rule 3a55-1 under the Act (17 CFR 240.3a55-1), which the Commission staff estimates will take 1 hour per exchange, for a total of 4 hours. Accordingly, the Commission staff estimates that the total number of hours necessary to comply with the requirements of Rule 17a-1 is 1,512 hours. The total internal cost of compliance for all respondents is \$98,280, based on an average cost per hour of \$65.

Written comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in

writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: July 5, 2016.

Brent J. Fields,
Secretary.

[FR Doc. 2016-16191 Filed 7-7-16; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: King County, Washington

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for a proposed project in King County, Washington.

FOR FURTHER INFORMATION CONTACT:

Lindsey Handel, Urban Area Engineer, Federal Highway Administration, 711 South Capitol Way, Suite 501, Olympia, WA 98501; telephone: (360) 753-9550; email: Lindsey.Handel@dot.gov.

Jane Lewis, Project Coordinator, Washington State Convention Center, c/o Pine Street Group L.L.C., 1500 Fourth Ave., Suite 600, Seattle, WA 98101; telephone: (206) 340-9897; email: wsc@pinest.com.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with WSCC, will prepare an EIS on the Washington State Convention Center Addition Project to construct an addition to the Washington State Convention Center. The project requires FHWA approvals for closure of access to an Interstate ramp and use of Interstate airspace (air and ground lease), and related breaks in access.

Preliminary alternatives under consideration include: (1) Taking no action; (2) construct approximately 1.50 million square feet of gross floor area composed of approximately 1.26 million square feet of addition to the convention

center and 262,000 square feet of related ancillary development.

The FHWA along with WSCC are holding a public scoping meeting on July 20, 2016, from 5:30 p.m. to 7 p.m. at the Washington State Convention Center, 800 Convention Place, Room 206, Seattle, WA to solicit public comments regarding the scope of issues to be addressed in the NEPA EIS. The public will be notified by a flyer that will be mailed to interested agencies, organizations, and individuals affected by the project, as well as published in The Seattle Times and the Daily Journal of Commerce. In addition, notice of the EIS Scoping meeting will be posted at locations on the project site. The meeting will include a brief presentation followed by public comments.

Agencies, Tribes, and the public are encouraged to submit comments on the purpose and need and preliminary range of alternatives during the scoping period. Comments must be received by July 26, 2016, to be included in the formal scoping record. To ensure that the full range of issues related to this proposed action is addressed, and all the significant issues identified, comments and suggestions are invited from interested parties during the scoping period. Comments concerning this proposal will be accepted at the public meeting or can be sent by mail to: Lindsey Handel, Urban Area Engineer, Federal Highway Administration, 711 South Capitol Way, Suite 501, Olympia, WA 98501; telephone: (360) 753-9550; email: Lindsey.Handel@dot.gov.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Daniel Mathis,

Division Administrator, Washington Division, Federal Highway Administration.

[FR Doc. 2016-16204 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2013-0147]

Driver Qualifications: Skill Performance Evaluation; Virginia Department of Motor Vehicles; Exemption Renewal for Virginia Department of Motor Vehicles

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemption; request for comments.

SUMMARY: FMCSA announces its decision to renew the Virginia Department of Motor Vehicles (DMV) exemption on behalf of truck and bus drivers who are licensed in the Commonwealth of Virginia and need a Skill Performance Evaluation (SPE) certificate from FMCSA to operate commercial motor vehicles (CMV) in interstate commerce. The exemption enables interstate CMV drivers who are licensed in Virginia and are subject to the Federal SPE requirements under 49 CFR 391.49 to continue to fulfill the Federal requirements with a State-issued SPE and to operate CMVs in interstate commerce anywhere in the United States.

DATES: This decision is effective July 9, 2016, and will expire July 9, 2018, and may be renewed. Comments must be received on or before August 9, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) number FMCSA-2013-0147 by 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, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

- *Hand Delivery:* Ground Floor, Room W12-140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. E.D.T., Monday through Friday, except Federal holidays.

- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and docket number for this notice. Please 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 for further information.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or to Room W12-140, DOT Building, 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 acknowledgement 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS) which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Ms. Eileen Nolan, Office of Carrier, Driver and Vehicle Safety, Medical Programs Division, (202) 366-4001, fmcamedical@dot.gov, FMCSA, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs) 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 allows the Agency to renew exemptions at the end of the 2-year period.

On July 8, 2014, FMCSA granted Virginia a 2-year exemption that enables interstate CMV drivers licensed in Virginia who are subject to the Federal SPE requirements under 49 CFR 391.49 to fulfill the Federal requirements with a State-issued SPE (79 FR 38659). The requirements of the exemption were outlined in this notice and will therefore not be repeated. Virginia has established its own SPE program that is essentially identical to the current FMCSA SPE program to include an application process modeled on the FMCSA process. In addition, State personnel who have completed SPE training identical to that of FMCSA personnel currently administer the SPE program and conduct the skill

evaluation according to the same procedures and testing criteria used by FMCSA. If the driver passes the skill evaluation, the State issues the SPE certificate. Virginia maintains records of applications, testing, and certificates issued, which are available, as required, for periodic review by FMCSA. On behalf of CMV drivers licensed in the Commonwealth of Virginia, the State requested renewal of the exemption from 49 CFR 391.49 concerning FMCSA's SPE certificate process for drivers who have experienced an impairment or loss of a limb.

II. Basis for Renewing Exemption

The Agency's decision regarding this exemption is based on the fact that Virginia's SPE program is essentially identical to the current FMCSA program. Virginia continues to adhere to the application process modeled on the FMCSA process. State personnel who conduct the skill evaluation complete the same training as FMCSA personnel conducting the test and follow the same procedures and testing criteria used by FMCSA. FMCSA has conducted ongoing monitoring and onsite SPE program reviews and Virginia continues to maintain records of applications, testing, and certificates issued for periodic review by FMCSA. At the time Virginia DMV submitted its request for exemption renewal to the Agency, it had issued 13 new and 25 renewal SPE certificates. Based upon FMCSA's analyses of the applications and the program as a whole, FMCSA has determined that no safety vulnerabilities are associated with Virginia's renewal request. The renewal of the exemption is granted.

Consequently, FMCSA has concluded that renewing the exemption allows the Virginia SPE program to achieve the level of safety required by 49 U.S.C. 31315.

If a Virginia-licensed driver would prefer not to opt for the streamlined SPE process, the driver may still apply for a FMCSA-issued SPE. However, FMCSA may still exercise its discretion and call upon Virginia DMV to provide assistance in conducting the road evaluation needed to complete an SPE application, depending on the volume of applications.

III. Terms and Conditions

The FMCSA grants the renewal of the exemption to allow the Virginia DMV to conduct SPE's on drivers who have experienced an impairment or loss of a limb and are licensed in the Commonwealth of Virginia. The following terms and conditions apply to

the State and any drivers who receive a State-issued SPE certificate:

- Virginia must establish and maintain its own SPE program that is essentially identical to the current FMCSA program.
- The State must maintain an application process modeled on the FMCSA process and submit information concerning the application process to FMCSA's Medical Programs Division for review, as required.
- State personnel who conduct the skill test must complete SPE training identical to that of FMCSA personnel currently administering the Federal SPE program.
- The skill evaluation and scoring for the SPE must be done using the same procedures and testing criteria used by FMCSA.
- Virginia must maintain records of applications, testing, and certificates issued for periodic review by FMCSA.
- Virginia must submit a monthly report to FMCSA listing the names and license number of each driver tested by the State and the result of the test (pass or fail).
- Each driver who receives a State-issued SPE must carry a copy of the certificate when driving for presentation to authorized Federal, State, or local law enforcement officials.

IV. Preemption of State Laws and Regulations

An exemption granted under the authority of 49 U.S.C. 31315(b) preempts State laws and regulations that conflict with or are inconsistent with the exemption. The decision to grant Virginia's request amounts to automatic Federal ratification of the State issued SPE certificate and therefore prohibits other jurisdictions from requiring a separate FMCSA-issued SPE. The State-issued certificate must be treated as if it had been issued by FMCSA. Virginia-licensed drivers who receive the State-issued SPE are allowed to operate CMVs in interstate commerce anywhere in the United States.

V. Request for Comments

Interested parties possessing information that would otherwise show that granting this exemption is not achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted, and if safety is being compromised or if continuation of exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the Virginia DMV exemption.

VI. Conclusion

The Agency does not intend its decision to pressure other States to take action to implement State-run SPE programs. Virginia is the first State to submit an application on behalf of its drivers to provide an alternative to the Federal SPE process. Other States are welcome to make similar applications if they believe it is appropriate to do so and they have the resources to meet terms and conditions comparable to those provided in this exemption.

Issued on: June 29, 2016.

T.F. Scott Darling, III,

Acting Administrator.

[FR Doc. 2016-16197 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2015-0180]

Agency Information Collection Activities; New Information Collection Request: 391.41 CMV Driver Medication Form

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment on the approval of a new Information Collection (IC) titled, *391.41 CMV Driver Medication Form*. Comments received in response to this notice are sent to the OMB Desk Officer to address. This IC is voluntary and may be utilized by medical examiners (MEs) responsible for issuing Medical Examiner's Certificates (MECs) to commercial motor vehicle (CMV) drivers. MEs that choose to use this IC will do so in an effort to communicate with treating healthcare professionals who are responsible for prescribing certain medications, so that the ME fully understands the reasons the medications have been prescribed. The information obtained by the ME when utilizing this IC will assist the ME in determining if the driver is medically certified according to the physical qualifications standards outlined in 49 CFR 391.41 and to ensure that there are no disqualifying medical conditions or underlying medical conditions and

prescribed medications that could adversely affect their safe driving ability or cause incapacitation constituting a risk to the public.

DATES: Please send your comments to this notice by August 8, 2016. OMB must receive your comments by this date to act quickly on the ICR.

ADDRESSES: All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA-2015-0180. Interested persons are invited to submit written comments on the proposed IC to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to oir_submission@omb.eop.gov, faxed to (202) 395-6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001.

SUPPLEMENTARY INFORMATION:

Title: 391.41 CMV Driver Medication Form.

OMB Control Number: 2126-00XX.

Type of Request: New collection.

Respondents: Prescribing healthcare professionals.

Estimated Number of Respondents: 1,082,200 (total number of prescribing healthcare providers in the U.S.).

Estimated Time per Response: 8 minutes.

Expiration Date: N/A. This is a new ICR.

Frequency of Response: Voluntary.

Estimated Total Annual Burden:

144,293 hours [1,082,200 responses × 8 minutes to complete response/60 minutes = 144,293].

Background: The primary mission of FMCSA is to reduce crashes, injuries, and fatalities involving large trucks and buses. The Secretary of Transportation has delegated to FMCSA its responsibility under 49 U.S.C. 31136 and 31502 to prescribe regulations that ensure that CMVs are operated safely. As part of this mission, the Agency's Medical Programs Division works to ensure that CMV drivers engaged in interstate commerce operations are physically qualified and able to safely perform their work.

Information used to determine and certify driver medical fitness must be collected in order for our highways to be safe. FMCSA is the Federal government agency authorized to require the collection of this information and the authorizing regulations are located at 49 CFR parts 390-399. FMCSA is required by statute to establish standards for the physical qualifications of drivers who operate CMVs in interstate commerce for non-excepted industries [49 U.S.C. 31136(a)(3) and 31502(b)]. The regulations discussing this collection are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR part 390-399. FMCSRs at 49 CFR 391.41 set forth the physical qualification standards that interstate CMV drivers who are subject to part 391 must meet, with the exception of commercial driver's license/commercial learner's permit (CDL/CLP) drivers transporting migrant workers (who must meet the physical qualification standards set forth in 49 CFR 398.3). The FMCSRs covering driver physical qualification records are found at 49 CFR 391.43, which specify that a medical examination be performed on CMV drivers subject to part 391 who operate in interstate commerce. The results of the examination shall be recorded in accordance with the requirements set forth in that section.

49 CFR 391.41(b)(12) states that a person is physically qualified to drive a CMV if that person does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug and does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by 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 CMV.

In 2006, FMCSA's Medical Review Board (MRB) deliberated on the topic of the use of Schedule II medications. The MRB considered information provided in a 2006 FMCSA sponsored Evidence Report and a subsequent Medical Expert Panel (MEP) to examine the relationship between the licit use of Schedule II medications and the risk for a motor vehicle crash. In 2013, FMCSA tasked the MRB with updating the opinions and recommendations of the 2006 Evidence Report and MEP.

On September 10, 2013, the MRB and Motor Carrier Safety Advisory Committee (MCSAC) met jointly to hear presentations on the licit use of Schedule II medications and their

regulation, and on U.S. Department of Transportation drug and alcohol testing protocols. Subsequently, the committees engaged in a discussion on the issue as it applies to CMV drivers. On September 11, 2013, the MRB discussed the issue in greater detail as its task to present a report to the Agency relating to CMV drivers and Schedule II medication use and to develop a form for MEs on the National Registry of Certified Medical Examiners (National Registry) to send to treating clinicians of CMV drivers to expound on the use of these medications by driver applicants. On October 22, 2013, the MRB submitted their recommendations to FMCSA. A MEP convened to provide an updated opinion on *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance*. The FMCSA revised the task of the MRB instructing them to review an updated evidence report and the MEP opinion that was furnished subsequent to its deliberations on *Schedule II Opioids and Stimulants & CMV Crash Risk and Driver Performance: Evidence Report and Systematic Review*. FMCSA directed the MRB to consider this report's findings and confer with the MCSAC on this topic during a joint meeting in October 2014. The MRB met in public meetings on July 29-30, 2014, and developed Schedule II medication recommendations. The MRB presented these recommendations to the MCSAC in a joint public meeting on October 27, 2014, where they were deliberated by both committees. As a result, FMCSA's MRB and MCSAC provided joint recommendations related to the use of Schedule II medications by CMV drivers. Because there is moderate evidence to support the contention that the licit use of opioids increases the risk of motor vehicle crashes and impacts indirect measures of driver performance negatively, included was the recommendation that FMCSA develop a standardized medication questionnaire to assist the certified ME when reviewing prescription medications that have been disclosed during the history and physical examination for CMV driver certification. The two advisory groups recommended to FMCSA that the standardized CMV driver medication questionnaire be voluntary and include the following information and questions:

1. Questionnaire should be titled *391.41 CMV Driver Medication Questionnaire*.

2. Questionnaire should request the following information:

a. Identifying name and date of birth of the CMV driver.

b. Introductory paragraph stating purpose of the CMV Driver Medication Report.

c. Statements of § 391.41(b)(12) (Physical Qualifications of Drivers relating to driver use of scheduled substances) and The Driver's Role, as found in the Medical Examination Report form found at the end of 49 CFR 391.43 (*Medical Examination; Certificate of Physical Examination*).

d. Name, state of licensure, signature, address and contact information of the prescribing healthcare provider, as well as the date the form was completed.

e. Name, signature, date, address and contact information of the certified ME.

3. Report should include the following information:

a. 1—List all medications and dosages that you have prescribed to the above named individual.

b. 2—List any other medications and dosages that you are aware have been prescribed to the above named individual by another treating healthcare provider.

c. 3—What medical conditions are being treated with these medications?

d. 4—It is my medical opinion that, considering the mental and physical requirements of operating a CMV and with awareness of a CMV driver's role (consistent with *The Driver's Role* statement on page 2 of the form), I believe my patient: (a) Has no medication side effects from medication(s) that I prescribe that would adversely affect the ability to operate a CMV safely; and (2) has no medical condition(s) that I am treating with the above medication(s) that would adversely affect the ability to operate a CMV safely.

The public interest in, and right to have, safe highways requires the assurance that drivers of CMVs can safely perform the increased physical and mental demands of their duties. FMCSA's medical standards provide this assurance by requiring drivers to be examined and medically certified as physically and mentally qualified to drive.

The purpose for collecting this information is to assist the ME in determining if the driver is medically qualified under 49 CFR 391.41 and to ensure that there are no disqualifying medical conditions that could adversely affect their safe driving ability or cause incapacitation constituting a risk to the public. 49 CFR 391.41(b)(12) states that a person is physically qualified to drive a CMV if that person does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug and does not use any non-Schedule I

drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by 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 CMV.

The use of this IC is at the discretion of the ME to facilitate communication with treating healthcare professionals who are responsible for prescribing certain medications so that the ME fully understands the reasons the medications have been prescribed. This information will assist the ME in determining whether the underlying medical condition and the prescribed medication will impact the driver's safe operation of a CMV. Therefore, there is no required collection frequency.

The *391.41 CMV Driver Medication Form* will be available as a fillable PDF or may be downloaded from the FMCSA Web site. Prescribing healthcare providers will be able to fax or scan and email the report to the certified ME. Consistent with the OMB's commitment to minimizing respondents' recordkeeping and paperwork burdens and the increased use of secure electronic modes of communication, the Agency anticipates that approximately 50 percent of the *391.41 CMV Driver Medication Forms* will be transmitted electronically.

The information collected from the *391.41 CMV Driver Medication Form*, will be used by the certified ME that requested the completion of the form and will become part of the CMV driver's medical record maintained by the certified ME. Therefore, the information will not be available to the public. The FMCSRs covering driver physical qualification records are found at 49 CFR 391.43, which specify that a medical examination be performed on CMV drivers subject to part 391 who operate in interstate commerce. The results of the examination shall be recorded in accordance with the requirements set forth in that section. MEs are required to maintain records of the CMV driver medical examinations they conduct. Disclaimer language is displayed at the end of the medical form to declare sensitive information on the form must be handled and maintained securely to prevent inadvertent disclosure. The language also states the form is for official use only, by authorized persons, and the form should be properly disposed of when no longer required.

Discussion of Comments Received

A. Overview of Comments

In response to the **Federal Register** notice published on November 25, 2015, requesting public comment concerning the necessity of the proposed IC, the accuracy of the estimated burden, how the quality of collected information could be enhanced, and ways in which the burden could be minimized without reducing the quality of the collected information (80 FR 73871), FMCSA received 14 comments. The commenters included certified MEs, CMV drivers, training organizations, the American Trucking Associations (ATA), the Owner-Operator Independent Drivers Association (OOIDA), and the American College of Occupational and Environmental Medicine (ACOEM).

The first area of comments involved the effectiveness of the *391.41 CMV Driver Medication Form*. The second area of comments discussed the burden hours and costs. The final area of comments were issues that were considered outside the scope of this ICR and the optional use of the *391.41 CMV Driver Medication Form*. These comments will be briefly summarized with an explanation as to why the issues raised are not within the scope of this notice.

Five commenters expressed support for the ICR and two commenters explicitly opposed the ICR. The remaining seven neither supported nor opposed the ICR, but raised concerns or provided suggestions for changes to the optional form.

The following sections provide details regarding specific issues raised by the commenters.

B. Effectiveness of the *391.41 CMV Driver Medication Form*

ACOEM acknowledged that the current process used by MEs is clearly inadequate but also feels that the form falls far short of being able to adequately assess whether a driver will be impaired by medications or an underlying medical condition. They also stated that many healthcare providers do not fully understand the safety risks and responsibilities of the CMV driver and would rely on the patient's statement that the medication does not impair the driver's ability to safely operate a CMV. Therefore, they believe that the prescribing healthcare provider statements would not be reliable. ACOEM also believes that the form does not go far enough to address the use of opioids by drivers and the rapid increase in adverse effects of opioid use and suggests that FMCSA strive for a form that becomes the standard of

practice that requires the treating provider and the ME to be aware of medications and conditions, including opioid use.

Others commented that some physicians have no problem stating that their patient is safe to drive a CMV while taking these medications leaving the ME that disagrees and is not willing to issue the driver a MEC with a driver that is angry based on the differing opinions. OOIDA stated that the form would be a direct challenge to the treating physician according to § 391.41(b)(12)(ii) that states "A person is physically qualified to drive a commercial motor vehicle if that person does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in § 392.107, 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 vehicle." They believe that this form challenges the opinion of the driver's treating physician and puts it in the hands of a stranger with no knowledge of the driver's background and who is unfamiliar with the driver's medical history.

FMCSA Response

FMCSA is providing the *391.43 CMV Driver Medication Form* at the request of MEs to be used at their discretion, and as a resource for assisting MEs in making medical certification determinations of interstate CMV drivers. Use of the form is voluntary and MEs may do so in an effort to communicate with treating healthcare providers who are responsible for prescribing certain medications, so that the ME fully understands the reasons the medications have been prescribed. Information about the driver's role was specifically added to the form to assist those healthcare providers that do not fully understand the safety risks and responsibilities of the CMV driver and in an effort to obtain reliable data. The form was specifically designed to address any medications that a driver is taking that may impair his/her ability to safely operate a CMV and was not intended to address only opioids.

The information obtained by the ME when utilizing the optional *391.41 CMV Driver Medication Form* will assist the ME in determining if the driver is medically qualified under 49 CFR 391.41 and to ensure that there are no disqualifying medical conditions or underlying medical conditions and prescribed medications that could

adversely affect the driver's safe driving ability or cause incapacitation constituting a risk to the public. The decision to certify a driver is a discretionary decision that rests with the certifying ME. MEs may disqualify a driver who takes any medications or combination of medications and substances that may impair or interfere with safe driving practices.

C. Burden Hours and Costs

Several commenters expressed concern that prescribing healthcare providers would not respond in a timely manner or at all, and that delays would be costly to drivers and motor carriers. ATA stated that FMCSA should consider the impact of potential delays to driver recertification, because the form does not advise prescribing healthcare providers to complete and return the form to the requesting ME within a specific timeframe, nor does it require MEs to certify a driver who is medically qualified even in the absence of the completed form. They expressed concern that the lack of such language could result in unnecessary and costly delays that would penalize qualified drivers due to circumstances that are out of their control. ATA recommended that if a prescribing healthcare provider is unable to return the form to a ME in a timely manner, FMCSA should advise MEs to continue to use their own judgement and certify drivers in these circumstances if they find them to be medically qualified.

Others commented that MEs will find the proposed form to be too restrictive and excessive explaining that although a full list of medications seems to be a good idea, it could significantly increase the effort required by the prescribing healthcare providers which is counterproductive to obtaining their assistance. Suggestions were made to ask the prescribing healthcare provider a single question such as is the driver taking any other medications that may be a risk to safe driving, to list only those medications that would negatively affect the ability of the driver to safely operate a CMV, or to only ask about medications that are of concern that the patient reported. Dr. Michael Megehee recommended including a statement that FMCSA guidelines require the ME to ask the prescribing healthcare provider for assistance in determining whether the driver is safe to operate a CMV and they meet the FMCSRs and that although the ME considers the opinions of treating physicians, the ME is responsible for making the final medical qualification determination.

ATA stated that while this IC may be a useful tool to many MEs in

determining whether a driver is medically qualified, in certain cases, it will not always be necessary. They believe that in most situations, the ME should be able to verify the accuracy of the information provided by the driver and the need for the medication based upon their training and experience in performing medical examinations and a robust conversation with the driver. They suggested that to avoid any unnecessary and costly delays to drivers and carriers alike, FMCSA should emphasize to MEs that the form is strictly voluntary and not a de facto standard when performing medical examinations. They also suggested that the form be consistent with the newly revised MER Form, MCSA-5875 by limiting its inquiry into medications that the driver is currently prescribed and that the prescribing healthcare provider should only report those medications that they can confirm have been prescribed. They stated that asking for all prescribed medications imposes a burden on healthcare providers without any significant positive impact on safety and suggested asking healthcare providers to list those medications that a driver is currently prescribed and would negatively affect their ability to safely operate a CMV will dramatically limit the collection burden without diminishing the quality of the information being collected.

OOIDA stated that there will be an increase in the number of inconsistencies in the medical certification process as MEs with no personal relationship with the driver attempt to evaluate a great deal of long-term medication usage. They stated that the proposed use of the *391.41 CMV Driver Medication Form* invites second guessing of a primary physician by MEs who are empowered by an unreliable medical form and that it invites the ME to question every medication and dosage which has been previously prescribed. They feel that this IC will only increase problems drivers have already experienced with MDs, which have resulted in higher costs and lengthier delays for drivers. Ultimately, they stated that the IC will lead to higher costs and longer wait times for drivers as they complete the examination with a ME and that it is already a common occurrence for the ME to conduct excessive testing beyond what is required under the current medical examination form. OOIDA points out that the IC is not limited to Schedule II drugs and could include items with no perceptible link to the safe operation of a CMV and believes that requesting an unlimited amount of

information is not helpful to determining a driver's fitness to operate a CMV and that there is no need to require a listing of any prescribed drugs beyond those regulated by § 382.213: Controlled substance use.

FMCSA Response

FMCSA does not believe that the form will add any time to the certification decision nor is it necessary to advise the ME to make a certification decision at any specified time after sending the *391.41 CMV Driver Medication Form* to the prescribing healthcare provider. In addition, the Medical Examiner's Certification Integration final rule provides a determination pending category that allows the driver to continue to operate a CMV as long as the driver has an unexpired MEC, for a maximum of 45 days, if the ME needs additional information to make a certification decision making additional delays unlikely.

As previously stated, the form was specifically designed to address any prescription medications that a driver is taking that may impair his/her ability to safely operate a CMV. Therefore, the Agency does not believe that the form is too restrictive or excessive nor will it significantly increase the effort required by the prescribing healthcare providers. Instead, the Agency believes that the form will be a useful resource for MEs in making a medical certification decision of drivers that are taking prescribed medications.

Because the prescribing healthcare provider is not trained regarding the FMCSRs and may not be a certified ME, FMCSA does not believe that asking the prescribing healthcare provider a single question such as is the driver taking any other medications that may be a risk to safe driving, to list only those medications that would negatively affect the ability of the driver to safely operate a CMV, or to only ask about medications that are of concern that the patient reported would provide reliable information to assist the ME in making a medical certification decision. FMCSA is not requiring MEs to use the *391.41 CMV Driver Medication Form*, use of the form is completely voluntary. Therefore, it would not be appropriate to add a statement that FMCSA is requiring MEs to ask the prescribing healthcare provider for assistance in determining whether the driver is safe to operate a CMV and that they meet the FMCSRs. The fact that the ME is responsible for making the final medical certification determination is stated on the form.

FMCSA continues to emphasize that the *391.41 CMV Driver Medication Form* is optional and may be used at the

discretion of the ME as a resource for the ME to communicate with prescribing healthcare providers, enabling the ME to make a more informed medical certification determination. When used, this form will supplement the MER Form, MCSA-5875 by asking for all medications that the prescribing healthcare provider has prescribed and any other medications that they are aware have been prescribed by another treating healthcare provider, and was designed to address any prescription medications that a driver is taking that may impair his/her ability to safely operate a CMV. The Agency does not feel that asking for all medications prescribed on this optional form imposes a burden on healthcare providers without any significant positive impact on safety and that limiting the collection to only medications that a driver is currently prescribed that the prescribing healthcare provider feels would negatively affect their ability to safely operate a CMV would diminish the quality of the information being collected.

Interstate CMV drivers are required to use a certified ME listed on the National Registry for their medical examination and certification. Therefore, in many cases the driver is going to a ME that they do not have a personal relationship with. The use of the optional *391.41 CMV Driver Medication Form* does not change this fact nor does it have a negative impact. The *391.41 CMV Driver Medication Form* is a tool to collect information that the MEs already collect at their discretion when performing driver examinations. This optional form will serve as a resource for the ME to use in communicating with prescribing healthcare providers, enabling the ME to make a more informed medical certification determination. The decision to certify a driver is a discretionary decision that continues to rest with the certifying ME. As previously stated, MEs may disqualify a driver who takes any medications or combination of medications and substances that may impair or interfere with safe driving practices.

D. Issues Outside the Scope of This Notice

A number of respondents submitted comments on topics that were outside the scope of what was proposed in this notice. This notice specifically requested comments related to the proposed IC and optional form to be used as an IC tool.

1. Schedule II Medication Use

OIDA disputed the fact that there is moderate evidence of increased risk due to Schedule II drug use and stated that the paucity of data shows that few CMV drivers have had problems with licit Schedule II drug use, or even prescription medications. They also stated that studies do not show that a significant number of CMV operators are crashing due to prescription medication use and that because insufficient data exists regarding the use of Schedule II drugs by CMV drivers should be an indication to the MRB and FMCSA that there are very few CMV drivers who have had problems with licit Schedule II drug usage.

Dr. Kurt T. Hegmann stated that this form should not be adopted for opioids/Schedule II medications, because this form is not evidence-based, not validated, there is no objective test to figure out who is unsafe and will crash if using opioids/Schedule II medications, and the form will cause a false sense of security that both endorses narcotics-using truck drivers and a method to sign the form to approve them to drive under the influence, and is likely to inadvertently further increase fatalities. He also stated that the form appears to evade the FDA-supported advice on opioid prescription labels that uniformly warn against vehicle operation and suggested we adopt the 2006 MEP recommendation to eliminate the potential exception that a prescriber who thought someone could drive, would be allowed to drive on opioids. Dr. Hegmann believes that this form will not help the Agency meet its primary mission. Instead he states that individuals using opioids should not drive trucks and instead should be tapered and/or de-toxed and then resume driving off those medications.

On the other hand, ACOEM, stated that the form does not go far enough to address the use of opioids by drivers and the rapid increase in adverse effects of opioid use. They pointed out that the original proposed version of this form goes back to the 2006 Schedule II Medication Panel and had significantly more content, which would have given the treating provider and the ME a clearer understanding of the impairment risks of the medications. They suggested any form incorporate some of the recommendations from the MRB and MCSAC joint Task 14-3: Schedule II Controlled Substances and CMV Drivers including the recommendation that a driver should not be medically qualified to operate a CMV while he/she is under treatment with narcotics or any narcotic derivative without exception. They go

on to explain that because the current exception remains in the FMCSRs (40 CFR 391.41(b)(12)(ii)), they recommend guidelines be provided to MEs regarding the use of narcotics.

FMCSA Response

Although optional use of the 391.41 CMV Driver Medication Form was introduced as a result of the MRB and MCSAC recommendations related to the use of Schedule II medications by CMV drivers, the recommendation was for FMCSA to develop a standardized form to assist the certified ME when reviewing prescription medications that have been disclosed during the history and physical examination for CMV driver certification. Therefore, the form was not designed to specifically address Schedule II medications. The form was designed to address any prescription medications that a driver is taking that may impair his/her ability to safely operate a CMV. FMCSA is not considering a change in the regulations or guidance that would prohibit or advise the ME regarding Schedule II medications at this time. Therefore, these comments are outside of the scope of this notice.

2. Qualifications of the ME

Several commenters stated that a ME might not be qualified to make a medical qualification decision if the driver uses Schedule II medications, because of a lack of training in pharmacology.

OOIDA stated that the personal physician is best equipped to review a driver's medical history and suggested that a personal physician be the one to review the driver's medical history and make the decision whether a medication will adversely affect the driver's ability to safely operate a CMV.

Dr. Hegmann advocated for implementation of the MRB's recommendation that ME eligibility be limited to those medically trained (*i.e.*, MD, DO, PA and NPs). He stated that the concept that these medically untrained examiners can make an informed judgment about driver impairment from narcotics, assess how opioids may interact with other medications, provide guidance to truck drivers, and judge fitness to drive is factually false. Dr. Hegmann feels that FMCSA does not rely on recommendations of the MRB and will selectively use whichever source of guidance is least restrictive which is directly contrary to the central, stated purpose of the Agency.

FMCSA Response

FMCSA responded to the question of who is qualified to be a ME in the National Registry of Certified Medical Examiners final rule (77 FR 24106, April 20, 2012), and is not considering a change to the regulation in 49 CFR 390.103, Eligibility requirements for medical examiner certification in this notice. Therefore, these comments are outside the scope of this notice.

Public Comments Invited: FMCSA requests that you comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for FMCSA to perform its functions, (2) the accuracy of the estimated burden, (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information, and (4) ways that the burden could be minimized without reducing the quality of the collected information. Comments received in response to this notice are sent to the OMB Desk Officer to address.

Issued under the authority delegated in 49 CFR 1.87 on: June 30, 2016.

G. Kelly Regal,

Associate Administrator, Office of Research and Information Technology.

[FR Doc. 2016-16199 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2015-0345]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 19 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions were granted January 21, 2016. The exemptions expire on January 21, 2018.

FOR FURTHER INFORMATION CONTACT:

Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> and/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.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. Background

On December 21, 2015, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (80 FR 79414). That notice listed 19 applicants' case histories. The 19 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption 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. Accordingly, FMCSA has evaluated the 19 applications on their merits and made a determination to grant exemptions to each of them.

III. Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

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 without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 19 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, central serous chorioretinopathy, central vision loss, complete loss of vision, optic atrophy, optic neuropathy, partial optic atrophy, phthisis, prosthetic eye, pseudophakia, refractive amblyopia, and retinal detachment. In most cases, their eye conditions were not recently developed. Ten of the applicants were either born with their vision impairments or have had them since childhood. The 9 individuals that sustained their vision conditions as adults have had it for a range of 5 to 42 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 19 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision in careers ranging for 3 to 38 years. In the

past three years, no drivers were involved in crashes, and 2 drivers were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the December 21, 2015 notice (80 FR 79414).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA-1998-3637.

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision

deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., "Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process," Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 19 applicants, no drivers were involved in crashes, and 2 drivers were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and

driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 19 applicants listed in the notice of December 21, 2015 (80 FR 79414).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 19 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

V. Discussion of Comments

FMCSA received no comments in this proceeding.

VI. Conclusion

Based upon its evaluation of the 19 exemption applications, FMCSA exempts the following drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)):

Raed A. Abdelrahim (NH),
 Dominic A. Berube (MA),
 Gary L. Best (MI),
 Therron K. Billings (VA),
 Lucien A. Fregeau (CT),
 Michael A. Gibbons (PA),
 Fred M. Hill, Jr. (LA),
 Freddie H. Johnson (ID),
 Timothy C. Kohn (MO),
 John D. Morgan (PA),
 Brian M. Olivas (TX),
 Douglas Pitts (OH),
 Jesus R. Ponce (NY),
 Eddie R. Schaefer (TX),
 Brian J. Stoltie (SC),
 Terry A. Strong (CA),
 Michael A. Terry (IN),
 Russell A. Wilkinson (FL),
 Timothy W. Youngblood, Jr. (TX)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: June 28, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016-16198 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2016-0059]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

In accordance with part 235 of Title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by a document dated May 25, 2016, Norfolk Southern Railway (NS) petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of a signal system. FRA assigned the petition Docket Number FRA-2016-0059.

Applicant: Norfolk Southern Railway, Mr. B. L. Sykes, Chief Engineer, C&S Engineering, 1200 Peachtree Street NE., Atlanta, GA 30309.

NS seeks approval of the modification of power-operated Switch 1723 at

Control Point (CP) BATH, at Milepost (MP) SP 172.29, on the NS Frankfort District, at Muncie, IN. Switch 1723 will be converted to a hand-operated switch. The existing 120RC signal at BATH will be moved southeast so that the new hand-operated switch will be outside the CP limits. The switch is to be converted to a hand-operated switch to improve operations at this location.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12-140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12-140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 22, 2016 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the

commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy. See also <http://www.regulations.gov/#!privacyNotice> for the privacy notice of [regulations.gov](http://www.regulations.gov).

Issued in Washington, DC.

Patrick T. Warren,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 2016-16127 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2016 0069]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PINKY; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 8, 2016.

ADDRESSES: Comments should refer to docket number MARAD-2016-0069. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of

Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PINKY is:

INTENDED COMMERCIAL USE OF VESSEL: Shuttle and Parasail Vessel.

GEOGRAPHIC REGION: "New York".

The complete application is given in DOT docket MARAD-2016-0069 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

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 complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: June 30, 2016.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2016-16260 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before August 8, 2016.

Address Comments To: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on June 30, 2016.

Ryan Paquet,

Director, Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
20250-N	ELI LILLY AND COMPANY.	173.196(a), 173.199(A), 178.603, 178.609(D).	To authorize the transportation in commerce of certain infectious substances in specially designed packaging (freezers). (mode 1).
20251-N	SALCO PRODUCTS INC	172.203(a), 178.345-1, 180.413.	To authorize the manufacture, mark, sale and use of manway assemblies constructed from stabilized polyethylene for installation on certain DOT specification cargo tank motor vehicles in transporting certain hazardous materials. (mode 1).
20252-N	LUXFER INC	173.302(a), 180.205, 177.834(h).	To authorize the manufacture, marking, sale and use of non-DOT specification fully wrapped carbon fiber composite cylinder with a no-load sharing polymer liner for the transport of certain hazardous materials. (modes 1, 2, 3).
20254-N	P.J. HELICOPTERS, INC.	173.315(j), 172.101(h)(i), 172.301(c), 172.302(c).	To authorize the transportation in commerce in the U.S. only of certain hazardous materials by 14 CFR Part 133 Rotorcraft External Load Operations transporting hazardous materials attached to or suspended from an aircraft and 14 CFR Part 135 operations transporting hazardous materials on board an aircraft. (mode 4).
20257-N	VEOLIA ES TECHNICAL SOLUTIONS LLC.	173.21(b), 173.51(a), 173.54(a), 173.56(b).	To authorize the one-time, one-way transportation of unapproved explosives by motor vehicle. (mode 1).
20258-N	WINCO FIREWORKS	173.62(c), 172.310(c)	To authorize the one-way transportation in commerce of Division 1.4G consumer fireworks in non-DOT specification fiberboard non-bulk out packagings under the terms and conditions specified when transported by private, contract or common carrier. (mode 1).
20261-N	SAFT S.A	173.185(a)	To authorize the transportation in commerce of prototype and low production lithium ion cells and batteries and lithium metal cells and batteries by cargo-only aircraft. (mode 4).

[FR Doc. 2016-16066 Filed 7-7-16; 8:45 am]
 BILLING CODE 4909-60-M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office

of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before August 8, 2016.

Address Comments to: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of

Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on June 28, 2016.

Ryan Paquet,
 Director, Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
12102-M	VEOLIA ES TECHNICAL SOLUTIONS LLC.	173.56(b) and 173.56(i)	To modify the special permit to authorize an additional Division 4.1 material to be transported using the special permit.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
15552-M	POLY-COAT SYSTEMS, INC.	173.241, 173.242, 173.242, 173.243, 107.503(B), and 107.503(C).	To modify the special permit to authorize an alternate test method for determining chemical compatibility for FRP cylinders.
15839-M	SENSORS, INC	172.301(c) and 177.834(h).	To modify the special permit to authorize an additional cylinder carrying case.

[FR Doc. 2016-16063 Filed 7-7-16; 8:45 am]

BILLING CODE 4909-60-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Application of LIMA NY Corp. for Commuter Air Carrier Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order To Show Cause (Order 2016-7-1) Docket DOT-OST-2015-0014.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding LIMA NY Corp. fit, willing, and able, and awarding it commuter air carrier authority to conduct scheduled commuter service.

DATES: Persons wishing to file objections should do so no later than July 15, 2016.

ADDRESSES: Objections and answers to objections should be filed in Docket DOT-OST-2015-0014 and addressed to Docket Operations, (M-30, Room W12-140), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Barbara Snoden, Air Carrier Fitness Division (X-56, Room W86-471), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366-4834.

Dated: July 1, 2016.

Jenny T. Rosenberg,
Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2016-16196 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary, Washington, DC

Application of Tropic Ocean Airways, LLC for Commuter Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 2016-7-2), Docket DOT-OST-2015-0259.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Tropic Ocean Airways, LLC, fit, willing, and able, and awarding it Commuter Air Carrier Authorization.

DATES: Persons wishing to file objections should do so no later than July 15, 2016.

ADDRESSES: Objections and answers to objections should be filed in Docket DOT-OST-2015-0259 and addressed to U.S. Department of Transportation, Docket Operations, (M-30, Room W12-140), 1200 New Jersey Avenue SE., West Building Ground Floor, Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Damon D. Walker, Air Carrier Fitness Division (X-56, Room W86-465), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366-7785.

Dated: July 1, 2016.

Jenny T. Rosenberg,
Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2016-16195 Filed 7-7-16; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, August 11, 2016.

FOR FURTHER INFORMATION CONTACT: Donna Powers at 1-888-912-1227 or (954) 423-7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be held Thursday, August 11, 2016, at 1:00 p.m., Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Donna Powers. For more information please contact: Donna Powers at 1-888-912-1227 or (954) 423-7977 or write: TAP Office, 1000 S. Pine Island Road, Plantation, FL 33324 or contact us at the Web site: <http://www.improveirs.org>. The committee will be discussing various issues related to Tax Forms and Publications and public input is welcomed.

Dated: July 1, 2016.

Otis Simpson,
Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16153 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: The Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will conduct an open meeting and will solicit public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, August 10, 2016.

FOR FURTHER INFORMATION CONTACT: Otis Simpson at 1-888-912-1227 or 202-317-3332.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Wednesday, August 10, 2016, at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Otis Simpson. For more information please contact: Otis Simpson at 1-888-912-1227 or 202-317-3332, TAP Office, 1111 Constitution Avenue NW., Room 1509, National Office, Washington, DC 20224, or contact us at the Web site: <http://www.improveirs.org>.

The committee will be discussing various issues related to the Taxpayer Assistance Centers and public input is welcomed.

Dated: July 1, 2016.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16151 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, August 17, 2016.

FOR FURTHER INFORMATION CONTACT: Linda Rivera at 1-888-912-1227 or (202) 317-3337.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Wednesday, August 17, 2016, at 2:30

p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Linda Rivera. For more information please contact: Ms. Rivera at 1-888-912-1227 or (202) 317-3337, or write TAP Office, 1111 Constitution Avenue NW., Room 1509, National Office, Washington, DC 20224, or contact us at the Web site: <http://www.improveirs.org>.

The committee will be discussing Toll-free issues and public input is welcomed.

Dated: July 1, 2016.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16154 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, August 18, 2016.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1-888-912-1227 or (202) 317-4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, August 18, 2016, at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Antoinette Ross. For more information please contact: Antoinette Ross at 1-888-912-1227 or (202) 317-4110, or write TAP Office, 1111 Constitution Avenue NW., Room 1509, National Office, Washington, DC 20224, or

contact us at the Web site: <http://www.improveirs.org>.

The committee will be discussing various issues related to Taxpayer Communications and public input is welcome.

Dated: July 1, 2016.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16156 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Kim Vinci at 1-888-912-1227 or 916-974-5086.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, August 31, 2016, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information please contact: Kim Vinci at 1-888-912-1227 or 916-974-5086, TAP Office, 4330 Watt Ave., Sacramento, CA 95821, or contact us at the Web site: <http://www.improveirs.org>.

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: July 1, 2016.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16150 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****Open Meeting of the Taxpayer
Advocacy Panel Notices and
Correspondence Project Committee**

AGENCY: Internal Revenue Service (IRS),
Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, August 24, 2016.

FOR FURTHER INFORMATION CONTACT: Theresa Singleton at 1-888-912-1227 or 202-317-3329.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Wednesday, August 24, 2016, at 12:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of

intent to participate must be made with Theresa Singleton. For more information please contact: Theresa Singleton at 1-888-912-1227 or 202-317-3329, TAP Office, 1111 Constitution Avenue NW., Room 1509-National Office, Washington, DC 20224, or contact us at the Web site: <http://www.improveirs.org>.

The agenda will include a discussion on various letters, and other issues related to written communications from the IRS.

Dated: July 1, 2016.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016-16155 Filed 7-7-16; 8:45 am]

BILLING CODE 4830-01-P



FEDERAL REGISTER

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Friday,

No. 131

July 8, 2016

Part II

Department of the Treasury

Fiscal Service

Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies; Notices

DEPARTMENT OF THE TREASURY**Fiscal Service****[(Dept. Circular 570; 2016 Revision)]****Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies****Effective July 1, 2016**

This Circular is published annually for the information of Federal bond-approving officers and persons required to give bonds to the United States consistent with 31 CFR 223.16. (Interim changes are published in the **Federal Register** and on the internet as they occur). Other information pertinent to Federal sureties may be obtained from the U.S. Department of the Treasury, Bureau of the Fiscal Service, Surety Bond Section, 3700 East-West Highway, Room 6D22, Hyattsville, MD 20782, Telephone (202) 874-6850 or Fax (202) 874-9978.

The most current list of Treasury authorized companies is always available through the Internet at www.fiscal.treasury.gov/fsreports/ref/suretyBnd/c570.htm. In addition, applicable laws, regulations, and application information are also available at the same site.

Please note that the underwriting limitation published herein is on a per bond basis but this does not limit the amount of a bond that a company can write. Companies are allowed to write bonds with a penal sum over their underwriting limitation as long as they protect the excess amount with reinsurance, coinsurance or other methods as specified at 31 CFR 223.10-11. Please refer to Note (b) at the end of this publication.

The following companies have complied with the law and the regulations of the U.S. Department of the Treasury. Those listed in the front of this Circular are acceptable as sureties and reinsurers on Federal bonds under Title 31 of the United States Code, Sections 9304 to 9308 [See Note (a)]. Those listed in the back are acceptable only as reinsurers on Federal bonds under 31 CFR 223.3(b) [See Note (e)].

If we can be of any assistance, please feel free to contact the Surety Bond Section at (202) 874-6850.

Patricia M. Greiner,*Assistant Commissioner for Management (CFO).*

IMPORTANT INFORMATION IS CONTAINED IN THE NOTES AT THE END OF THIS CIRCULAR. PLEASE READ THE NOTES CAREFULLY.

Certified Companies**ACCREDITED SURETY AND CASUALTY COMPANY, INC. (NAIC #26379)**

BUSINESS ADDRESS: P.O. Box 140855, Orlando, FL 32814-0855. PHONE: (407) 629-2131. UNDERWRITING LIMITATION b/: \$2,164,000. SURETY LICENSES c,f/: AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Florida.

ACE American Insurance Company (NAIC #22667)

BUSINESS ADDRESS: 436 Walnut Street, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$257,882,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

ACE Property and Casualty Insurance Company (NAIC #20699)

BUSINESS ADDRESS: 436 WALNUT STREET, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$199,590,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

ACSTAR INSURANCE COMPANY (NAIC #22950)

BUSINESS ADDRESS: 30 SOUTH ROAD, FARMINGTON, CT 06032. PHONE: (860) 415-8400. UNDERWRITING LIMITATION b/: \$2,634,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Aegis Security Insurance Company (NAIC #33898)

BUSINESS ADDRESS: P.O. Box 3153, Harrisburg, PA 17105. PHONE: (717)

657-9671. UNDERWRITING LIMITATION b/: \$5,644,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

ALL AMERICA INSURANCE COMPANY (NAIC #20222)

BUSINESS ADDRESS: P.O. BOX 351, VAN WERT, OH 45891-0351. PHONE: (419) 238-1010. UNDERWRITING LIMITATION b/: \$14,597,000. SURETY LICENSES c,f/: AZ, CA, CT, GA, IL, IN, IA, KY, MD, MA, MI, NV, NJ, NY, NC, OH, OK, TN, TX, VA. INCORPORATED IN: Ohio.

Allegheny Casualty Company (NAIC #13285) ¹

BUSINESS ADDRESS: One Newark Center, 20th Floor, Newark, NJ 07102. PHONE: (800) 333-4167. UNDERWRITING LIMITATION b/: \$2,260,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New Jersey.

ALLEGHENY SURETY COMPANY (NAIC #34541)

BUSINESS ADDRESS: 4217 Steubenville Pike, Pittsburgh, PA 15205. PHONE: (412) 921-3077. UNDERWRITING LIMITATION b/: \$194,000. SURETY LICENSES c,f/: PA. INCORPORATED IN: Pennsylvania.

ALLIED Property and Casualty Insurance Company (NAIC #42579)

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220. PHONE: (515) 508-4211. UNDERWRITING LIMITATION b/: \$5,890,000. SURETY LICENSES c,f/: AL, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NM, NY, ND, OH, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

Allied World Insurance Company (NAIC #22730)

BUSINESS ADDRESS: 199 Water Street, New York, NY 10038. PHONE: (646) 794-0500. UNDERWRITING LIMITATION b/: \$67,664,000.

SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: New Hampshire.

Allied World Specialty Insurance Company (NAIC #16624)

BUSINESS ADDRESS: 199 WATER STREET, NEW YORK, NY 10038.
PHONE: (646) 794-0500.
UNDERWRITING LIMITATION b/: \$40,569,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Delaware.

Alterra Reinsurance USA Inc. (NAIC #10829)²

AMCO Insurance Company (NAIC #19100)

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220.
PHONE: (515) 508-4211.
UNDERWRITING LIMITATION b/: \$20,626,000. SURETY LICENSES c./f/: AL, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, ME, MD, MI, MN, MS, MO, MT, NE, NV, NM, NY, NC, ND, OH, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Iowa.

AMERICAN ALTERNATIVE INSURANCE CORPORATION (NAIC #19720)

BUSINESS ADDRESS: 555 COLLEGE ROAD EAST, P.O. BOX 5241, PRINCETON, NJ 08543. PHONE: (609) 243-4200. UNDERWRITING LIMITATION b/: \$19,946,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Delaware.

American Automobile Insurance Company (NAIC #21849)

BUSINESS ADDRESS: 225 W. WASHINGTON STREET, SUITE 1800, CHICAGO, IL 60606-3484. PHONE: (888) 466-7883. UNDERWRITING LIMITATION b/: \$17,460,000. SURETY LICENSES c./f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA,

ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Missouri.

AMERICAN BANKERS INSURANCE COMPANY OF FLORIDA (NAIC #10111)

BUSINESS ADDRESS: 11222 QUAIL ROOST DRIVE, MIAMI, FL 33157-6596. PHONE: (305) 253-2244.
UNDERWRITING LIMITATION b/: \$48,325,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Florida.

American Casualty Company of Reading, Pennsylvania (NAIC #20427)

BUSINESS ADDRESS: 333 S. WABASH AVE, CHICAGO, IL 60604. PHONE: (312) 822-5000. UNDERWRITING LIMITATION b/: \$15,080,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Pennsylvania.

AMERICAN CONTRACTORS INDEMNITY COMPANY (NAIC #10216)³

BUSINESS ADDRESS: 601 South Figueroa Street, 16th Floor, Los Angeles, CA 90017. PHONE: (310) 649-0990. UNDERWRITING LIMITATION b/: \$11,305,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: California.

American Fire and Casualty Company (NAIC #24066)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$3,952,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA,

WV, WI, WY. INCORPORATED IN: New Hampshire.

American Guarantee and Liability Insurance Company (NAIC #26247)

BUSINESS ADDRESS: 1400 AMERICAN LANE, TOWER I, 18TH FLOOR, SCHAUMBURG, IL 60196-1056. PHONE: (847) 605-6000.
UNDERWRITING LIMITATION b/: \$18,029,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: New York.

American Home Assurance Company (NAIC #19380)

BUSINESS ADDRESS: 175 WATER STREET, 18TH FLOOR, NEW YORK, NY 10038. PHONE: (212) 770-7000.
UNDERWRITING LIMITATION b/: \$664,080,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: New York.

American Insurance Company (The) (NAIC #21857)

BUSINESS ADDRESS: 225 W. WASHINGTON STREET, SUITE 1800, CHICAGO, IL 60606-3484. PHONE: (888) 466-7883. UNDERWRITING LIMITATION b/: \$22,225,000. SURETY LICENSES c./f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, GU, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Ohio.

AMERICAN ROAD INSURANCE COMPANY (THE) (NAIC #19631)

BUSINESS ADDRESS: One American Road, MD 7600, Dearborn, MI 48126-2701. PHONE: (313) 337-1102.
UNDERWRITING LIMITATION b/: \$25,110,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Michigan.

American Safety Casualty Insurance Company (NAIC #39969)

BUSINESS ADDRESS: 250 Commercial Street, Suite 5000, Manchester, NH

03101. PHONE: (603) 656-2233. UNDERWRITING LIMITATION b/: \$12,741,000. SURETY LICENSES c./f/: AL, AK, AS, AZ, AR, CA, CO, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Oklahoma.

American Southern Insurance Company (NAIC #10235)

BUSINESS ADDRESS: P.O. Box 723030, Atlanta, GA 31139-0030. PHONE: (404) 266-9599. UNDERWRITING LIMITATION b/: \$3,831,000. SURETY LICENSES c./f/: AL, AZ, AR, CO, DE, DC, FL, GA, IL, IN, KS, KY, MD, MI, MN, MS, MO, NE, NJ, NY, NC, OH, PA, SC, TN, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Kansas.

American Surety Company (NAIC #31380)

BUSINESS ADDRESS: 250 East 96th Street, Suite 202, Indianapolis, IN 46240. PHONE: (317) 875-8700. UNDERWRITING LIMITATION b/: \$1,026,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WY. INCORPORATED IN: Indiana.

Amerisure Insurance Company (NAIC #19488)

BUSINESS ADDRESS: P.O. Box 2060, Farmington Hills, MI 48331-3586. PHONE: (248) 615-9000. UNDERWRITING LIMITATION b/: \$23,868,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

Amerisure Mutual Insurance Company (NAIC #23396)

BUSINESS ADDRESS: P.O. Box 2060, Farmington Hills, MI 48331-3586. PHONE: (248) 615-9000. UNDERWRITING LIMITATION b/: \$61,661,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

Amerisure Partners Insurance Company (NAIC #11050)

BUSINESS ADDRESS: P. O. Box 2060, Farmington Hills, MI 48331-3586. PHONE: (248) 615-9000. UNDERWRITING LIMITATION b/: \$2,388,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NM, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

Antilles Insurance Company (NAIC #10308)

BUSINESS ADDRESS: P.O. Box 9023507, San Juan, PR 00902-3507. PHONE: (787) 474-4900. UNDERWRITING LIMITATION b/: \$4,477,000. SURETY LICENSES c./f/: PR. INCORPORATED IN: Puerto Rico.

Arch Insurance Company (NAIC #11150)

BUSINESS ADDRESS: 300 Plaza Three, Jersey City, NJ 07311-1107. PHONE: (201) 743-4000. UNDERWRITING LIMITATION b/: \$82,654,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Missouri.

Arch Reinsurance Company (NAIC #10348)

BUSINESS ADDRESS: 445 South Street, Suite 220, P.O. Box 1988, Morristown, NJ 07962-1988. PHONE: (973) 898-9575. UNDERWRITING LIMITATION b/: \$37,489,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV. INCORPORATED IN: Delaware.

Argonaut Insurance Company (NAIC #19801)

BUSINESS ADDRESS: P.O. BOX 469011, SAN ANTONIO, TX 78246. PHONE: (800) 470-7958. UNDERWRITING LIMITATION b/: \$75,285,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Illinois.

ASPEN AMERICAN INSURANCE COMPANY (NAIC #43460)

BUSINESS ADDRESS: 175 Capital Boulevard, Suite 300, Rocky Hill, CT 06067. PHONE: (860) 258-3500. UNDERWRITING LIMITATION b/: \$26,855,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Texas.

Associated Indemnity Corporation (NAIC #21865)

BUSINESS ADDRESS: 225 W. WASHINGTON STREET, SUITE 1800, CHICAGO, IL 60606-3484. PHONE: (888) 466-7883. UNDERWRITING LIMITATION b/: \$8,710,000. SURETY LICENSES c./f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, GU, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: California.

Atlantic Specialty Insurance Company (NAIC #27154)

BUSINESS ADDRESS: 605 Highway 169 North, Suite 800, Plymouth, MN 55441. PHONE: (952) 852-2431. UNDERWRITING LIMITATION b/: \$62,234,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: New York.

Auto-Owners Insurance Company (NAIC #18988)

BUSINESS ADDRESS: P.O. BOX 30660, LANSING, MI 48909-8160. PHONE: (517) 323-1200. UNDERWRITING LIMITATION b/: \$877,795,000. SURETY LICENSES c./f/: AL, AZ, AR, CO, FL, GA, ID, IL, IN, IA, KS, KY, MI, MN, MS, MO, NE, NV, NM, NC, ND, OH, OR, PA, SC, SD, TN, UT, VA, WA, WI. INCORPORATED IN: Michigan.

AXIS Insurance Company (NAIC #37273)

BUSINESS ADDRESS: 11680 Great Oaks Way, Ste. 500, Alpharetta, GA 30022. PHONE: (678) 746-9400. UNDERWRITING LIMITATION b/: \$56,508,000. SURETY LICENSES c./f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY,

LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

AXIS Reinsurance Company (NAIC #20370)

BUSINESS ADDRESS: 11680 Great Oaks Way, Suite 500, Alpharetta, GA 30022. PHONE: (678) 746-9400. UNDERWRITING LIMITATION b/: \$86,086,000. SURETY LICENSES c,f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

Bankers Insurance Company (NAIC #33162)

BUSINESS ADDRESS: P.O. BOX 15707, ST. PETERSBURG, FL 33733. PHONE: (727) 823-4000. UNDERWRITING LIMITATION b/: \$7,668,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Florida.

Bankers Standard Insurance Company (NAIC #18279)

BUSINESS ADDRESS: 436 WALNUT STREET, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$15,330,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Beazley Insurance Company, Inc. (NAIC #37540)

BUSINESS ADDRESS: 30 Batterson Park Road, Farmington, CT 06032. PHONE: (860) 677-3700. UNDERWRITING LIMITATION b/: \$11,915,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Berkley Insurance Company (NAIC #32603)

BUSINESS ADDRESS: 475 STEAMBOAT ROAD, GREENWICH, CT 06830. PHONE: (203) 542-3800. UNDERWRITING LIMITATION b/: \$440,222,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Berkley Regional Insurance Company (NAIC #29580)

BUSINESS ADDRESS: 11201 Douglas Avenue, Urbandale, IA 50322. PHONE: (515) 473-3174. UNDERWRITING LIMITATION b/: \$67,992,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Berkshire Hathaway Homestate Insurance Company (NAIC #20044)

BUSINESS ADDRESS: 1314 Douglas Street, Omaha, NE 68102-1944. PHONE: (402) 393-7255. UNDERWRITING LIMITATION b/: \$116,770,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Nebraska.

Berkshire Hathaway Specialty Insurance Company (NAIC #22276)

BUSINESS ADDRESS: 1314 Douglas Street, Suite 1400, Omaha, NE 68102-1944. PHONE: (402) 916-3000. UNDERWRITING LIMITATION b/: \$304,411,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Nebraska.

BITCO GENERAL INSURANCE CORPORATION (NAIC #20095)

BUSINESS ADDRESS: 320 18TH STREET, ROCK ISLAND, IL 61201-8744. PHONE: (309) 786-5401. UNDERWRITING LIMITATION b/: \$27,515,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE,

DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

BOND SAFEGUARD INSURANCE COMPANY (NAIC #27081)

BUSINESS ADDRESS: 10002 Shelbyville Road, Suite 100, Louisville, KY 40223-2979. PHONE: (615) 553-9500. UNDERWRITING LIMITATION b/: \$3,606,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, KS, KY, LA, ME, MD, MA, MN, MS, MO, MP, MT, NV, NH, NJ, NM, NC, ND, OH, OK, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: South Dakota.

Bondex Insurance Company (NAIC #12965)

BUSINESS ADDRESS: P.O. Box 6, Florham Park, NJ 07932. PHONE: (973) 377-7000. UNDERWRITING LIMITATION b/: \$338,000. SURETY LICENSES c,f/: DE, NJ, NY, PA. INCORPORATED IN: New Jersey.

Boston Indemnity Company, Inc. (NAIC #30279)

BUSINESS ADDRESS: 4 High Street, Suite 206, North Andover, MA 01845. PHONE: (973) 377-7000. UNDERWRITING LIMITATION b/: \$503,000. SURETY LICENSES c,f/: AL, AZ, AR, CT, DE, DC, FL, GA, ID, IN, KS, KY, LA, ME, MA, MN, MS, MT, NE, NV, NC, ND, OK, PA, SD, TN, WV. INCORPORATED IN: South Dakota.

Brierfield Insurance Company (NAIC #10993)

BUSINESS ADDRESS: 6300 University Parkway, Sarasota, FL 34240-8424. PHONE: (800) 226-3224 x-2726. UNDERWRITING LIMITATION b/: \$868,000. SURETY LICENSES c,f/: AL, AR, GA, MS, TN. INCORPORATED IN: Mississippi.

BRITISH AMERICAN INSURANCE COMPANY (NAIC #32875)

BUSINESS ADDRESS: P.O. Box 1590, Dallas, TX 75221-1590. PHONE: (214) 443-5500. UNDERWRITING LIMITATION b/: \$3,421,000. SURETY LICENSES c,f/: TX. INCORPORATED IN: Texas.

Capitol Indemnity Corporation (NAIC #10472)

BUSINESS ADDRESS: P.O. Box 5900, Madison, WI 53705-0900. PHONE: (608) 829-4200. UNDERWRITING LIMITATION b/: \$18,331,000.

SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Capitol Preferred Insurance Company, Inc. (NAIC #10908)

BUSINESS ADDRESS: 2255 Killearn Center Boulevard, Tallahassee, FL 32309. PHONE: (850) 521-0742. UNDERWRITING LIMITATION b/: \$2,606,000. SURETY LICENSES c.f/: FL, GA, SC. INCORPORATED IN: Florida.

Carolina Casualty Insurance Company (NAIC #10510)

BUSINESS ADDRESS: 11201 Douglas Avenue, Urbandale, IA 50322. PHONE: (515) 473-3000. UNDERWRITING LIMITATION b/: \$9,911,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

Centennial Casualty Company (NAIC #34568)

BUSINESS ADDRESS: 2200 Woodcrest Place, Suite 200, Birmingham, AL 35209. PHONE: (205) 414-2600. UNDERWRITING LIMITATION b/: \$6,628,000. SURETY LICENSES c.f/: AL. INCORPORATED IN: Alabama.

CENTRAL MUTUAL INSURANCE COMPANY (NAIC #20230)

BUSINESS ADDRESS: P.O. BOX 351, VAN WERT, OH 45891-0351. PHONE: (419) 238-1010. UNDERWRITING LIMITATION b/: \$55,984,000. SURETY LICENSES c.f/: AZ, CA, CO, CT, DE, GA, IL, IN, IA, KY, MD, MA, MI, NV, NH, NJ, NM, NY, NC, OH, OK, PA, TN, TX, VA. INCORPORATED IN: Ohio.

CENTURY SURETY COMPANY (NAIC #36951)

BUSINESS ADDRESS: 550 Polaris Parkway, Westerville, OH 43082. PHONE: (614) 895-2000. UNDERWRITING LIMITATION b/: \$13,024,000. SURETY LICENSES c.f/: AZ, IN, OH, WV, WI. INCORPORATED IN: Ohio.

Charter Oak Fire Insurance Company (The) (NAIC #25615)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183.

PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$25,565,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Cherokee Insurance Company (NAIC #10642)

BUSINESS ADDRESS: 34200 Mound Road, Sterling Heights, MI 48310. PHONE: (800) 201-0450 x-3400. UNDERWRITING LIMITATION b/: \$15,278,000. SURETY LICENSES c.f/: AL, AZ, AR, CA, CO, CT, DE, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

CHUBB INDEMNITY INSURANCE COMPANY (NAIC #12777)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (212) 612-4000. UNDERWRITING LIMITATION b/: \$15,076,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

Cincinnati Casualty Company (The) (NAIC #28665)

BUSINESS ADDRESS: P.O. Box 145496, Cincinnati, OH 45250-5496. PHONE: (513) 870-2000. UNDERWRITING LIMITATION b/: \$33,650,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

Cincinnati Insurance Company (The) (NAIC #10677)

BUSINESS ADDRESS: P.O. BOX 145496, CINCINNATI, OH 45250-5496. PHONE: (513) 870-2000. UNDERWRITING LIMITATION b/: \$407,593,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD,

TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

CITIZENS INSURANCE COMPANY OF AMERICA (NAIC #31534)

BUSINESS ADDRESS: 808 NORTH HIGHLANDER WAY, HOWELL, MI 48843-1070. PHONE: (517) 546-2160. UNDERWRITING LIMITATION b/: \$66,036,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CO, CT, DE, DC, GA, HI, IL, IN, IA, KS, ME, MD, MA, MI, MN, MS, MO, MT, NE, NH, NJ, NM, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI. INCORPORATED IN: Michigan.

COLONIAL AMERICAN CASUALTY AND SURETY COMPANY (NAIC #34347)

BUSINESS ADDRESS: 1400 AMERICAN LANE, TOWER I, 18TH FLOOR, SCHAUMBURG, IL 60196-1056. PHONE: (847) 605-6000. UNDERWRITING LIMITATION b/: \$2,232,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Maryland.

COLONIAL SURETY COMPANY (NAIC #10758)

BUSINESS ADDRESS: 123 Tice Boulevard, Suite 250, Woodcliff Lake, NJ 07677. PHONE: (201) 573-8788. UNDERWRITING LIMITATION b/: \$3,162,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Continental Casualty Company (NAIC #20443)

BUSINESS ADDRESS: 333 S. WABASH AVE, CHICAGO, IL 60604. PHONE: (312) 822-5000. UNDERWRITING LIMITATION b/: \$765,476,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Illinois.

**CONTINENTAL HERITAGE
INSURANCE COMPANY (NAIC
#39551)**

BUSINESS ADDRESS: 6140
PARKLAND BLVD, STE 321,
MAYFIELD HEIGHTS, OH 44124.
PHONE: (440) 229-3420.
UNDERWRITING LIMITATION b/:
\$713,000. SURETY LICENSES c.f/:
AZ, CA, CO, DC, FL, GA, ID, IL, IN,
IA, KY, LA, ME, MD, MN, MS, NE,
NV, NJ, ND, OH, PA, SC, SD, TN, TX,
UT, VA, WA, WV. INCORPORATED
IN: Florida.

**Continental Insurance Company (The)
(NAIC #35289)**

BUSINESS ADDRESS: 333 S. WABASH
AVE, CHICAGO, IL 60604. PHONE:
(312) 822-5000. UNDERWRITING
LIMITATION b/: \$146,927,000.
SURETY LICENSES c.f/: AL, AK, AZ,
AR, CA, CO, CT, DE, DC, FL, GA, GU,
HI, ID, IL, IN, IA, KS, KY, LA, ME,
MD, MA, MI, MN, MS, MO, MP, MT,
NE, NV, NH, NJ, NM, NY, NC, ND,
OH, OK, OR, PA, PR, RI, SC, SD, TN,
TX, UT, VT, VA, VI, WA, WV, WI,
WY. INCORPORATED IN:
Pennsylvania.

**CONTRACTORS BONDING AND
INSURANCE COMPANY (NAIC
#37206)**

BUSINESS ADDRESS: 9025 N.
Lindbergh Drive, Peoria, IL 61615.
PHONE: (309) 692-1000.
UNDERWRITING LIMITATION b/:
\$11,426,000. SURETY LICENSES
c.f/: AL, AK, AZ, AR, CA, CO, CT, DE,
DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
LA, ME, MD, MA, MI, MN, MS, MO,
MT, NE, NV, NH, NJ, NM, NY, NC, TN,
ND, OH, OK, OR, PA, RI, SC, SD, TN,
TX, UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Illinois.

**Cooperativa de Seguros Multiples de
Puerto Rico (NAIC #18163)**

BUSINESS ADDRESS: P.O. BOX
363846, SAN JUAN, PR 00936-3846.
PHONE: (787) 622-3575 x-2512.
UNDERWRITING LIMITATION b/:
\$16,415,000. SURETY LICENSES
c.f/: PR. INCORPORATED IN: Puerto
Rico.

**CorePointe Insurance Company (NAIC
#10499)**

BUSINESS ADDRESS: 401 South Old
Woodward Avenue, Suite 300,
Birmingham, MI 48009. PHONE: (800)
782-9164. UNDERWRITING
LIMITATION b/: \$5,683,000. SURETY
LICENSES c.f/: AL, AK, AZ, AR, CA,
CO, CT, DE, DC, FL, GA, HI, ID, IL,
IN, IA, KS, KY, LA, ME, MD, MA, MI,
MN, MS, MO, MT, NE, NV, NH, NJ,
NM, NY, NC, ND, OH, OK, OR, PA,

RI, SC, SD, TN, TX, UT, VT, VA, WA,
WV, WI, WY. INCORPORATED IN:
Michigan.

**CUMIS INSURANCE SOCIETY, INC.
(NAIC #10847)**

BUSINESS ADDRESS: P.O. Box 1084,
Madison, WI 53701. PHONE: (608)
238-5851. UNDERWRITING
LIMITATION b/: \$74,947,000.
SURETY LICENSES c.f/: AL, AK, AZ,
AR, CA, CO, CT, DE, DC, FL, GA, GU,
HI, ID, IL, IN, IA, KS, KY, LA, ME,
MD, MA, MI, MN, MS, MO, MT, NE,
NV, NH, NJ, NM, NY, NC, ND, OH,
OK, OR, PA, PR, RI, SC, SD, TN, TX,
UT, VT, VA, VI, WA, WV, WI, WY.
INCORPORATED IN: Iowa.

**CUMIS Specialty Insurance Company,
Inc. (NAIC #12758)**

BUSINESS ADDRESS: Post Office Box
1084, Madison, WI 53701. PHONE:
(608) 238-5851. UNDERWRITING
LIMITATION b/: \$5,100,000. SURETY
LICENSES c.f/: AL, CA, CT, DC, FL,
GA, HI, ID, IL, IN, IA, KS, KY, MD,
MA, MI, MN, MO, NE, NV, NJ, NY,
NC, OH, OK, OR, PA, SC, SD, TX, UT,
VA, WA, WI, WY. INCORPORATED
IN: Iowa.

**Developers Surety and Indemnity
Company (NAIC #12718)**

BUSINESS ADDRESS: P.O. BOX 19725,
IRVINE, CA 92623-9725. PHONE:
(949) 263-3300. UNDERWRITING
LIMITATION b/: \$7,446,000. SURETY
LICENSES c.f/: AL, AK, AZ, AR, CA,
CO, CT, DE, DC, FL, GA, HI, ID, IL,
IN, IA, KS, KY, LA, ME, MD, MA, MI,
MN, MS, MO, MT, NE, NV, NH, NJ,
NM, NY, NC, ND, OH, OK, OR, PA,
RI, SC, SD, TN, TX, UT, VT, VA, VI,
WA, WV, WI, WY. INCORPORATED
IN: Iowa.

**ELECTRIC INSURANCE COMPANY
(NAIC #21261)**

BUSINESS ADDRESS: 75 Sam Fonzo
Drive, Beverly, MA 01915-1000.
PHONE: (978) 921-2080.
UNDERWRITING LIMITATION b/:
\$54,555,000. SURETY LICENSES
c.f/: AL, AK, AZ, AR, CA, CO, CT, DE,
DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
LA, ME, MD, MA, MI, MN, MS, MO,
MT, NE, NV, NH, NJ, NM, NY, NC,
ND, OH, OK, OR, PA, PR, RI, SC, SD,
TN, TX, UT, VT, VA, WA, WV, WI,
WY. INCORPORATED IN:
Massachusetts.

**Employers Insurance Company of
Wausau (NAIC #21458)**

BUSINESS ADDRESS: 175 Berkeley
Street, Boston, MA 02116. PHONE:
(617) 357-9500. UNDERWRITING
LIMITATION b/: \$138,339,000.

SURETY LICENSES c.f/: AL, AK, AZ,
AR, CA, CO, CT, DE, DC, FL, GA, HI,
ID, IL, IN, IA, KS, KY, LA, ME, MD,
MA, MI, MN, MS, MO, MT, NE, NV,
NH, NJ, NM, NY, NC, ND, OH, OK,
OR, PA, PR, RI, SC, SD, TN, TX, UT,
VT, VA, VI, WA, WV, WI, WY.
INCORPORATED IN: Wisconsin.

**Employers Mutual Casualty Company
(NAIC #21415)**

BUSINESS ADDRESS: P. O. BOX 712,
DES MOINES, IA 50306-0712.
PHONE: (515) 280-2511.
UNDERWRITING LIMITATION b/:
\$127,629,000. SURETY LICENSES
c.f/: AL, AK, AZ, AR, CA, CO, CT, DE,
DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
LA, ME, MD, MA, MI, MN, MS, MO,
MT, NE, NV, NH, NJ, NM, NY, NC,
OH, OK, OR, PA, RI, SC, SD, TN, TX,
UT, VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Iowa.

**Endurance American Insurance
Company (NAIC #10641)**

BUSINESS ADDRESS: 4
MANHATTANVILLE ROAD,
PURCHASE, NY 10577. PHONE: (914)
468-8000. UNDERWRITING
LIMITATION b/: \$26,267,000.
SURETY LICENSES c.f/: AL, AK, AZ,
CO, DE, DC, GA, HI, ID, IL, IN, IA, KS,
KY, LA, MD, MA, MI, MS, MO, MT,
NE, NV, NH, NJ, NM, NY, ND, OH,
OK, OR, PA, RI, SC, SD, TN, TX, UT,
VT, WA, WV, WI, WY.
INCORPORATED IN: Delaware.

**Endurance Reinsurance Corporation of
America (NAIC #11551)**

BUSINESS ADDRESS: 4
MANHATTANVILLE ROAD,
PURCHASE, NY 10577. PHONE: (914)
468-8000. UNDERWRITING
LIMITATION b/: \$47,665,000.
SURETY LICENSES c.f/: AL, AK, AZ,
AR, CA, CO, CT, DE, DC, FL, GA, GU,
HI, ID, IL, IN, IA, KS, KY, LA, ME,
MD, MA, MI, MN, MS, MO, MT, NE,
NV, NJ, NM, NY, NC, ND, OH, OK,
OR, PA, PR, RI, SC, SD, TN, TX, UT,
VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Delaware.

**Erie Insurance Company (NAIC
#26263)**

BUSINESS ADDRESS: 100 ERIE
INSURANCE PLACE, ERIE, PA 16530.
PHONE: (814) 870-2000.
UNDERWRITING LIMITATION b/:
\$33,462,000. SURETY LICENSES
c.f/: DC, IL, IN, KY, MD, MN, NY, NC,
OH, PA, TN, VA, WV, WI.
INCORPORATED IN: Pennsylvania.

Everest Reinsurance Company (NAIC #26921)

BUSINESS ADDRESS: P.O. Box 830, Liberty Corner, NJ 07938-0830. PHONE: (908) 604-3000. UNDERWRITING LIMITATION b/: \$321,089,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Evergreen National Indemnity Company (NAIC #12750)

BUSINESS ADDRESS: 6140 PARKLAND BLVD, STE 321, MAYFIELD HEIGHTS, OH 44124. PHONE: (440) 229-3420. UNDERWRITING LIMITATION b/: \$3,055,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WY. INCORPORATED IN: Ohio.

Executive Risk Indemnity Inc. (NAIC #35181)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (908) 903-2000. UNDERWRITING LIMITATION b/: \$126,714,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Explorer Insurance Company (NAIC #40029)

BUSINESS ADDRESS: P.O. BOX 85563, SAN DIEGO, CA 92186-5563. PHONE: (858) 350-2400 x-2550. UNDERWRITING LIMITATION b/: \$10,147,000. SURETY LICENSES c./f.: AZ, CA, CO, CT, HI, ID, IL, IN, IA, MD, MA, MI, MS, MT, NJ, NV, NM, OR, PA, TN, TX, UT, VT, VA, WA, WV. INCORPORATED IN: California.

Fair American Insurance and Reinsurance Company (NAIC #35157)

BUSINESS ADDRESS: One Liberty Plaza, 165 Broadway, New York, NY 10006. PHONE: (212) 365-2200. UNDERWRITING LIMITATION b/: \$24,182,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO,

MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: New York.

Farmers Alliance Mutual Insurance Company (NAIC #19194)

BUSINESS ADDRESS: P.O. Box 1401, McPherson, KS 67460. PHONE: (620) 241-2200. UNDERWRITING LIMITATION b/: \$16,564,000. SURETY LICENSES c./f.: CO, ID, IA, KS, MN, MO, MT, NE, NM, ND, OK, SD. INCORPORATED IN: Kansas.

Farmington Casualty Company (NAIC #41483)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$29,133,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Farmland Mutual Insurance Company (NAIC #13838)

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220. PHONE: (515) 508-3300. UNDERWRITING LIMITATION b/: \$17,059,000. SURETY LICENSES c./f.: AL, AZ, AR, CA, CO, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, MD, MI, MN, MS, MO, MT, NE, NV, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

FCCI Insurance Company (NAIC #10178)

BUSINESS ADDRESS: 6300 University Parkway, Sarasota, FL 34240-8424. PHONE: (800) 226-3224. UNDERWRITING LIMITATION b/: \$53,562,000. SURETY LICENSES c./f.: AL, AZ, AR, CO, FL, GA, IL, IN, IA, KS, KY, LA, MD, MI, MS, MO, NE, NC, OH, OK, PA, SC, TN, TX, VA. INCORPORATED IN: Florida.

Federal Insurance Company (NAIC #20281)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (908) 903-2000. UNDERWRITING LIMITATION b/: \$1,186,080,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI,

SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Indiana.

FEDERATED MUTUAL INSURANCE COMPANY (NAIC #13935)

BUSINESS ADDRESS: 121 EAST PARK SQUARE, OWATONNA, MN 55060. PHONE: (507) 455-5200. UNDERWRITING LIMITATION b/: \$286,243,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Minnesota.

Fidelity and Deposit Company of Maryland (NAIC #39306)

BUSINESS ADDRESS: 1400 AMERICAN LANE, TOWER I, 18TH FLOOR, SCHAUMBURG, IL 60196-1056. PHONE: (847) 605-6000. UNDERWRITING LIMITATION b/: \$14,738,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Maryland.

FIDELITY AND GUARANTY INSURANCE COMPANY (NAIC #35386)

BUSINESS ADDRESS: One Tower Square, Hartford, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$1,929,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

Fidelity and Guaranty Insurance Underwriters, Inc. (NAIC #25879)

BUSINESS ADDRESS: One Tower Square, Hartford, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$8,620,000. SURETY LICENSES c./f.: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Financial Casualty & Surety, Inc. (NAIC #35009)

BUSINESS ADDRESS: 3131 Eastside, Suite 600, Houston, TX 77098. PHONE: (800) 392-1604. UNDERWRITING LIMITATION b/: \$1,506,000. SURETY LICENSES c,f/: AZ, CA, CT, DE, FL, GA, ID, IN, IA, KS, LA, MD, MI, MN, MS, MO, MT, NV, NJ, NY, NC, ND, OH, PA, SC, SD, TN, TX, UT, VT, VA, WA, WV. INCORPORATED IN: Texas.

Financial Pacific Insurance Company (NAIC #31453)

BUSINESS ADDRESS: P.O. BOX 73909, CEDAR RAPIDS, IA 52407-3909. PHONE: (319) 399-5700. UNDERWRITING LIMITATION b/: \$10,205,000. SURETY LICENSES c,f/: AK, AZ, AR, CA, CO, FL, ID, IL, IA, KS, MN, MO, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, WI. INCORPORATED IN: California.

Fireman's Fund Insurance Company (NAIC #21873)

BUSINESS ADDRESS: 225 W. WASHINGTON STREET, SUITE 1800, CHICAGO, IL 60606-3484. PHONE: (888) 466-7883. UNDERWRITING LIMITATION b/: \$121,481,000. SURETY LICENSES c,f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: California.

First Founders Assurance Company (NAIC #12150)

BUSINESS ADDRESS: 6 Mill Ridge Lane, Chester, NJ 07930-2486. PHONE: (908) 879-0990. UNDERWRITING LIMITATION b/: \$408,000. SURETY LICENSES c,f/: NJ, NY. INCORPORATED IN: New Jersey.

First Insurance Company of Hawaii, Ltd. (NAIC #41742)

BUSINESS ADDRESS: P.O. Box 2866, Honolulu, HI 96803. PHONE: (808) 527-7777. UNDERWRITING LIMITATION b/: \$27,495,000. SURETY LICENSES c,f/: GU, HI. INCORPORATED IN: Hawaii.

First Liberty Insurance Corporation (The) (NAIC #33588)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$2,237,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA,

MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Illinois.

First Net Insurance Company (NAIC #10972)

BUSINESS ADDRESS: 424 WEST O'BRIEN DRIVE, STE 202, HAGATNA, GU 96910. PHONE: (671) 477-8613. UNDERWRITING LIMITATION b/: \$1,150,000. SURETY LICENSES c,f/: GU, MP. INCORPORATED IN: Guam.

General Casualty Company Of Wisconsin (NAIC #24414)

BUSINESS ADDRESS: One General Drive, Sun Prairie, WI 53596. PHONE: (608) 837-4440. UNDERWRITING LIMITATION b/: \$24,603,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

General Reinsurance Corporation (NAIC #22039)

BUSINESS ADDRESS: 120 LONG RIDGE ROAD, STAMFORD, CT 06902-1843. PHONE: (203) 328-5000. UNDERWRITING LIMITATION b/: \$1,105,051,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

GRANGE INSURANCE COMPANY OF MICHIGAN (NAIC #11136)

BUSINESS ADDRESS: 671 South High Street, P.O. Box 1218, Columbus, OH 43216-1218. PHONE: (614) 445-2900. UNDERWRITING LIMITATION b/: \$3,991,000. SURETY LICENSES c,f/: MI. INCORPORATED IN: Ohio.

GRANGE MUTUAL CASUALTY COMPANY (NAIC #14060)

BUSINESS ADDRESS: 671 South High Street, Columbus, OH 43206-1014. PHONE: (614) 445-2900. UNDERWRITING LIMITATION b/: \$102,818,000. SURETY LICENSES c,f/: AL, GA, IL, IN, IA, KS, KY, MO, OH, PA, SC, TN, VA, WI. INCORPORATED IN: Ohio.

GRANITE RE, INC. (NAIC #26310)

BUSINESS ADDRESS: 14001 Quailbrook Drive, Oklahoma City, OK

73134. PHONE: (405) 752-2600. UNDERWRITING LIMITATION b/: \$2,004,000. SURETY LICENSES c,f/: AL, AZ, AR, CO, FL, GA, ID, IL, IN, IA, KS, KY, LA, MD, MI, MN, MS, MO, MT, NE, NV, NM, NC, ND, OH, OK, PA, SC, SD, TN, TX, UT, VA, WV, WI, WY. INCORPORATED IN: Oklahoma.

Granite State Insurance Company (NAIC #23809)

BUSINESS ADDRESS: 175 WATER STREET, 18TH FLOOR, NEW YORK, NY 10038. PHONE: (212) 770-7000. UNDERWRITING LIMITATION b/: \$3,141,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

GRAY CASUALTY & SURETY COMPANY (THE) (NAIC #10671)

BUSINESS ADDRESS: P.O. Box 6202, Metairie, LA 70009-6202. PHONE: (504) 888-7790. UNDERWRITING LIMITATION b/: \$1,434,000. SURETY LICENSES c,f/: AL, AZ, AR, CA, DC, GA, IL, KY, LA, MD, MS, MO, NV, NM, NY, NC, OK, PA, SC, TN, TX. INCORPORATED IN: Louisiana.

GRAY INSURANCE COMPANY (THE) (NAIC #36307)

BUSINESS ADDRESS: P.O. BOX 6202, METAIRIE, LA 70009-6202. PHONE: (504) 888-7790. UNDERWRITING LIMITATION b/: \$9,076,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Louisiana.

Great American Alliance Insurance Company (NAIC #26832)

BUSINESS ADDRESS: 301 E. Fourth Street, Cincinnati, OH 45202. PHONE: (513) 369-5000. UNDERWRITING LIMITATION b/: \$2,981,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

Great American Insurance Company (NAIC #16691)

BUSINESS ADDRESS: 301 E. Fourth Street, Cincinnati, OH 45202. PHONE: (513) 369-5000. UNDERWRITING LIMITATION b/: \$152,110,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

GREAT AMERICAN INSURANCE COMPANY OF NEW YORK (NAIC #22136)

BUSINESS ADDRESS: 301 E. Fourth Street, Cincinnati, OH 45202. PHONE: (513) 369-5000. UNDERWRITING LIMITATION b/: \$4,827,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

Great Northern Insurance Company (NAIC #20303)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (908) 903-2000. UNDERWRITING LIMITATION b/: \$46,923,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Indiana.

Greenwich Insurance Company (NAIC #22322) 4**Guarantee Company of North America USA (The) (NAIC #36650)**

BUSINESS ADDRESS: One Towne Square, Suite 1470, Southfield, MI 48076-3725. PHONE: (248) 281-0281 x-66012. UNDERWRITING LIMITATION b/: \$16,955,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Michigan.

Hanover Insurance Company (The) (NAIC #22292)

BUSINESS ADDRESS: 440 LINCOLN STREET, WORCESTER, MA 01653-

0002. PHONE: (508) 853-7200. UNDERWRITING LIMITATION b/: \$143,592,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New Hampshire.

HARCO NATIONAL INSURANCE COMPANY (NAIC #26433)

BUSINESS ADDRESS: 702 OBERLIN ROAD, RALEIGH, NC 27605-0800. PHONE: (919) 833-1600. UNDERWRITING LIMITATION b/: \$16,466,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Hartford Accident and Indemnity Company (NAIC #22357)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$237,223,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Hartford Casualty Insurance Company (NAIC #29424)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$90,439,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Indiana.

Hartford Fire Insurance Company (NAIC #19682)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$1,344,052,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY,

NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Hartford Insurance Company of Illinois (NAIC #38288)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$128,932,000. SURETY LICENSES c.f/: CT, HI, IL, MI, NY, PA. INCORPORATED IN: Illinois.

Hartford Insurance Company of the Midwest (NAIC #37478)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$47,331,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Indiana.

Hartford Insurance Company of the Southeast (NAIC #38261)

BUSINESS ADDRESS: One Hartford Plaza, Hartford, CT 06155-0001. PHONE: (860) 547-5000. UNDERWRITING LIMITATION b/: \$5,557,000. SURETY LICENSES c.f/: CT, FL, GA, KS, LA, MI, PA. INCORPORATED IN: Connecticut.

Hudson Insurance Company (NAIC #25054)

BUSINESS ADDRESS: 100 William Street, 5th Floor, New York, NY 10038. PHONE: (212) 978-2800. UNDERWRITING LIMITATION b/: \$45,787,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

IMT Insurance Company (NAIC #14257)

BUSINESS ADDRESS: P.O. Box 1336, Des Moines, IA 50306-1336. PHONE: (515) 327-2777. UNDERWRITING LIMITATION b/: \$13,814,000. SURETY LICENSES c.f/: AZ, IL, IA, MN, MO, NE, ND, SD, WI. INCORPORATED IN: Iowa.

Indemnity Company of California (NAIC #25550)

BUSINESS ADDRESS: P.O. BOX 19725, IRVINE, CA 92623-9725. PHONE:

(949) 263-3300. UNDERWRITING LIMITATION b/: \$1,554,000. SURETY LICENSES c,f/: AK, AZ, CA, CO, DC, GA, HI, ID, IN, KS, MD, MI, MS, MT, NE, NV, NM, NC, ND, OK, OR, SC, UT, VT, VA, WA, WV, WY. INCORPORATED IN: California.

Indemnity Insurance Company of North America (NAIC #43575)

BUSINESS ADDRESS: 436 WALNUT STREET, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$12,072,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Indemnity National Insurance Company (NAIC #18468)

BUSINESS ADDRESS: 4800 Old Kingston Pike, Knoxville, TN 37919. PHONE: (865) 934-4360. UNDERWRITING LIMITATION b/: \$1,174,000. SURETY LICENSES c,f/: AL, AZ, AR, CO, GA, KY, LA, MS, NV, NM, OK, SC, TN, TX, UT. INCORPORATED IN: Mississippi.

Indiana Lumbermens Mutual Insurance Company (NAIC #14265)

BUSINESS ADDRESS: 2005 Markert Street, Suite 1200, Philadelphia, PA 19103. PHONE: (267) 825-9206. UNDERWRITING LIMITATION b/: \$1,512,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Indiana.

Inland Insurance Company (NAIC #23264)

BUSINESS ADDRESS: P.O. Box 80468, Lincoln, NE 68501. PHONE: (402) 435-4302. UNDERWRITING LIMITATION b/: \$18,285,000. SURETY LICENSES c,f/: AZ, CO, IA, KS, MN, MO, MT, NE, ND, OK, SD, WY. INCORPORATED IN: Nebraska.

Insurance Company Of North America (NAIC #22713)

BUSINESS ADDRESS: 436 WALNUT STREET, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$23,356,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS,

KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Insurance Company of the State of Pennsylvania (The) (NAIC #19429)

BUSINESS ADDRESS: 175 WATER STREET, 18TH FLOOR, NEW YORK, NY 10038. PHONE: (212) 770-7000. UNDERWRITING LIMITATION b/: \$7,719,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Insurance Company of the West (NAIC #27847)

BUSINESS ADDRESS: P.O. BOX 85563, SAN DIEGO, CA 92186-5563. PHONE: (858) 350-2400 x-2550. UNDERWRITING LIMITATION b/: \$60,544,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: California.

Insurors Indemnity Company (NAIC #43273)

BUSINESS ADDRESS: P.O. Box 2683, Waco, TX 76702-2683. PHONE: (254) 759-3703 x-3727. UNDERWRITING LIMITATION b/: \$1,430,000. SURETY LICENSES c,f/: AR, NM, OK, TX. INCORPORATED IN: Texas.

INTEGRAND ASSURANCE COMPANY (NAIC #26778)

BUSINESS ADDRESS: P.O. Box 70128, San Juan, PR 00936-8128. PHONE: (787) 781-0707 x-200. UNDERWRITING LIMITATION b/: \$5,982,000. SURETY LICENSES c,f/: PR, VI. INCORPORATED IN: Puerto Rico.

Integrity Mutual Insurance Company (NAIC #14303)

BUSINESS ADDRESS: P.O. Box 539, Appleton, WI 54912-0539. PHONE: (920) 734-4511. UNDERWRITING LIMITATION b/: \$4,562,000. SURETY LICENSES c,f/: IL, IA, MN, OH, WI. INCORPORATED IN: Wisconsin.

International Fidelity Insurance Company (NAIC #11592)⁵

BUSINESS ADDRESS: One Newark Center, Newark, NJ 07102-5207.

PHONE: (973) 624-7200. UNDERWRITING LIMITATION b/: \$6,228,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: New Jersey.

IRONSHORE INDEMNITY INC. (NAIC #23647)

BUSINESS ADDRESS: P.O. BOX 3407, NEW YORK, NY 10008. PHONE: (646) 826-6600. UNDERWRITING LIMITATION b/: \$15,397,000. SURETY LICENSES c,f/: AL, AK, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Minnesota.

IRONSHORE SPECIALTY INSURANCE COMPANY (NAIC #25445)

BUSINESS ADDRESS: P.O. BOX 3407, New York, NY 10008. PHONE: (646) 826-6600. UNDERWRITING LIMITATION b/: \$33,395,000. SURETY LICENSES c,f/: AZ. INCORPORATED IN: Arizona.

ISLAND INSURANCE COMPANY, LIMITED (NAIC #22845)

BUSINESS ADDRESS: P.O. Box 1520, Honolulu, HI 96806-1520. PHONE: (808) 564-8200. UNDERWRITING LIMITATION b/: \$12,723,000. SURETY LICENSES c,f/: HI. INCORPORATED IN: Hawaii.

LEXINGTON NATIONAL INSURANCE CORPORATION (NAIC #37940)

BUSINESS ADDRESS: P.O. BOX 6098, LUTHERVILLE, MD 21094. PHONE: (410) 625-0800. UNDERWRITING LIMITATION b/: \$1,691,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WY. INCORPORATED IN: Florida.

Lexon Insurance Company (NAIC #13307)

BUSINESS ADDRESS: 10002 Shelbyville Rd, Suite 100, Louisville, KY 40223. PHONE: (615) 553-9500. UNDERWRITING LIMITATION b/: \$5,257,000. SURETY LICENSES c,f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS,

KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NJ, NM, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Texas.

Liberty Insurance Corporation (NAIC #42404)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$23,966,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Liberty Mutual Fire Insurance Company (NAIC #23035)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$130,075,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Liberty Mutual Insurance Company (NAIC #23043)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$1,276,747,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Massachusetts.

LM Insurance Corporation (NAIC #33600)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$11,521,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Lyndon Property Insurance Company (NAIC #35769)

BUSINESS ADDRESS: 14755 North Outer Forty Rd., Suite 400, St. Louis, MO 63017. PHONE: (636) 536-5600. UNDERWRITING LIMITATION b/: \$15,498,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Missouri.

Manufacturers Alliance Insurance Company (NAIC #36897)

BUSINESS ADDRESS: P.O. Box 3031, Blue Bell, PA 19422-0754. PHONE: (610) 397-5000. UNDERWRITING LIMITATION b/: \$5,919,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CO, CT, DE, DC, ID, IN, KS, KY, LA, ME, MD, MI, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, OH, PA, RI, SC, SD, TN, UT, VT, VA, WA. INCORPORATED IN: Pennsylvania.

MARKEL INSURANCE COMPANY (NAIC #38970)

BUSINESS ADDRESS: 4521 Highwoods Parkway, Glen Allen, VA 23060. PHONE: (804) 747-0136. UNDERWRITING LIMITATION b/: \$35,287,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Massachusetts Bay Insurance Company (NAIC #22306)

BUSINESS ADDRESS: 440 LINCOLN STREET, WORCESTER, MA 01653-0002. PHONE: (508) 853-7200 x-8554476. UNDERWRITING LIMITATION b/: \$6,422,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New Hampshire.

Merchants Bonding Company (Mutual) (NAIC #14494)

BUSINESS ADDRESS: P.O. Box 14498, DES MOINES, IA 50306-3498. PHONE: (515) 243-8171. UNDERWRITING LIMITATION b/: \$8,967,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT,

NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

Merchants National Bonding, Inc. (NAIC #11595)

BUSINESS ADDRESS: P.O. Box 14498, DES MOINES, IA 50306-3498. PHONE: (515) 243-8171. UNDERWRITING LIMITATION b/: \$1,229,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

Michigan Millers Mutual Insurance Company (NAIC #14508)

BUSINESS ADDRESS: P.O. Box 30060, Lansing, MI 48909-7560. PHONE: (517) 482-6211 x-7754. UNDERWRITING LIMITATION b/: \$5,057,000. SURETY LICENSES c.f/: AZ, AR, CA, CO, GA, ID, IL, IN, IA, KS, KY, MI, MN, MO, MT, NE, NY, NC, ND, OH, OK, OR, PA, SD, TN, VA, WA, WI, WY. INCORPORATED IN: Michigan.

Mid-Century Insurance Company (NAIC #21687)

BUSINESS ADDRESS: P.O. Box 4402, WOODLAND HILLS, CA 91365. PHONE: (323) 932-3200. UNDERWRITING LIMITATION b/: \$102,364,000. SURETY LICENSES c.f/: AL, AZ, AR, CA, CO, FL, GA, HI, ID, IL, IN, IA, KS, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SD, TN, TX, UT, VT, VA, WA, WI, WY. INCORPORATED IN: California.

MID-CONTINENT CASUALTY COMPANY (NAIC #23418)

BUSINESS ADDRESS: P.O. Box 1409, Tulsa, OK 74101. PHONE: (918) 587-7221. UNDERWRITING LIMITATION b/: \$13,811,000. SURETY LICENSES c.f/: AL, AZ, AR, CO, IL, IN, IA, KS, KY, LA, MN, MS, MO, MT, NE, NM, NC, OH, OK, SC, TN, TX, UT, VA, WA, WY. INCORPORATED IN: Ohio.

Motorists Commercial Mutual Insurance Company (NAIC #13331)

BUSINESS ADDRESS: 471 East Broad Street, Columbus, OH 43215. PHONE: (614) 225-8211. UNDERWRITING LIMITATION b/: \$15,009,000. SURETY LICENSES c.f/: AZ, CA, CO, CT, DE, DC, GA, ID, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MO, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT,

VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Ohio.

**Motorists Mutual Insurance Company
(NAIC #14621)**

BUSINESS ADDRESS: 471 East Broad Street, Columbus, OH 43215. PHONE: (614) 225-8211. UNDERWRITING LIMITATION b/: \$55,386,000. SURETY LICENSES c,f/: IN, KY, MI, OH, PA, WV. INCORPORATED IN: Ohio.

Motors Insurance Corporation (NAIC #22012)

BUSINESS ADDRESS: 300 GALLERIA OFFICENTRE, SOUTHFIELD, MI 48034. PHONE: (248) 263-6900. UNDERWRITING LIMITATION b/: \$74,681,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

**Munich Reinsurance America, Inc.
(NAIC #10227)**

BUSINESS ADDRESS: 555 COLLEGE ROAD EAST, P.O. Box 5241, Princeton, NJ 08543. PHONE: (609) 243-4200. UNDERWRITING LIMITATION b/: \$486,489,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

**National American Insurance Company
(NAIC #23663)**

BUSINESS ADDRESS: P.O. Box 9, Chandler, OK 74834. PHONE: (405) 258-0804. UNDERWRITING LIMITATION b/: \$6,554,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MI, MN, MS, MO, MT, NE, NV, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Oklahoma.

National Casualty Company (NAIC #11991)

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220. PHONE: (480) 365-4000. UNDERWRITING LIMITATION b/: \$13,408,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO,

MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

**NATIONAL FARMERS UNION
PROPERTY AND CASUALTY
COMPANY (NAIC #16217)**

BUSINESS ADDRESS: One General Drive, Sun Prairie, WI 53596. PHONE: (608) 837-4440. UNDERWRITING LIMITATION b/: \$4,327,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

**National Fire & Marine Insurance
Company (NAIC #20079)**

BUSINESS ADDRESS: 1314 Douglas Street, Suite 1400, Omaha, NE 68102-1944. PHONE: (402) 916-3000. UNDERWRITING LIMITATION b/: \$569,586,000. SURETY LICENSES c,f/: NE. INCORPORATED IN: Nebraska.

**National Fire Insurance Company of
Hartford (NAIC #20478)**

BUSINESS ADDRESS: 333 S. WABASH AVE, CHICAGO, IL 60604. PHONE: (312) 822-5000. UNDERWRITING LIMITATION b/: \$12,510,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

National Indemnity Company (NAIC #20087)

BUSINESS ADDRESS: 1314 Douglas Street, Suite 1400, Omaha, NE 68102-1944. PHONE: (402) 916-3000. UNDERWRITING LIMITATION b/: \$8,561,681,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NM, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Nebraska.

**National Liability & Fire Insurance
Company (NAIC #20052)**

BUSINESS ADDRESS: 1314 Douglas Street, Suite 1400, Omaha, NE 68102-1944. (402) 916-3000. UNDERWRITING LIMITATION b/: \$95,708,000. SURETY LICENSES c,f/: AL, AK, CA, CT, DE, DC, HI, ID, IL, IA, KS, KY, MD, MA, MI, MS, MO,

NE, NH, NJ, NM, NY, ND, OH, OK, RI, SC, SD, TX, UT, VT, VA, WA, WY. INCORPORATED IN: Connecticut.

National Surety Corporation (NAIC #21881)

BUSINESS ADDRESS: 225 W. WASHINGTON STREET, SUITE 1800, CHICAGO, IL 60606-3484. PHONE: (888) 466-7883. UNDERWRITING LIMITATION b/: \$14,010,000. SURETY LICENSES c,f/: AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MP, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WY. INCORPORATED IN: Illinois.

**NATIONAL TRUST INSURANCE
COMPANY (NAIC #20141)**

BUSINESS ADDRESS: 6300 University Parkway, Sarasota, FL 34240-8424. PHONE: (800) 226-3224. UNDERWRITING LIMITATION b/: \$3,684,000. SURETY LICENSES c,f/: AZ, FL, GA, IL, IN, IA, KY, LA, MD, MI, MS, MO, NE, NC, OK, SC, TN, TX. INCORPORATED IN: Indiana.

**National Union Fire Insurance
Company of Pittsburgh, PA (NAIC #19445)**

BUSINESS ADDRESS: 175 WATER STREET, 18TH FLOOR, NEW YORK, NY 10038. PHONE: (212) 770-7000. UNDERWRITING LIMITATION b/: \$668,283,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

**Nationwide Agribusiness Insurance
Company (NAIC #28223)**

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220. PHONE: (515) 508-3300. UNDERWRITING LIMITATION b/: \$7,163,000. SURETY LICENSES c,f/: AL, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

**Nationwide Mutual Insurance
Company (NAIC #23787)**

BUSINESS ADDRESS: ONE WEST NATIONWIDE BLVD., 1-04-701, COLUMBUS, OH 43215-2220.

PHONE: (614) 249-7111.
 UNDERWRITING LIMITATION b/:
 \$1,167,441,000. SURETY LICENSES
 c./: AL, AK, AZ, AR, CA, CO, CT, DE,
 DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
 LA, ME, MD, MA, MI, MN, MS, MO,
 MT, NE, NV, NH, NJ, NM, NY, NC,
 ND, OH, OK, OR, PA, RI, SC, SD, TN,
 TX, UT, VT, VA, VI, WA, WV, WI,
 WY. INCORPORATED IN: Ohio.

**NAVIGATORS INSURANCE
 COMPANY (NAIC #42307)**

BUSINESS ADDRESS: 400 Atlantic
 Street, 8th Floor, Stamford, CT 06901.
 PHONE: (203) 905-6090.
 UNDERWRITING LIMITATION b/:
 \$95,027,000. SURETY LICENSES
 c./: AL, AK, AZ, AR, CA, CO, CT, DE,
 DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
 LA, ME, MD, MA, MI, MN, MS, MO,
 MT, NE, NV, NH, NJ, NM, NY, NC,
 ND, OH, OK, OR, PA, RI, SC, SD, TN,
 TX, UT, VT, VA, WA, WV, WI, WY.
 INCORPORATED IN: New York.

**New Hampshire Insurance Company
 (NAIC #23841)**

BUSINESS ADDRESS: 175 WATER
 STREET, 18TH FLOOR, NEW YORK,
 NY 10038. PHONE: (212) 770-7000.
 UNDERWRITING LIMITATION b/:
 \$7,959,000. SURETY LICENSES c./:
 AL, AK, AZ, AR, CA, CO, CT, DE, DC,
 FL, GA, HI, ID, IL, IN, IA, KS, KY, LA,
 ME, MD, MA, MI, MN, MS, MO, MT,
 NE, NV, NH, NJ, NM, NY, NC, ND,
 OH, OR, PA, PR, RI, SC, SD, TN, TX,
 UT, VT, VA, WA, WV, WI, WY.
 INCORPORATED IN: Illinois.

**NGM Insurance Company (NAIC
 #14788)**

BUSINESS ADDRESS: 55 WEST
 STREET, KEENE, NH 03431. PHONE:
 (904) 380-7282. UNDERWRITING
 LIMITATION b/: \$98,604,000.
 SURETY LICENSES c./: AL, AZ, AR,
 CO, CT, DE, DC, FL, GA, ID, IL, IN,
 IA, KS, KY, LA, ME, MD, MA, MI,
 MS, MO, MT, NE, NV, NH, NJ, NM,
 NY, NC, ND, OH, OK, OR, PA, RI, SC,
 SD, TN, TX, UT, VT, VA, WA, WV,
 WI, WY. INCORPORATED IN:
 Florida.

**NORTH AMERICAN SPECIALTY
 INSURANCE COMPANY (NAIC
 #29874)**

BUSINESS ADDRESS: 650 ELM
 STREET, MANCHESTER, NH 03101.
 PHONE: (603) 644-6600.
 UNDERWRITING LIMITATION b/:
 \$31,838,000. SURETY LICENSES
 c./: AL, AK, AZ, AR, CA, CO, CT, DE,
 DC, FL, GA, HI, ID, IL, IN, IA, KS, KY,
 LA, ME, MD, MA, MI, MN, MS, MO,
 MT, NE, NV, NH, NJ, NM, NY, NC,
 ND, OH, OK, OR, PA, PR, RI, SC, SD,

TN, TX, UT, VT, VA, WA, WV, WI,
 WY. INCORPORATED IN: New
 Hampshire.

**NOVA Casualty Company (NAIC
 #42552)**

BUSINESS ADDRESS: 5 WATERSIDE
 CROSSING, SUITE 201, WINDSOR,
 CT 06095. PHONE: (860) 683-4250.
 UNDERWRITING LIMITATION b/:
 \$9,176,000. SURETY LICENSES c./:
 AL, AK, AZ, AR, CA, CO, CT, DE, DC,
 FL, GA, HI, ID, IL, IN, IA, KS, KY, LA,
 ME, MD, MA, MI, MN, MS, MO, MT,
 NE, NV, NH, NJ, NM, NY, NC, ND,
 OH, OK, OR, PA, RI, SC, SD, TN, TX,
 UT, VT, VA, WA, WI, WY.
 INCORPORATED IN: New York.

**Ohio Casualty Insurance Company
 (The) (NAIC #24074)**

BUSINESS ADDRESS: 175 Berkeley
 Street, Boston, MA 02116. PHONE:
 (617) 357-9500. UNDERWRITING
 LIMITATION b/: \$153,699,000.
 SURETY LICENSES c./: AL, AK, AZ,
 AR, CA, CO, CT, DE, DC, FL, GA, HI,
 ID, IL, IN, IA, KS, KY, LA, ME, MD,
 MA, MI, MN, MS, MO, MT, NE, NV,
 NH, NJ, NM, NY, NC, ND, OH, OK,
 OR, PA, RI, SC, SD, TN, TX, UT, VT,
 VA, WA, WV, WI, WY.
 INCORPORATED IN: New
 Hampshire.

**Ohio Farmers Insurance Company
 (NAIC #24104)**

BUSINESS ADDRESS: P.O. Box 5001,
 Westfield Center, OH 44251-5001.
 PHONE: (330) 887-0101.
 UNDERWRITING LIMITATION b/:
 \$199,714,000. SURETY LICENSES
 c./: AL, AZ, AR, CO, DE, FL, GA, IL,
 IN, IA, KY, LA, MD, MA, MI, MN,
 MS, MO, MT, NE, NV, NJ, NM, NY,
 NC, ND, OH, OK, PA, RI, SC, SD, TN,
 TX, UT, VA, WA, WV, WI, WY.
 INCORPORATED IN: Ohio.

**Ohio Indemnity Company (NAIC
 #26565)**

BUSINESS ADDRESS: 250 East Broad
 Street, 7th Floor, Columbus, OH
 43215-0000. PHONE: (614) 228-2800.
 UNDERWRITING LIMITATION b/:
 \$4,549,000. SURETY LICENSES c./:
 AL, AK, AZ, AR, CA, CO, CT, DE, DC,
 FL, GA, HI, ID, IL, IN, IA, KS, KY, LA,
 ME, MD, MI, MN, MS, MO, MT, NE,
 NV, NH, NJ, NM, NY, NC, ND, OH,
 OK, OR, PA, RI, SC, SD, TN, TX, UT,
 VT, VA, WA, WV, WI, WY.
 INCORPORATED IN: Ohio.

**Ohio Security Insurance Company
 (NAIC #24082)**

BUSINESS ADDRESS: 175 Berkeley
 Street, Boston, MA 02116. PHONE:
 (617) 357-9500. UNDERWRITING

LIMITATION b/: \$1,547,000. SURETY
 LICENSES c./: AL, AK, AZ, AR, CA,
 CO, CT, DE, DC, FL, GA, ID, IL, IN,
 IA, KS, KY, LA, ME, MD, MA, MI,
 MN, MS, MO, MT, NE, NV, NH, NJ,
 NM, NY, NC, ND, OH, OK, OR, PA,
 RI, SC, SD, TN, TX, UT, VT, VA, WA,
 WV, WI, WY. INCORPORATED IN:
 New Hampshire.

**Oklahoma Surety Company (NAIC
 #23426)**

BUSINESS ADDRESS: P.O. Box 1409,
 Tulsa, OK 74101. PHONE: (918) 587-
 7221. UNDERWRITING LIMITATION
 b/: \$1,550,000. SURETY LICENSES
 c./: AR, KS, OH, OK, TX.
 INCORPORATED IN: Ohio.

**OLD DOMINION INSURANCE
 COMPANY (NAIC #40231)**

BUSINESS ADDRESS: 55 WEST
 STREET, KEENE, NH 03431. PHONE:
 (904) 380-7282. UNDERWRITING
 LIMITATION b/: \$3,460,000. SURETY
 LICENSES c./: CT, DE, FL, GA, ME,
 MD, MA, NH, NY, NC, PA, RI, SC,
 TN, VT, VA. INCORPORATED IN:
 Florida.

**Old Republic General Insurance
 Corporation (NAIC #24139)**

BUSINESS ADDRESS: 307 NORTH
 MICHIGAN AVENUE, CHICAGO, IL
 60601. PHONE: (312) 346-8100.
 UNDERWRITING LIMITATION b/:
 \$50,017,000. SURETY LICENSES
 c./: AL, AK, AZ, AR, CA, CO, CT, DE,
 DC, FL, GA, ID, IL, IN, IA, KS, KY,
 LA, ME, MD, MA, MI, MN, MS, MO,
 MT, NE, NV, NH, NJ, NM, NY, NC,
 ND, OH, OK, OR, PA, RI, SC, SD, TN,
 TX, UT, VT, VA, WA, WV, WI, WY.
 INCORPORATED IN: Illinois.

**Old Republic Insurance Company
 (NAIC #24147)**

BUSINESS ADDRESS: P.O. Box 789,
 Greensburg, PA 15601-0789. PHONE:
 (724) 834-5000. UNDERWRITING
 LIMITATION b/: \$103,399,000.
 SURETY LICENSES c./: AL, AK, AZ,
 AR, CA, CO, CT, DE, DC, FL, GA, GU,
 HI, ID, IL, IN, IA, KS, KY, LA, ME,
 MD, MA, MI, MN, MS, MO, MT, NE,
 NV, NH, NJ, NM, NY, NC, ND, OH,
 OK, OR, PA, PR, RI, SC, SD, TN, TX,
 UT, VT, VA, VI, WA, WV, WI, WY.
 INCORPORATED IN: Pennsylvania.

**Old Republic Surety Company (NAIC
 #40444)**

BUSINESS ADDRESS: P.O. BOX 1635,
 MILWAUKEE, WI 53201-1635.
 PHONE: (262) 797-2640.
 UNDERWRITING LIMITATION b/:
 \$5,835,000. SURETY LICENSES c./:
 AL, AZ, AR, CA, CO, DC, FL, GA, ID,
 IL, IN, IA, KS, MD, MN, MS, MO, MT,

NE, NV, NM, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Pacific Indemnity Company (NAIC #20346)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (908) 903-2000. UNDERWRITING LIMITATION b/: \$293,025,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

PACIFIC INDEMNITY INSURANCE COMPANY (NAIC #18380)

BUSINESS ADDRESS: 348 WEST O'BRIEN DRIVE, HAGATNA, GU 96910. PHONE: (671) 477-1663. UNDERWRITING LIMITATION b/: \$1,985,000. SURETY LICENSES c,f/: GU, MP. INCORPORATED IN: Guam.

PARTNER REINSURANCE COMPANY OF THE U.S. (NAIC #38636)

BUSINESS ADDRESS: ONE GREENWICH PLAZA, GREENWICH, CT 06830-6352. PHONE: (203) 485-4200. UNDERWRITING LIMITATION b/: \$129,571,000. SURETY LICENSES c,f/: AL, AZ, CA, CO, DC, IL, KS, MI, MS, NE, NY, TX, UT, WA. INCORPORATED IN: New York.

PARTNERRE INSURANCE COMPANY OF NEW YORK (NAIC #10006)

BUSINESS ADDRESS: One Greenwich Plaza, Greenwich, CT 06830-6352. PHONE: (203) 485-4200. UNDERWRITING LIMITATION b/: \$10,937,000. SURETY LICENSES c,f/: AL, AZ, CA, CO, DE, DC, ID, IL, IN, IA, KS, KY, MD, MI, MN, MS, MT, NE, NJ, NM, NY, ND, OH, OK, OR, PA, RI, SC, SD, TX, UT, VT, VA, WA, WV, WI. INCORPORATED IN: New York.

Pekin Insurance Company (NAIC #24228)

BUSINESS ADDRESS: 2505 COURT STREET, PEKIN, IL 61558. PHONE: (309) 346-1161. UNDERWRITING LIMITATION b/: \$12,566,000. SURETY LICENSES c,f/: AZ, IL, IN, IA, MI, OH, WI. INCORPORATED IN: Illinois.

Pennsylvania Manufacturers Indemnity Company (NAIC #41424)

BUSINESS ADDRESS: P.O. Box 3031, Blue Bell, PA 19422-0754. PHONE: (610) 397-5000. UNDERWRITING

LIMITATION b/: \$6,949,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DE, DC, ID, IN, KS, KY, LA, ME, MD, MI, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, OH, PA, RI, SC, SD, TN, UT, VT, VA, WA. INCORPORATED IN: Pennsylvania.

Pennsylvania Manufacturers' Association Insurance Company (NAIC #12262)

BUSINESS ADDRESS: P.O. Box 3031, Blue Bell, PA 19422-0754. PHONE: (610) 397-5000. UNDERWRITING LIMITATION b/: \$25,173,000. SURETY LICENSES c,f/: AL, AK, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IA, KS, KY, LA, ME, MD, MA, MI, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, OH, OK, PA, RI, SC, SD, TN, TX, UT, VT, WA, WV. INCORPORATED IN: Pennsylvania.

Pennsylvania National Mutual Casualty Insurance Company (NAIC #14990)

BUSINESS ADDRESS: P.O. Box 2361, Harrisburg, PA 17105-2361. PHONE: (717) 234-4941. UNDERWRITING LIMITATION b/: \$57,141,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, DE, DC, FL, GA, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NJ, NM, NY, NC, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI. INCORPORATED IN: Pennsylvania.

PHILADELPHIA INDEMNITY INSURANCE COMPANY (NAIC #18058)

BUSINESS ADDRESS: One Bala Plaza, Suite 100, Bala Cynwyd, PA 19004-1403. PHONE: (610) 617-7900. UNDERWRITING LIMITATION b/: \$204,752,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI. INCORPORATED IN: Pennsylvania.

PLATTE RIVER INSURANCE COMPANY (NAIC #18619)

BUSINESS ADDRESS: P.O. Box 5900, Madison, WI 53705-0900. PHONE: (608) 829-4200. UNDERWRITING LIMITATION b/: \$4,222,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Nebraska.

Plaza Insurance Company (NAIC #30945)

BUSINESS ADDRESS: 518 East Broad Street, Columbus, OH 43215. PHONE: (614) 464-5000. UNDERWRITING LIMITATION b/: \$2,679,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

ProCentury Insurance Company (NAIC #21903)

BUSINESS ADDRESS: 550 Polaris Parkway, Westerville, OH 43082. PHONE: (614) 895-2000. UNDERWRITING LIMITATION b/: \$4,326,000. SURETY LICENSES c,f/: AK, AZ, AR, CA, DE, DC, GA, IL, IN, IA, KS, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, ND, OK, OR, PA, SC, SD, TX, UT, WV, WI, WY. INCORPORATED IN: Michigan.

Progressive Casualty Insurance Company (NAIC #24260)

BUSINESS ADDRESS: P.O. BOX 89490, CLEVELAND, OH 44101-6490. PHONE: (440) 461-5000. UNDERWRITING LIMITATION b/: \$161,009,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

Progressive Northwestern Insurance Company (NAIC #42919)

BUSINESS ADDRESS: P.O. BOX 89490, CLEVELAND, OH 44101-6490. PHONE: (440) 461-5000. UNDERWRITING LIMITATION b/: \$39,618,000. SURETY LICENSES c,f/: AK, AZ, AR, CA, CO, CT, DE, DC, GA, HI, ID, IN, IA, KS, KY, LA, ME, MD, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI. INCORPORATED IN: Ohio.

Protective Insurance Company (NAIC #12416)

BUSINESS ADDRESS: 111 Congressional Blvd., Suite 500, Carmel, IN 46032. PHONE: (317) 636-9800 x-2632. UNDERWRITING LIMITATION b/: \$20,488,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT,

VT, VA, WA, WV, WI, WY.
INCORPORATED IN: Indiana.

Regent Insurance Company (NAIC #24449)

BUSINESS ADDRESS: One General Drive, Sun Prairie, WI 53596. PHONE: (608) 837-4440. UNDERWRITING LIMITATION b/: \$2,858,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Republic—Franklin Insurance Company (NAIC #12475)

BUSINESS ADDRESS: P.O. Box 530, Utica, NY 13503-0530. PHONE: (315) 734-2000. UNDERWRITING LIMITATION b/: \$5,045,000. SURETY LICENSES c.f/: CT, DE, DC, GA, IL, IN, KS, MD, MA, MI, NH, NJ, NY, NC, OH, PA, RI, TN, TX, VA, WI. INCORPORATED IN: Ohio.

RLI Indemnity Company (NAIC #28860) 6

RLI Insurance Company (NAIC #13056)

BUSINESS ADDRESS: 9025 N. Lindbergh Drive, Peoria, IL 61615. PHONE: (309) 692-1000. UNDERWRITING LIMITATION b/: \$75,101,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Roche Surety and Casualty Company, Inc. (NAIC #42706)

BUSINESS ADDRESS: 4107 N. HIMES AVE 2ND FLOOR, TAMPA, FL 33607. PHONE: (813) 623-5042. UNDERWRITING LIMITATION b/: \$940,000. SURETY LICENSES c.f/: AK, AZ, AR, CT, DE, FL, GA, HI, ID, IN, IA, KS, LA, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, VA, WA. INCORPORATED IN: Florida.

Rockwood Casualty Insurance Company (NAIC #35505)

BUSINESS ADDRESS: 654 Main Street, Rockwood, PA 15557. PHONE: (814) 926-4661. UNDERWRITING LIMITATION b/: \$7,155,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CO, DC, GA, ID, IL, IN, IA, KS, KY, LA, MD, MI, MN, MS, MO, MT, NV, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD,

TX, UT, VA, WV. INCORPORATED IN: Pennsylvania.

SAFECO Insurance Company of America (NAIC #24740)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$139,336,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New Hampshire.

Safety National Casualty Corporation (NAIC #15105)

BUSINESS ADDRESS: 1832 Schuetz Road, St. Louis, MO 63146-3540. PHONE: (314) 995-5300. UNDERWRITING LIMITATION b/: \$152,697,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Missouri.

Sagamore Insurance Company (NAIC #40460)

BUSINESS ADDRESS: 111 Congressional Blvd., Suite 500, Carmel, IN 46032. PHONE: (317) 636-9800 x-7433. UNDERWRITING LIMITATION b/: \$12,507,000. SURETY LICENSES c.f/: AL, AK, AZ, CO, CT, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MS, MO, MT, NE, NJ, NM, NY, NC, OH, OR, PA, RI, SC, SD, TN, TX, UT, VT, WA, WV, WI, WY. INCORPORATED IN: Indiana.

SECURA INSURANCE, A Mutual Company (NAIC #22543)

BUSINESS ADDRESS: P.O. Box 819, Appleton, WI 54912-0819. PHONE: (920) 739-3161. UNDERWRITING LIMITATION b/: \$35,307,000. SURETY LICENSES c.f/: AZ, AR, CO, ID, IL, IN, IA, KS, KY, MI, MN, MO, MT, NE, NV, NM, ND, OH, OK, OR, PA, SD, TN, UT, WA, WI, WY. INCORPORATED IN: Wisconsin.

Selective Insurance Company of America (NAIC #12572)

BUSINESS ADDRESS: 40 WANTAGE AVENUE, BRANCHVILLE, NJ 07890. PHONE: (973) 948-3000. UNDERWRITING LIMITATION b/: \$52,078,000. SURETY LICENSES

c.f/: AL, AK, AZ, CT, DE, DC, GA, IL, IN, IA, KS, KY, MD, MA, MI, MN, MS, MO, MT, NE, NJ, NY, NC, ND, OH, OR, PA, RI, SC, SD, TN, TX, VA, WA, WV, WI, WY. INCORPORATED IN: New Jersey.

Seneca Insurance Company, Inc. (NAIC #10936)

BUSINESS ADDRESS: 160 Water Street, New York, NY 10038-4922. PHONE: (212) 344-3000. UNDERWRITING LIMITATION b/: \$13,837,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

Sentry Insurance A Mutual Company (NAIC #24988)

BUSINESS ADDRESS: 1800 NORTH POINT DRIVE, STEVENS POINT, WI 54481-8020. PHONE: (715) 346-6000. UNDERWRITING LIMITATION b/: \$417,232,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

Sentry Select Insurance Company (NAIC #21180)

BUSINESS ADDRESS: 1800 NORTH POINT DRIVE, STEVENS POINT, WI 54481-8020. PHONE: (715) 346-6000. UNDERWRITING LIMITATION b/: \$23,196,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Wisconsin.

SERVICE INSURANCE COMPANY (NAIC #36560)

BUSINESS ADDRESS: 702 OBERLIN ROAD, RALEIGH, NC 27605-0800. PHONE: (919) 833-1600. UNDERWRITING LIMITATION b/: \$3,732,000. SURETY LICENSES c.f/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MI, MS, MO, MT, NE, NV, NM, NC, ND, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Florida.

SERVICE INSURANCE COMPANY INC. (THE) (NAIC #28240)

BUSINESS ADDRESS: 80 Main Street, West Orange, NJ 07052. PHONE: (973) 731-7650. UNDERWRITING LIMITATION b/: \$701,000. SURETY LICENSES c,f/: CT, DE, MD, MA, NH, NJ, NY, PA, RI, VA. INCORPORATED IN: New Jersey.

SIRIUS AMERICA INSURANCE COMPANY (NAIC #38776)

BUSINESS ADDRESS: 140 BROADWAY, 32ND FLOOR, NEW YORK, NY 10005-1108. PHONE: (212) 312-2500. UNDERWRITING LIMITATION b/: \$51,758,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DC, GA, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MS, MT, NE, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TX, UT, VA, WA, WV, WI. INCORPORATED IN: New York.

SOUTHWEST MARINE AND GENERAL INSURANCE COMPANY (NAIC #12294)

BUSINESS ADDRESS: 412 Mt. Kemble Ave, Suite 300C, Morristown, NJ 07960. PHONE: (800) 774-2755. UNDERWRITING LIMITATION b/: \$6,177,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Arizona.

St. Paul Fire and Marine Insurance Company (NAIC #24767)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$386,393,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

ST. PAUL GUARDIAN INSURANCE COMPANY (NAIC #24775)

BUSINESS ADDRESS: One Tower Square, Hartford, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$2,521,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV,

WI, WY. INCORPORATED IN: Connecticut.

St. Paul Mercury Insurance Company (NAIC #24791)

BUSINESS ADDRESS: One Tower Square, Hartford, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$12,495,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Standard Fire Insurance Company (The) (NAIC #19070)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$118,554,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Star Insurance Company (NAIC #18023)

BUSINESS ADDRESS: 26255 American Drive, Southfield, MI 48034. PHONE: (248) 358-1100. UNDERWRITING LIMITATION b/: \$31,411,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Michigan.

StarNet Insurance Company (NAIC #40045)

BUSINESS ADDRESS: 11201 Douglas Avenue, Urbandale, IA 50322. PHONE: (515) 473-3000. UNDERWRITING LIMITATION b/: \$11,430,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Starr Indemnity & Liability Company (NAIC #38318)

BUSINESS ADDRESS: 399 Park Avenue, 8th Floor, New York, NY 10022. PHONE: (646) 227-6400.

UNDERWRITING LIMITATION b/: \$184,757,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Texas.

State Auto Property and Casualty Insurance Company (NAIC #25127)

BUSINESS ADDRESS: 518 EAST BROAD STREET, COLUMBUS, OH 43215. PHONE: (614) 464-5000. UNDERWRITING LIMITATION b/: \$65,535,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WV, WI, WY. INCORPORATED IN: Iowa.

State Automobile Mutual Insurance Company (NAIC #25135)

BUSINESS ADDRESS: 518 EAST BROAD STREET, COLUMBUS, OH 43215. PHONE: (614) 464-5000. UNDERWRITING LIMITATION b/: \$43,994,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

State Farm Fire and Casualty Company (NAIC #25143)

BUSINESS ADDRESS: ONE STATE FARM PLAZA, BLOOMINGTON, IL 61710. PHONE: (309) 766-2311. UNDERWRITING LIMITATION b/: \$1,419,677,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Stillwater Property and Casualty Insurance Company (NAIC #16578)

BUSINESS ADDRESS: P.O. Box 45126, Jacksonville, FL 32232-5126. PHONE: (800) 849-6140. UNDERWRITING LIMITATION b/: \$11,020,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: New York.

SureTec Insurance Company (NAIC #10916)

BUSINESS ADDRESS: 1330 POST OAK BLVD, SUITE 1100, HOUSTON, TX 77056. PHONE: (713) 812-0800. UNDERWRITING LIMITATION b/: \$8,656,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Texas.

SURETY BONDING COMPANY OF AMERICA (NAIC #24047)

BUSINESS ADDRESS: 333 S. WABASH AVE, CHICAGO, IL 60604. PHONE: (312) 822-5000. UNDERWRITING LIMITATION b/: \$830,000. SURETY LICENSES c,f/: AL, AZ, AR, CA, CO, DE, DC, GA, ID, IL, IN, KS, MN, MO, MT, NE, NV, NM, NY, ND, OK, OR, SC, SD, TN, TX, UT, WV, WY. INCORPORATED IN: South Dakota.

Swiss Reinsurance America Corporation (NAIC #25364)

BUSINESS ADDRESS: 175 KING STREET, ARMONK, NY 10504-1606. PHONE: (914) 828-8000. UNDERWRITING LIMITATION b/: \$358,107,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI. INCORPORATED IN: New York.

TEXAS PACIFIC INDEMNITY COMPANY (NAIC #20389)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (214) 754-0777. UNDERWRITING LIMITATION b/: \$739,000. SURETY LICENSES c,f/: AR, OK, TX. INCORPORATED IN: Texas.

TRANSATLANTIC REINSURANCE COMPANY (NAIC #19453)

BUSINESS ADDRESS: One Liberty Plaza, 165 Broadway, NEW YORK, NY 10006. PHONE: (212) 365-2200. UNDERWRITING LIMITATION b/: \$457,511,000. SURETY LICENSES c,f/: AK, AZ, AR, CA, CO, DE, DC, GA, ID, IL, IN, IA, KS, KY, LA, MI, MN, MS, NE, NV, NJ, NM, NY, OH, OK, PA, SD, UT, WA, WI. INCORPORATED IN: New York.

Travelers Casualty and Surety Company (NAIC #19038)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183.

PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$398,134,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Travelers Casualty and Surety Company of America (NAIC #31194)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$210,360,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Travelers Casualty Insurance Company of America (NAIC #19046)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$58,595,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Travelers Indemnity Company (The) (NAIC #25658)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$684,459,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

TRAVELERS INDEMNITY COMPANY OF AMERICA (THE) (NAIC #25666)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$19,073,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE,

NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Travelers Indemnity Company of Connecticut (The) (NAIC #25682)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$35,437,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

Travelers Property Casualty Company of America (NAIC #25674)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$44,386,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

U.S. Specialty Insurance Company (NAIC #29599)

BUSINESS ADDRESS: 13403 Northwest Freeway, Houston, TX 77040. PHONE: (713) 462-1000. UNDERWRITING LIMITATION b/: \$52,572,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Texas.

UNITED CASUALTY AND SURETY INSURANCE COMPANY (NAIC #36226)

BUSINESS ADDRESS: 1250 Hancock Street, Suite 803N, Quincy, MA 02169. PHONE: (617) 471-1112 x-109. UNDERWRITING LIMITATION b/: \$490,000. SURETY LICENSES c,f/: CT, FL, ME, MA, NH, NJ, NY, PA, RI. INCORPORATED IN: Massachusetts.

United Fire & Casualty Company (NAIC #13021)

BUSINESS ADDRESS: P.O. BOX 73909, CEDAR RAPIDS, IA 52407-3909. PHONE: (319) 399-5700. UNDERWRITING LIMITATION b/:

\$60,135,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Iowa.

UNITED FIRE & INDEMNITY COMPANY (NAIC #19496)

BUSINESS ADDRESS: P.O. BOX 73909, CEDAR RAPIDS, IA 52407-3909. PHONE: (319) 399-5700. UNDERWRITING LIMITATION b/: \$1,901,000. SURETY LICENSES c./f/: AL, CO, IN, KY, LA, MS, MO, NM, TX. INCORPORATED IN: Texas.

United States Fidelity and Guaranty Company (NAIC #25887)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$140,892,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Connecticut.

United States Fire Insurance Company (NAIC #21113)

BUSINESS ADDRESS: 305 Madison Avenue, Morristown, NJ 07962. PHONE: (973) 490-6600. UNDERWRITING LIMITATION b/: \$117,795,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Delaware.

United States Surety Company (NAIC #10656)

BUSINESS ADDRESS: 20 W. Aylesbury Road, Timonium, MD 21093. PHONE: (410) 453-9522. UNDERWRITING LIMITATION b/: \$4,251,000. SURETY LICENSES c./f/: CT, DE, DC, FL, GA, ME, MD, MA, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV. INCORPORATED IN: Maryland.

UNITED SURETY AND INDEMNITY COMPANY (NAIC #44423)

BUSINESS ADDRESS: P.O. BOX 2111, SAN JUAN, PR 00922-2111. PHONE: (787) 625-1105. UNDERWRITING LIMITATION b/: \$5,408,000. SURETY

LICENSES c./f/: PR. INCORPORATED IN: Puerto Rico.

Universal Surety Company (NAIC #25933)

BUSINESS ADDRESS: P.O. Box 80468, Lincoln, NE 68501. PHONE: (402) 435-4302. UNDERWRITING LIMITATION b/: \$13,741,000. SURETY LICENSES c./f/: AZ, AR, CO, ID, IL, IN, IA, KS, KY, MI, MN, MO, MT, NE, NM, ND, OH, OK, OR, SD, TX, UT, WA, WI, WY. INCORPORATED IN: Nebraska.

UNIVERSAL UNDERWRITERS INSURANCE COMPANY (NAIC #41181)

BUSINESS ADDRESS: 1400 AMERICAN LANE, TOWER I, 18TH FLOOR, SCHAUMBURG, IL 60196-1056. PHONE: (847) 605-6000. UNDERWRITING LIMITATION b/: \$33,965,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Illinois.

Utica Mutual Insurance Company (NAIC #25976)

BUSINESS ADDRESS: POST OFFICE BOX 530, UTICA, NY 13503-0530. PHONE: (315) 734-2000. UNDERWRITING LIMITATION b/: \$76,447,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

VerTerra Insurance Company (NAIC #10024)

BUSINESS ADDRESS: P.O. BOX 85563, SAN DIEGO, CA 92186-5563. PHONE: (858) 350-2400. UNDERWRITING LIMITATION b/: \$4,641,000. SURETY LICENSES c./f/: NJ, TX. INCORPORATED IN: Texas.

Vigilant Insurance Company (NAIC #20397)

BUSINESS ADDRESS: 15 Mountain View Road, Warren, NJ 07059. PHONE: (212) 612-4000. UNDERWRITING LIMITATION b/: \$30,623,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV,

WI, WY. INCORPORATED IN: New York.

Washington International Insurance Company (NAIC #32778)

BUSINESS ADDRESS: 475 NORTH MARTINGALE ROAD, SCHAUMBURG, IL 60173. PHONE: (603) 644-6600. UNDERWRITING LIMITATION b/: \$7,697,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New Hampshire.

West American Insurance Company (NAIC #44393)

BUSINESS ADDRESS: 175 Berkeley Street, Boston, MA 02116. PHONE: (617) 357-9500. UNDERWRITING LIMITATION b/: \$4,545,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY. INCORPORATED IN: Indiana.

WEST BEND MUTUAL INSURANCE COMPANY (NAIC #15350)

BUSINESS ADDRESS: 1900 South 18th Avenue, West Bend, WI 53095. PHONE: (262) 334-5571. UNDERWRITING LIMITATION b/: \$87,823,000. SURETY LICENSES c./f/: IL, IN, IA, KS, KY, MI, MN, MO, NE, OH, TN, WI. INCORPORATED IN: Wisconsin.

Westchester Fire Insurance Company (NAIC #10030)

BUSINESS ADDRESS: 436 Walnut Street, P.O. Box 1000, Philadelphia, PA 19106. PHONE: (215) 640-1000. UNDERWRITING LIMITATION b/: \$73,138,000. SURETY LICENSES c./f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Pennsylvania.

Western National Mutual Insurance Company (NAIC #15377)

BUSINESS ADDRESS: P.O. Box 1463, Minneapolis, MN 55440. PHONE: (952) 835-5350. UNDERWRITING LIMITATION b/: \$39,056,000. SURETY LICENSES c./f/: AK, AZ, AR, CA, CO, DE, ID, IL, IN, IA, KS, MD, MI, MN, MO, MT, NE, NV, NJ, NM,

ND, OH, OK, OR, PA, RI, SD, TX, UT, WA, WI, WY. INCORPORATED IN: Minnesota.

Western Surety Company (NAIC #13188)

BUSINESS ADDRESS: 333 S. WABASH AVE, CHICAGO, IL 60604. PHONE: (312) 822-5000. UNDERWRITING LIMITATION b/: \$131,504,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: South Dakota.

Westfield Insurance Company (NAIC #24112)

BUSINESS ADDRESS: P.O. Box 5001, Westfield Center, OH 44251-5001. PHONE: (330) 887-0101. UNDERWRITING LIMITATION b/: \$109,244,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Ohio.

Westfield National Insurance Company (NAIC #24120)

BUSINESS ADDRESS: P.O. Box 5001, Westfield Center, OH 44251-5001. PHONE: (330) 887-0101. UNDERWRITING LIMITATION b/: \$27,276,000. SURETY LICENSES c,f/: AL, AZ, CA, CO, DE, FL, GA, IL, IN, IA, KY, MD, MI, MN, NM, NC, ND, OH, OK, PA, SC, SD, TN, TX, VA, WV, WI. INCORPORATED IN: Ohio.

Westport Insurance Corporation (NAIC #39845)

BUSINESS ADDRESS: P.O. Box 2991, OVERLAND PARK, KS 66202-1391. PHONE: (913) 676-5200. UNDERWRITING LIMITATION b/: \$110,994,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Missouri.

XL Reinsurance America Inc. (NAIC #20583)

BUSINESS ADDRESS: SEAVIEW HOUSE, 70 SEAVIEW AVENUE, STAMFORD, CT 06902. PHONE: (203) 964-5200. UNDERWRITING LIMITATION b/: \$188,891,000.

SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: New York.

XL Specialty Insurance Company (NAIC #37885)

BUSINESS ADDRESS: SEAVIEW HOUSE, 70 SEAVIEW AVENUE, STAMFORD, CT 06902. PHONE: (203) 964-5200. UNDERWRITING LIMITATION b/: \$13,271,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Zurich American Insurance Company (NAIC #16535)

BUSINESS ADDRESS: 1400 AMERICAN LANE, TOWER I, 18TH FLOOR, SCHAUMBURG, IL 60196-1056. PHONE: (847) 605-6000. UNDERWRITING LIMITATION b/: \$707,582,000. SURETY LICENSES c,f/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MP, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, VI, WA, WV, WI, WY. INCORPORATED IN: New York.

Certified Reinsurer Companies

COMPANIES HOLDING CERTIFICATES OF AUTHORITY AS ACCEPTABLE REINSURING COMPANIES UNDER SECTION 223.3(b) OF TREASURY CIRCULAR NO. 297. [See Note (e)]

Markel Global Reinsurance Company (NAIC #10829)

BUSINESS ADDRESS: Ten Parkway North, Deerfield, IL 60015. PHONE: (908) 630-2700. UNDERWRITING LIMITATION b/: \$72,713,000. SURETY LICENSES c,f/:

Odyssey Reinsurance Company (NAIC #23680)

BUSINESS ADDRESS: 300 FIRST STAMFORD PLACE, STAMFORD, CT 06902. PHONE: (203) 977-8000. UNDERWRITING LIMITATION b/: \$287,498,000. SURETY LICENSES c,f/:

Phoenix Insurance Company (The) (NAIC #25623)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$130,218,000. SURETY LICENSES c,f/:

RENAISSANCE REINSURANCE U.S. INC. (NAIC #10357)

BUSINESS ADDRESS: 140 Broadway, Suite 4200, New York, NY 10005. PHONE: (212) 238-9600. UNDERWRITING LIMITATION b/: \$52,152,000. SURETY LICENSES c,f/:

ST. PAUL PROTECTIVE INSURANCE COMPANY (NAIC #19224)

BUSINESS ADDRESS: ONE TOWER SQUARE, HARTFORD, CT 06183. PHONE: (860) 277-0111. UNDERWRITING LIMITATION b/: \$22,725,000. SURETY LICENSES c,f/:

Footnotes

¹ Allegheny Casualty Company (NAIC #13285) redomesticated from Pennsylvania to New Jersey. The effective date of the redomestication is November 25, 2015.

² Alterra Reinsurance USA Inc. (NAIC #10829) changed its name to Markel Global Reinsurance Company. The effective date of the name change is September 2, 2015.

³ AMERICAN CONTRACTORS INDEMNITY COMPANY (NAIC #10216) is required by state law to conduct business in the state of Texas as TEXAS BONDING COMPANY. However, business is conducted in all other covered states as AMERICAN CONTRACTORS INDEMNITY COMPANY.

⁴ Greenwich Insurance Company (NAIC #22322) voluntarily relinquished its Treasury Certificate of Authority, effective June 30, 2016.

⁵ International Fidelity Insurance Company's (NAIC #11592) name is very similar to another company that is NOT certified by this Department. Please ensure that the name of the Company and the state of incorporation are exactly as they appear in this Circular. Do not hesitate to contact the Company to verify the authenticity of a bond.

⁶ RLI Indemnity Company (NAIC #28860) is no longer an acceptable surety on Federal bonds. The Company's Certificate of Authority issued by the Treasury was terminated, effective June 14, 2016. With respect to any bonds, including continuous bonds, currently in force with this Company, bond-approving officers should secure new bonds with acceptable sureties in those instances where a significant amount of liability remains outstanding. In addition, in no event, should bonds that are continuous in nature be renewed.

Notes

(a) All Certificates of Authority expire June 30, and are renewable July 1, annually. Companies holding Certificates of Authority

as acceptable sureties on Federal bonds are also acceptable as reinsuring companies.

(b) The Underwriting Limitations published herein are on a *per bond basis*. Treasury requirements do not limit the penal sum (face amount) of bonds which surety companies may provide. However, *when the penal sum exceeds a company's Underwriting Limitation, the excess must be protected by co-insurance, reinsurance, or other methods in accordance with 31 CFR Section 223.10, Section 223.11.* Treasury refers to a *bond of this type as an Excess Risk.* When Excess Risks on bonds in favor of the United States are protected by reinsurance, such reinsurance is to be effected by use of a *Federal reinsurance form* to be filed with the bond or within 45 days thereafter. In protecting such excess risks, the underwriting limitation in force on the day in which the bond was provided will govern

absolutely. For further assistance, contact the Surety Bond Section at (202) 874-6850.

(c) A surety company *must be licensed in the State or other area in which it provides a bond*, but need not be licensed in the State or other area in which the principal resides or where the contract is to be performed [28 Op. Atty. Gen. 127, Dec. 24, 1909; 31 CFR Section 223.5 (b)]. The term "other area" includes the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands.

License information in this Circular is provided to the Treasury Department by the companies themselves. *For updated license information, you may contact the company directly or the applicable State Insurance Department.* Refer to the list of state insurance departments at the end of this publication. For further assistance, contact the Surety Bond Section at (202) 874-6850.

(d) FEDERAL PROCESS AGENTS:

Treasury-approved surety companies are required to appoint Federal process agents in accord with 31 U.S.C. 9306 and 31 CFR 224.

(e) Companies holding Certificates of Authority as acceptable reinsuring companies are acceptable only as reinsuring companies on Federal bonds and may not directly write Federal bonds.

(f) Some companies may be Approved *surplus lines carriers* in various states. Such approval may indicate that the company is *authorized to write surety in a particular state, even though the company is not licensed in the state.* Questions related to this may be directed to the appropriate State Insurance Department. Refer to the list of state insurance departments at the end of this publication.

State insurance departments	Telephone No.
Alabama, Montgomery 36104	(334) 269-3550
Alaska, Anchorage 99501-3567	(907) 269-7900
Arizona, Phoenix 85018-7256	(602) 364-2499
Arkansas, Little Rock 72201-1904	(501) 371-2600
California, Sacramento 95814	(213) 897-8921
Colorado, Denver 80202	(303) 894-7499
Connecticut, Hartford 06142-0816	(860) 297-3800
Delaware, Dover 19904	(302) 674-7300
District of Columbia, Washington 20002	(202) 727-8000
Florida, Tallahassee 32399-6502	(850) 413-3140
Georgia, Atlanta 30334	(404) 656-2056
Hawaii, Honolulu 96813	(808) 586-2790
Idaho, Boise 83720-0043	(208) 334-4250
Illinois, Springfield 62767-0001	(217) 782-4515
Indiana, Indianapolis 46204-2787	(317) 232-2385
Iowa, Des Moines 50319-0065	(515) 281-5705
Kansas, Topeka 66612-1678	(785) 296-3071
Kentucky, Frankfort 40602-0517	(502) 564-3630
Louisiana, Baton Rouge 70802	(225) 342-1200
Maine, Augusta 04333-0034	(207) 624-8475
Maryland, Baltimore 21202-2272	(410) 468-2000
Massachusetts, Boston 02110	(617) 521-7794
Michigan, Lansing 48933-1020	(517) 284-8800
Minnesota, St. Paul 55101-2198	(651) 539-1500
Mississippi, Jackson 39201	(601) 359-3569
Missouri, Jefferson City 65102	(573) 751-4126
Montana, Helena 59601	(406) 444-2040
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42 CFR Part 8

Medication Assisted Treatment for Opioid Use Disorders; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8

RIN 0930-AA22

Medication Assisted Treatment for Opioid Use Disorders

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Final rule.

SUMMARY: This final rule increases access to medication-assisted treatment (MAT) with buprenorphine and the combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) in the office-based setting as authorized under the United States Code. Section 303(g)(2) of the Controlled Substances Act (CSA) allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled substances that have been approved by the Food and Drug Administration (FDA). Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time. After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. This final rule will expand access to MAT by allowing eligible practitioners to request approval to treat up to 275 patients under section 303(g)(2) of the CSA. The final rule also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.

DATES: *Effective Date:* This final rule is effective on August 8, 2016.

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Pharm.D., Public Health Advisor, Center for Substance Abuse Treatment, 240-276-2700.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at <http://www.gpo.gov/fdsys>.

I. Background

Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)) allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled

substances that have been approved by the Food and Drug Administration (FDA) for use in maintenance and detoxification treatment without registering as an opioid treatment program (OTP). Buprenorphine is a schedule III controlled substance under the CSA. To qualify to treat any patients with buprenorphine, the practitioner must be a physician, possess a valid license to practice medicine, be a registrant of the Drug Enforcement Administration (DEA), have the capacity to refer patients for appropriate counseling and other necessary ancillary services, and have completed required training.

The CSA also imposes a limit on the number of patients a practitioner may treat with certain types of FDA-approved narcotic drugs, such as buprenorphine, at any one time. Specifically, Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time. After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time.

Pursuant to 21 U.S.C. 823(g)(2)(B)(iii), the Secretary is authorized to change the patient limit by regulation.

A. Regulatory History

On March 30, 2016, the Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM), entitled, "Medication Assisted Treatment for Opioid Use Disorders", in the **Federal Register**, and invited comment on the proposed rule.¹ The comment period ended on May 31, 2016. In total, HHS received 498 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Individuals that currently prescribe buprenorphine and other health care professionals, such as nurse practitioners and pharmacists; health care policymakers; national organizations representing providers and public health agencies; and individuals who self-identified as current buprenorphine patients. A significant number of comments came from individuals who were part of a mass mail campaign organized by a national organization representing substance use disorder treatment specialists.

B. Overview of Final Rule

The final rule adopts the same basic structure and framework as the proposed rule: Subpart A sets forth the

general provisions of the rule; current subparts A, B, and C would change to subparts B, C, and D, respectively; the titles of these subparts would be revised to make it clear that they apply only to OTPs; subpart E is reserved and subpart F contains the final rule. Subpart A, § 8.1 details the scope of the rule and explains that the proposed rules in the new subpart F pertain only to those practitioners using a waiver under 21 U.S.C. 823(g)(2) with a patient limit of 101 to 275. Subpart A, § 8.2 provides the definitions that apply to the entirety of part 8 and § 8.3 discusses opioid treatment programs. Subpart F discusses the authorization to increase the patient limit to 275 patients. Subpart F, § 8.610 describes which practitioners are qualified for a patient limit of 275; subpart F, § 8.615 describes a qualified practice setting; subpart F, § 8.620 discusses the process to request a patient limit of 275; subpart F, § 8.625 details how a request will be processed; subpart F, § 8.630 describes what a practitioner must do to maintain the 275 patient limit; subpart F, § 8.635 is reserved; subpart F, § 8.640 details the renewal process for practitioners who desire to keep their 275 patient limit; subpart F, § 8.645 discusses the responsibilities of practitioners whose renewal request for the 275 patient limit was denied or who did not request for a renewal of the 275 patient limit; subpart F, § 8.650 details the conditions under which SAMHSA can suspend or revoke a patient limit increase approval; and subpart F, § 8.655 provides the rules applicable to patient limit increases in emergency situations.

HHS has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

HHS has changed the highest patient limit from 200 to 275.

HHS also changed § 8.610 by revising the language in this section. This change will allow additional addiction specialists to treat up to 275 patients by including all practitioners with additional credentialing as defined in § 8.2.

HHS has decided to delay the finalization of the proposed reporting requirements in § 8.635 and is publishing elsewhere in this issue of the **Federal Register** a Supplemental Notice of Proposed Rulemaking to solicit additional comments on the proposed reporting requirements prior to finalizing them. We expect to finalize the reporting requirements expeditiously.

HHS has responded to the comments received on the proposed rule, and provided an explanation of each of the

¹ 81 FR 17639 (Mar. 30, 2016).

changes made to the proposed rule in the preamble.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

HHS received a number of comments that expressed general support and advocacy for the proposed rule. Many of these comments pointed to the lives that will be saved and the long waitlists for MAT that will be shortened.

Commenters also noted that the rule provides parity with other conditions/medications and that the rule will help provide a research-based understanding of addiction.

There were also some comments that expressed disagreement with the proposed rule. These commenters said that MAT was not as effective as traditional models and that buprenorphine is a drug of diversion and misuse, and could result in poor outcomes. Some commenters cited a need for more providers rather than higher prescribing limits. Several commenters suggested that the application and renewal procedure and the recordkeeping and reporting requirements will dissuade physicians from applying for the higher patient limit.

A comment also suggested that very few additional patients will receive addiction treatment with buprenorphine as a result of the proposed rule, due to the small number of subspecialists eligible to treat an additional 100 patients each, unclear criteria for what constitutes a qualified practice setting, and continued poor reimbursement.

Given the evidence supporting buprenorphine-based MAT as an effective treatment for opioid use disorder and the magnitude of the opioid crisis, this rule is intended to increase access to buprenorphine-based MAT, prevent diversion, and ensure quality services are provided. With respect to the comment specifically related to the issues of subspecialty board certification and unclear criteria for a qualified practice setting, the final rule addresses these issues by replacing the "board certification" definition with an "additional credentialing" definition and also provides further clarity regarding the criteria for a qualified practice setting. HHS appreciates that increasing the patient limit for certain MAT providers is a complex issue and is not the only avenue for addressing the opioid public health crisis. HHS is promoting access to all forms of MAT for opioid use disorder through multiple activities included in the Secretary's

Opioid Initiative. Given the Secretary's authority to increase the patient limit on treatment under 21 U.S.C. 823(g)(2) by rulemaking, the rule is an essential element of a comprehensive approach to increasing access to MAT.

HHS also received a wide variety of comments related to the issue of MAT that did not specifically relate to a section of the proposed rule, but generally fell into five main categories. The categories and comments are as follows.

Other Practitioners

Many commenters wrote about the eligibility and role of nurse practitioners and/or physician assistants in prescribing buprenorphine. The vast majority of these commenters suggested that nurse practitioners and physician assistants should be allowed to prescribe buprenorphine under the new regulation. Two major associations wrote in support of registered nurses with addiction specialty training to be able to prescribe. Numerous comments stated that HHS needed to include other practitioners especially in order to reach rural and medically underserved regions.

HHS also received several comments opposed to allowing nurse practitioners and physician assistants to prescribe buprenorphine.

Questions related to expanding eligible prescribers are outside the scope of this rulemaking; the statute limits who is eligible to prescribe buprenorphine for MAT. 21 U.S.C. 823(g)(2) limits the practitioners eligible for waiver in this context to physicians, and, therefore, HHS is not authorized to include other types of providers in this rule. However, HHS recognizes the issues raised by commenters and the President's FY 2017 Budget proposes a buprenorphine demonstration program to allow advance practice providers to prescribe buprenorphine. This would allow HHS to begin testing other ways to improve access to buprenorphine throughout the country.

New Formulations

In the NPRM, HHS proposed that the Secretary would establish a process by which patients who are treated with medications covered under 21 U.S.C. 823(g)(2)(C), that have features that enhance safety or reduce diversion, as determined by the Secretary, may be counted differently toward the prescribing limit established in the proposed rule. Such medications are referred to here as "new formulations." HHS also proposed that the criteria for determining which if any of these new formulations may be considered, and

how these patients will be counted toward the patient limit, will be based on the following principles: (a) The relative risk of diversion associated with medications that become covered under 21 U.S.C. 823(g)(2)(C) after the effective date of the proposed rule; and (b) the time required to monitor patient safety, assure medication compliance and effectiveness, and deliver or coordinate behavioral health services.

HHS did not receive any comments that provided specific criteria to be used to count new formulations differently under the patient limit. One commenter suggested that abuse-deterrent labeling should not be a requirement. HHS did receive a small number of comments about new formulations which recommended that patients being treated with these new formulations not be counted against a patient limit. One commenter stated that HHS should establish a process for counting the patients differently if there is a risk to public health. Another commenter recommended the establishment of a process for evaluating new formulations that would be triggered by a petition from a product manufacturer, trade association, practitioner, State or local agency, or representatives of opioid use disorder patients or their families.

HHS received a number of comments recommending a cautious approach, including one suggestion to not count patients as fractions and another to consider the potential impact of a formulation-based counting methodology on practitioners and patient-driven recovery. One commenter expressed concern that new formulations that require less oversight from a practitioner may result in the reduction of psychosocial and other support services. HHS also received a comment that it is too soon to determine how patients treated with the new formulations should be counted.

HHS will review new formulations as they are approved by FDA for use in the treatment of opioid use disorder and is strongly supportive of innovative formulations that increase access to MAT.

With respect to the comments suggesting that no limit apply to patients treated with new formulations, HHS does not believe that raising the limit beyond that specified in this rule is warranted at this time.

After reviewing the comments, HHS has determined under the final rule, all patients treated with medications covered under 21 U.S.C. 823(g)(2)(C), including new formulations, will be counted against the patient limit established by this rule in the same

manner. HHS may choose to revisit this issue in the future.

Patient Cost and Coverage

HHS received several comments describing insurance-related issues that commenters believe affect access to treatment with buprenorphine. These comments, which are outside the scope of this rulemaking, focused on topics such as varying formats for requesting approval for treatment services and prescription coverage, reimbursement rates, coverage criteria, pharmacy practices, implementation of substance use disorder parity laws, and use of quality metrics. HHS received comments stating that the proposed rule does not address the many reasons why providers are not prescribing MAT to the fullest extent of their current waivers, including concerns about public and private insurer reimbursement for the additional reporting, documentation, and counseling as well as concerns about on-site DEA inspections.

HHS appreciates these comments and is aware of the issues associated with access to buprenorphine. However, these issues are beyond the scope of this rulemaking given HHS' regulatory authority under 21 U.S.C. 823(g)(2)(B)(iii).

Prescribing Practices

HHS received many comments that related to prescribing practices. One comment recommended that a prescriber of buprenorphine not be permitted to make a diagnosis of opioid use disorder or dependency in order to prevent the development of "pill mills." Another comment stated that Vivitrol® should be offered along with buprenorphine and another stated that it should be prescribed in place of buprenorphine.

Several commenters focused on limiting prescriptions of opioids. Others proposed limiting the allowable dosing of buprenorphine. One commenter recommended that the number of patients allowed for treatment by a waived practitioner should be tied to the recommended dose in order to incentivize physicians to prescribe appropriate doses of buprenorphine in an effort to decrease diversion. The commenter also stated that a physician treating 200 patients should not be allowed to prescribe more than an average of 2,800 mg of buprenorphine per day. HHS also received a comment that practitioners prescribing buprenorphine up to a higher patient limit should be required to see patients at least once a month.

HHS received a comment recommending that physicians obtain a written agreement from each patient stating that the patient: Will receive an initial assessment and treatment plan; will be subject to medication adherence and substance use monitoring; and understands all available treatment options, including all FDA-approved drugs for treatment of opioid use disorder and their potential risks and benefits. One commenter suggested that HHS issue firm recommendations on safe medication renewal quantities and weaning and reduction timeframes. Another commenter suggested taking into consideration the individual's age, gender, ethnicity, and culture during treatment.

HHS recognizes that there are multiple approaches to addressing opioid use disorder. However, many of these issues are beyond the scope of this rule.

Other Approaches to Opioid Use Disorders

Many comments provided suggestions on how to broadly address the problem of opioid use disorder. HHS received several comments noting that, despite being able to prescribe buprenorphine to only a limited number of patients, practitioners are not subject to any limits when prescribing opioids for pain. Some commenters recommended that either the limit to prescribe buprenorphine be removed or that an opioid prescribing limit be established. One commenter asked that if HHS believes that there should be a limit on the number of patients treated with buprenorphine, why HHS is not also seeking a limit on the number of patients prescribed schedule II opioids for chronic pain. And another commenter suggested that physicians who prescribe opioids should be required to offer treatment for opioid use disorders.

HHS also received a few comments that concerned treatment using antidepressants, anxiolytics, and antipsychotics where patient limits do not apply. The commenters felt the same concept should be applied to buprenorphine.

A buprenorphine patient limit was introduced in statute. HHS' rulemaking is intended to implement the statutory provisions. With respect to opioid prescribing, the Centers for Disease Control and Prevention (CDC) recently released the Guideline for Prescribing Opioids for Chronic Pain and SAMHSA supports the Providers' Clinical Support System-Opioid program, which is a national training and mentoring project that makes available at no cost

continuing medical education (CME) programs on the safe and effective use of opioids for treatment of chronic pain and safe and effective treatment of opioid use disorder. HHS received comments focused on the system of treatment for opioid use disorders, including the integration of behavioral health into primary care; screening for substance use disorders and connecting to treatment via Screening, Brief Intervention, and Referral to Treatment (SBIRT); reimbursement issues; and use of opioid antagonists such as naloxone in preventing opioid overdose.

A comment stated that the organization wanted to make sure patients receive long-term evidence-based care to treat opioid use disorder. HHS also received several comments stating that it needed to ensure that a full continuum of care is available for patients. While ongoing work is occurring throughout HHS on improving access to treatment, these specific issues are outside the scope of this rulemaking.

HHS also received a comment recommending that we consider additional strategies to incentivize primary care providers to apply for waivers to prescribe buprenorphine, including educational campaigns to address any misperceptions related to buprenorphine prescribing and DEA audits, greater dissemination of research and data regarding evidence-based MAT, and continual engagement with stakeholders to ensure the legal and regulatory framework is appropriate and effective. Another commenter also expressed the need for a national educational campaign about misuse of prescription opioid analgesics. One commenter recommended that HHS work with other local, State and Federal entities, including the Centers for Medicare & Medicaid Services (CMS), FDA, CDC, and DEA to develop education for the public that is both comprehensive and targeted to address the knowledge gaps of relevant stakeholders. HHS received comments expressing the importance of increasing the number of resources, training, and qualified personnel to prescribe buprenorphine and administer and monitor patients. Another commenter also felt that we should consider additional measures to educate physicians about best practices to minimize the risk of diversion, including the distribution of best practice guidance documents. An additional comment expressed concerns that clinics owned and operated by non-physicians, or employing part-time newly waived physicians, with no full-time addiction physician oversight

and supervision will greatly increase the potential for diversion. HHS intends to continue to work to educate eligible practitioners about the waiver process and ensure that the process is as efficient as possible.

HHS also received a comment expressing concerns that raising the limit will not sufficiently address improving access to individuals located in geographic regions where buprenorphine or other MAT medications are currently unavailable, because only a third of buprenorphine-waivered physicians are qualified to treat 100 patients at a time.

HHS shares the commenters' concern that some populations are geographically disadvantaged in terms of access to MAT. HHS believes this final rule will help address this concern by expanding the ability for physicians in all areas, including rural areas, to treat patients with opioid use disorder while minimizing the risk of diversion. In addition, the shift in policy from allowing a practitioner with a waiver to treat up to 200 patients in the NPRM to allowing a practitioner with a waiver to treat up to 275 patients is likely to have a significant impact in rural areas which are currently served by smaller numbers of practitioners with waivers.

HHS appreciates the many comments aiming to more broadly address the issue of opioid use. While this rule is more limited in scope, HHS is working to address some of the ideas expressed in the comments through other actions taken to implement the Secretary's Opioid Initiative.

Other Comments

HHS received several comments estimating the number of practitioners who would seek a waiver for the higher patient limit. For example, one comment stated that between 8 and 15 Vermont physicians would seek the additional waiver to treat 200 patients, noting that it would have the potential to increase access to office-based outpatient treatment services by between 25 and 50 percent from its current utilization rate. HHS considered these estimates as it calculated the Regulatory Impact Analysis (RIA) for the rule.

HHS received a comment asking why there were different rules for methadone and another one that asked why the rules were different than the rules in Canada.

Methadone is not included as part of this rule because methadone is a Schedule II drug, while the only medications covered under this rule are in Schedule III, IV, or V, pursuant to 21 U.S.C. 823(g)(2)(C). In addition, the

United States and Canada regulate opioid use disorder treatment under different laws.

HHS received a comment stating that impaired decision-making, especially for safety sensitive professions (*e.g.*, airline pilots, transit workers, health care professionals), posed public/patient safety concerns due to possible cognitive and motor impairment related to buprenorphine and stated that naltrexone may be considered as an alternative.

While this issue is beyond the scope of this rule, HHS encourages all practitioners to fully inform their patients about MAT, whether it is appropriate for an individual patient and, if so, which FDA-approved medications may be most appropriate for that patient.

Another commenter requested guidance on what constitutes an appropriate course of treatment and how "recovery" should be determined, which will enable them to meet the reporting requirements more successfully. An additional commenter requested that guidance specify whether or not an in-office induction is required.

HHS appreciates these comments and will bear them in mind as it develops guidance documents after the final rule goes into effect.

Subpart A—General Provisions

In the proposed rule, HHS proposed increasing the highest available patient limit for qualified practitioners to receive a waiver from 100 to 200. This proposed higher patient limit was intended to significantly increase patient capacity for practitioners qualified to prescribe at this level while also ensuring that waived practitioners would be able to provide comprehensive treatment associated with MAT.

Under the final rule, practitioners authorized to treat up to 275 patients will be required to meet infrastructure requirements that exceed those required for practitioners who have a waiver to treat 100 or fewer patients. HHS proposed additional criteria and responsibilities for practitioners to be able to treat up to the higher patient limit with the specific aims of ensuring quality of care and minimizing diversion. Importantly, the additional criteria and responsibilities were not intended to be unduly burdensome to practitioners who wish to expand their MAT treatment practice. Also, the rule does not add these additional requirements to practitioners who have a waiver to treat up to 100 patients under 21 U.S.C. 823(g)(2). The rule also creates an option for an increased

patient limit for practitioners responding to emergency situations that require immediate, increased access to medications covered under 21 U.S.C. 823(g)(2)(C). In addition, HHS included key definitions that will help practitioners understand and implement the requirements of this rule.

As proposed in the NPRM, this rule will be added to 42 CFR part 8 as subpart F. Accordingly, changes to part 8 were necessary to integrate the contents of the new regulations established by this rule into part 8. For example, part 8, subparts A, B, and C, had to be reordered as subparts B, C, and D, respectively. The titles of these subparts were revised to make it clear that they apply only to OTPs.

The comments and HHS' responses are set forth below.

Comment: HHS received several comments stating that raising the patient limit to 200 was not likely to make a significant impact on addressing the treatment gap. Some commenters suggested the limit should be raised to 500 patients or that there should be no patient limit at all. Other commenters supported the proposed limit of 200 patients. One commenter suggested that the patient limit be removed for physicians operating in a nationally accredited or State licensed substance use disorder treatment center.

Response: In the NPRM, HHS proposed raising the patient limit for certain qualified physicians to 200. This was based on a conservative estimate of the number of patients who could be treated by a single physician in a high-quality, evidence-based manner that minimizes the risk of diversion. However, prior to the NPRM, the proposed patient limit of 200 did not have the benefit of public comment. Although many commenters expressed that a 200 patient limit was appropriate, a number of commenters stated that the 200 patient limit was not sufficient to substantially address the treatment gap, with some commenters suggesting the limit be raised to 500 and others stating there should be no patient limit. HHS reviewed all pertinent comments and completed a reassessment of the available data. In particular, an analysis of the number of patients treated in OTPs—a set of structured clinics that deliver comprehensive care for opioid use disorder—helped to guide HHS' deliberation. Using data from the 2013 National Survey of Substance Abuse Treatment Services, the average number of patients who could be managed at any given time in an OTP ranged from 262 to 334, demonstrating that high-quality, evidence-based MAT could be provided to a larger number of patients

in this structured and regulated environment. Given that HHS expects that buprenorphine provision in the outpatient setting will involve a less structured and regulated environment, we believe setting the limit within the lower range of the average number of patients who could be treated in an OTP is prudent. Thus, based on our reassessment of the data and review of public comments, HHS has determined that increasing the patient limit to 275 balances the pressing need to expand access to MAT with the desire to ensure the provision of high-quality, evidence-based MAT while limiting the risk of diversion. We note that this rule is intended to expand access directly by increasing patient capacity for practitioners who get a waiver to treat more than 100 patients, and indirectly by increasing the incentive to enter into the field of addiction medicine or addiction psychiatry by expanding opportunities within the field.

Comment: HHS received a comment requesting that the rule provide some waiver increase for all certified office-based opioid treatment with buprenorphine physicians. The commenter also recommended that all physicians currently holding a waiver to prescribe up to 100 patients and who have been in good standing for the past year be allowed increases as follows: (1) If they are not board certified and not working in a qualified practice setting, they should be allowed to treat an additional 50 patients; (2) If they are not board certified but are working in a qualified practice setting, they should be allowed to treat an additional 100 patients; (3) If they are board certified but not working in a qualified practice setting, they should be allowed to treat an additional 150 patients; and (4) If they are board certified and are working in a qualified practice setting, they should be allowed to treat an additional 200 patients.

Response: The rule seeks to balance the increased accountability associated with the higher limit of 275 with the opportunity for practitioners to attain efficiencies of scale and provide two distinct and non-duplicative pathways by which practitioners can access the higher limit. This reflects HHS' desire to provide pathways to the higher limit to a range of motivated practitioners, with a modest and tolerable burden to the practitioner.

Comment: HHS received a comment recommending that ABAM-certified physicians not be limited in the number of patients to whom they can prescribe buprenorphine. HHS also received a comment encouraging HHS to lift the patient limit for any practitioner

providing MAT using buprenorphine in all programs licensed or certified by a State oversight agency for substance use.

Response: HHS appreciates the comment and the role of ABAM-certified practitioners and has modified the proposed rule to include these professionals among those eligible for the highest limit of 275. With respect to the comments suggesting that no limit apply to patients treated by practitioners in programs licensed or certified by a State oversight agency, HHS believes, for the reasons stated, that the 275 patient limit is the appropriate limit.

Comment: HHS received a comment recommending that the patient limit be based on the percentage of the practice that provides addiction treatment.

Response: Relevant patient limits in this context apply to a specific waived practitioner, not to a practice of multiple providers. Accordingly, HHS believes that the approach taken in the final rule provides the best available method to clearly establish a higher patient limit that can be monitored and enforced.

Comment: HHS received a comment requesting greater clarity about whether a patient treated with buprenorphine at an OTP is counted toward the practitioner's patient limit. The commenter recommended that patients treated in opioid treatment programs not be counted toward the patient limit.

Response: Patients receiving buprenorphine administered or dispensed by an OTP, from medication ordered under the program's DEA registration, are patients of the OTP and do not count toward any practitioner's patient limit.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments and additional information received, we have changed the proposed patient limit of 200 to 275 patients per practitioner for practitioners who meet the requirements laid out in the final rule.

Subpart A—Scope (§ 8.1)

HHS proposed that the scope of part 8 would cover rules that are applicable to OTPs, and to waived practitioners who seek to treat more than 100 patients with applicable medications. New subparts B through D under the final rule contain the rules relevant to OTPs. Subpart E is reserved and Subpart F contains the new final rule. Section 8.1 also explains that the rules in the new subpart F pertain only to those practitioners using a waiver under 21 U.S.C. 823(g)(2) with a patient limit of 101 to 275.

Summary of Regulatory Changes

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 8.1 without modification.

Subpart A—Definitions (§ 8.2)

HHS proposed definitions that would apply to the entirety of part 8. HHS also proposed revising definitions that would apply only to OTPs. Two definitions were proposed for elimination: "Registered opioid treatment program" and "opiate addiction."

HHS proposed a revised definition of "patient." At present, the definition of "patient" in § 8.2 is limited to those individuals receiving treatment at an OTP, which excludes those individuals receiving office-based opioid treatment with buprenorphine, *i.e.*, those practitioners subject to 21 U.S.C. 823(g)(2).

HHS proposed a revised definition of patient to make it inclusive of all persons receiving MAT with an opioid medication, consistent with the expanded scope of proposed revisions to 42 CFR part 8. HHS proposed that patient "means any individual who receives MAT from a practitioner or program subject to this part." Upon further review, we determined that modifications to the proposed definition of "patient" were needed to clarify the scope of patients covered under this rule (for purposes of the patient limit), and to distinguish such patients from opioid treatment program patients for which no patient limit applies. We are now defining patient as, for purposes of subparts B–E, meaning any individual who receives maintenance or detoxification treatment in an opioid treatment program. For purposes of subpart F patient means any individual who is dispensed or prescribed covered medications by a practitioner. The patient definition modifications reflected in the final rule are consistent with the intention of the NPRM. As we explained in the NPRM, if a practitioner, for example, provides cross-coverage for another practitioner and in the course of that coverage the covering practitioner provides a prescription for buprenorphine, the patient counts towards the cross-covering practitioner's patient limit until the prescription or medication has expired. However, if a cross-covering practitioner is merely available for consult but does not dispense or prescribe buprenorphine while the prescribing practitioner is away, the patients being covered do not count

towards the cross-covering practitioner's patient limit. Therefore, this definition is expected to help ensure consistency and clarity in how waived practitioners count patients towards the patient limit.

HHS proposed that the rule include the following definition of patient limit: "the maximum number of individual patients a practitioner may treat at any time using covered medications." Given the changes to the definition of "patient," the definition for "patient limit" was modified to mean the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time. This modification ensures alignment between the definition of "patient" and "patient limit."

Taken together, the definitions of "patient" and "patient limit" provide clear and fair guidance for regulatory enforcement and are expected to reduce undercounting of patients by practitioners. These definitions are also intended to clarify that patients who are not dispensed or prescribed medication covered by this rule should not be counted against a practitioner's patient limit. Accordingly, waived practitioners will be able to provide reciprocal cross-coverage to patients of other practitioners (assuming the dispensing or prescribing of covered medication is not involved) for brief periods, such as weekends or vacations, without requiring such patients to be added to the patient count of the practitioner who is providing cross-coverage.

Other new definitions proposed include "behavioral health services," "emergency situation," "nationally recognized evidence-based guidelines," "practitioner incapacity" and "waived practitioner."

HHS proposed to define "nationally recognized evidence-based guidelines" to mean a document produced by a national or international medical professional association, public health entity, or governmental body with the aim of ensuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions. Some examples include the American Society of Addiction Medicine (ASAM) National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use; SAMHSA's Treatment Improvement Protocol 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; the World Health Organization Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid

Dependence; the Department of Veterans Affairs/Department of Defense/Clinical Practice Guideline on Management of Substance Use Disorder; and the Federation of State Medical Boards' Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office. HHS expects that guidelines meeting this definition may change over time but does not plan to keep a list for practitioners to consult.

The definitions of "practitioner" and "practitioner incapacity" were modified to remove the term "waived" since that term does not appear in the regulatory text. In addition, the definition of "certification" was renamed "opioid treatment program certification" to clarify that the definition in § 8.2 specifically applies to certification of OTPs.

In addition, the final rule includes a definition of Medication-Assisted Treatment (MAT) that was provided in the preamble of the NPRM, but that was not inserted into the rule text of the NPRM. Accordingly, "Medication-Assisted Treatment" is now defined in the text of the final rule.

The final rule also replaced "board certification" with "additional credentialing" due to the removal of the term "subspecialty" with respect to practitioners that can request a higher limit outside of a qualified practice setting.

The comments and our responses are set forth below.

Comment: HHS received a small number of comments regarding the definition of patient as it relates to counting a patient towards the cross-covering practitioner's patient limit. One commenter requested that we develop a way for practitioners to provide coverage for other physicians without having to count these patients as part of their patient limit. Another commenter recommended that the patients served during cross-coverage count either toward the practitioner's patient limit for 30 days or the number of days' supply provided by the prescription, whichever is greater. Another commenter recommended that prescriptions for less than 30 days during cross-coverage should not count against the practitioner's patient limit.

Response: HHS is aware that providing coverage in a time-limited manner has posed a challenge to practitioners and patients. By defining "patient" for purposes of subpart F as, "any individual who is dispensed or prescribed covered medications by a practitioner," the definition links the patient to the practitioner who provides the patient with his or her covered medications. Such patients will remain

a patient of the prescribing practitioner for the duration of the prescription or for as long as the dispensed medication lasts. As noted above, in cases where a cross-covering practitioner does not provide a patient with covered medication, the patient will not count toward that practitioner's patient limit. In the event that the cross-covering practitioner dispenses or prescribes covered medication to a patient, the patient will only count towards the cross-covering practitioner for as long as the medication lasts or until the prescription expires.

Comment: HHS received one comment requesting additional examples of the types of guidelines that would satisfy the requirement to use nationally recognized evidence-based guidelines.

Response: HHS has added another example to the list provided in the preamble of the NPRM with regard to the definition of "nationally recognized evidence-based guidelines."

Comment: HHS received a comment that suggested the establishment of standards of care that DATA 2000 providers must follow.

Response: HHS requires in the rule the use of nationally recognized evidence-based guidelines, but declines to establish a specific standard of care in regulating the practice of medicine as it exceeds the scope of the Secretary's authority.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and after considering the comments received, HHS is modifying several of the proposed definitions in § 8.2 to enhance clarity and consistency with the scope of 21 U.S.C. 823(g)(2). Specifically, HHS has modified the definitions for "patient" and "patient limit," and modified the terms "practitioner" and "practitioner incapacity." Finally, HHS removed the term "board certification" and added "additional credentialing" to clarify that all practitioners who currently qualify to treat up to 100 patients are eligible for the higher patient limit if they are included as specialists as described in 21 U.S.C. 823 (g)(2)(G)(ii)(I)-(III).

Subparts B, C, and D—Opioid Treatment Programs (§§ 8.3 Through 8.34)

HHS proposed retitling subparts B, C, and D §§ 8.3 through 8.34 so as to implement the addition of subpart F. We proposed changes to these sections limited to changing the mailing address for program certification and accreditation body approval and updating terms, such as "opiate" and

“opiate addiction” to “opioid” and “opioid use disorder,” respectively.

The comments and our responses are set forth below.

Comment: HHS received one comment that recommended that it develop result-oriented performance standards for methadone maintenance treatment programs (also referred to as opioid treatment programs); provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of programs’ performance; and assure increased program oversight oriented toward performance standards.

Response: HHS is not addressing the performance standards for opioid treatment programs in this rule.

Comment: HHS received a comment stating that the Federal government should be putting pressure on States to open access to care through OTPs in States that are more likely to prohibit opioid treatment programs from operating.

Response: HHS is committed to increasing access to MAT through various strategies, but cannot address this specific issue through the final rule.

Summary of Regulatory Changes

HHS did not receive any comments related to §§ 8.3 through 8.34 that were capable of being addressed in the final rule. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions §§ 8.3 through 8.34 without modification.

Subpart F—Which Practitioners Are Eligible for a Patient Limit of 275 (§ 8.610)

Proposed § 8.610 described how practitioners can qualify for the 200 patient limit. Such practitioners would be required to possess subspecialty board certification in addiction medicine or addiction psychiatry or practice in a qualified practice setting as defined in the rule. In either case, practitioners with the higher limit would have to possess a waiver to treat 100 patients for at least 1 year in order to gain experience treating at the higher limit. The purpose of offering the 200 patient limit to practitioners in these two categories was to recognize the benefit offered to patients by either: (1) The advanced training, knowledge, and skill of practitioners with a subspecialty board certification; or (2) the higher level of direct service provision and care coordination envisioned in the qualified practice setting. This approach would restrict access to the 200 patient limit to a subset of the practitioners waived to provide care up to 100 patients. In addition to ensuring higher quality of

care, the criteria for the higher limit would be intended to minimize the risk of diversion of controlled substances to illicit use and accidental exposure that could result from increased prescribing of buprenorphine. A practitioner with board certification in an addiction subspecialty would have to have the training and experience necessary to recognize and address behaviors associated with increased risk of diversion. In the qualified practice settings, HHS believes that the care team and practice systems will function to help ensure this same level of care. HHS requested comments on this proposed approach, including comments on whether there are other ways for HHS to ensure quality and safety while encouraging practitioners to take on additional patients.

The comments and HHS responses are set forth below.

Comment: HHS received numerous comments expressing concerns about the restrictive nature of the requirement to obtain subspecialty board certification in order to reach the higher patient limit.

Response: HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. HHS believes that this new requirement balances the need to maintain a qualified workforce while having realistic expectations that do not prohibit capable practitioners from increasing their patient limits.

Comment: One comment expressed concerns that the rule will create a two-tiered system resulting in patients with the same diagnosis receiving markedly different quality and intensity of services, and recommended that we create a continuum of care whereby all patients with the same diagnosis receive equally high quality, evidence-based care.

Response: HHS disagrees that the rule creates a two-tiered system. Rather, it extends and enhances the system that currently exists in an effort to improve access to treatment for those with opioid use disorders.

Comment: HHS received a comment recommending that we implement an accreditation initiative for qualified practitioners seeking to increase the number of patients for whom they prescribe buprenorphine.

Response: HHS does not believe this approach is warranted at this time.

Comment: HHS received a comment stating that all physicians who currently have credentials provided by one of the following professional organizations be eligible to request the increased patient

limit: (1) ABAM; (2) ASAM; (3) American Board of Psychiatry and Neurology (ABPN); and (4) American Osteopathic Association. Another commenter recommended that HHS allow osteopathic physicians who are also boarded in other areas to be board-certified in addiction medicine.

Response: HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. However, given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should additional credentialing as defined in § 8.2 to safely and appropriately provide treatment up to 275 patients outside of a qualified practice setting. Therefore, HHS declines to incorporate some of the proposed approaches into the rule.

Comment: HHS received a small number of comments requesting a grandfathering clause for physicians who are currently working full time in the addiction field and who have missed the option to become board certified without doing a fellowship by the change in the availability of the ABAM exam.

Response: Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should have additional credentialing as defined in § 8.2.

Comment: HHS received a comment recommending that physicians who have been recognized by SAMHSA for their Science and Service to their office-based treatment patients should be given priority when applying for the increased patient limit.

Response: Given the significant responsibility associated with prescribing the applicable medications covered under the final rule, HHS believes that practitioners should have additional credentialing as defined in § 8.2 or practice in a qualified practice setting to safely and appropriately provide treatment to up to 275 patients. We believe most, if not all, of these practitioners will meet these requirements. Therefore, HHS declines to incorporate this approach into the rule.

Comment: HHS received a comment recommending that OTP licensure be the only pathway to creating addiction treatment programs that treat more than 100 patients.

Response: HHS believes that the pathways outlined in the final rule provide appropriate pathways through which practitioners can become eligible to prescribe buprenorphine to up to 275

patients, while taking into account quality care and risk of diversion. Given OTP capacities and other regulatory requirements, limiting access to treating up to 275 patients to OTPs would reduce the ability to increase access to care in as meaningful a way as can be accomplished through the pathways included in the final rule.

Comment: HHS received several comments recommending an alternate pathway for non-specialists in addiction medicine, which would require them to complete an additional 36 hours of addiction-related CME every three years. HHS received another comment proposing an alternate pathway that includes 24 hours of training, with Naloxone education as a part of that training.

Response: HHS has revised the language from § 8.610(b)(1), allowing practitioners who possess additional credentialing as defined in § 8.2 to become eligible for the higher, 275-patient limit. However, given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should have additional credentialing as defined in § 8.2 to safely and appropriately provide treatment to up to 275 patients outside of a qualified practice setting. Therefore, HHS has declined to incorporate this approach into the rule.

Comment: HHS received a comment suggesting that an alternate pathway be considered on a case by case basis in highly rural areas where practitioners may not be board certified or part of a qualified practice setting. The commenter recommended that providers who request the higher patient limit in these settings be required to have a mentor with extensive expertise and with whom they have regular consultation.

Response: Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should be board certified or practicing in a qualified practice setting to safely and appropriately provide this treatment to up to 275 patients. Therefore, HHS has declined to incorporate this approach into the rule.

Comment: HHS received a comment that it should not raise the patient limit for any practitioner who has not completed an accredited fellowship or residency in addiction medicine.

Response: HHS believes that the pathways outlined in the final rule provide appropriate pathways through which practitioners can become eligible to prescribe buprenorphine to up to 275 patients, while taking into account quality care and risk of diversion.

Limiting access to treating up to 275 patients to practitioners who have completed accredited fellowships or residencies in addiction medicine would reduce the ability to increase access to care in as meaningful a way as can be accomplished through the pathways included in the final rule. Therefore, HHS has declined to incorporate this approach into the rule.

Comment: HHS received a comment recommending that, in addition to providing current pathways to become eligible for the higher patient limit, HHS reserve the authority to identify any additional criteria that could make a practitioner qualified to apply for the higher limit.

Response: HHS retains this authority.

Comment: HHS received a few comments about the length of time it takes for practitioners to qualify to treat the higher patient limit. These comments noted that it will take two years for new practitioners to become eligible to prescribe buprenorphine to the higher patient limit and some suggested creating a faster pathway.

Response: In more than doubling the patient limit as a result of the final rule for certain practitioners with a 100 patient limit, HHS believes it is critical to ensure that practitioners who obtain the higher patient limit have at least one year of experience prescribing at the current highest patient limit. Practitioners who have had a waiver to treat up to 100 patients for at least a year will be eligible to apply for the higher limit immediately.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, HHS replaced “board certification” with “additional credentialing” in § 8.2 which will allow additional practitioners to become eligible for the 275-patient limit. At the beginning of § 8.610, we replaced the text that states that “A practitioner is eligible for a patient limit of 200,” with language that states the total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C. 823(g)(2)(B)(iii) is 275. Other than increasing the applicable patient limit to 275 (the basis for which has been discussed elsewhere in this preamble) the modified language does not reflect an intention to substantively change any other aspect of the patient limit from that which was proposed in the NPRM. Rather, the language modification is intended to align the final rule’s text with the terminology used in 21 U.S.C. 823(g)(2)(B)(iii).

Subpart F—Qualified Practice Setting (§ 8.615)

HHS proposed § 8.615 to describe the necessary elements of a qualified practice setting, which can include practices with as few as one waived provider as long as these criteria are met, and can include both private practices and community-based clinics. Necessary elements of a qualified practice setting would include: (1) The ability to offer patients professional coverage for medical emergencies during hours when the practitioner’s practice is closed; this does not need to involve another waived practitioner, only that coverage be available for patients experiencing an emergency even when the office is closed; (2) the ability to ensure access to patient case-management services including behavioral health services; (3) health information technology (health IT) systems such as electronic health records, when practitioners are required to use it in the practice setting in which he or she practices; (4) participation in a prescription drug monitoring program (PDMP), where operational, and in accordance with State law. PDMP means a statewide electronic database that collects designated data on substances dispensed in the State. For practitioners providing care in their capacity as employees or contractors of a Federal government agency, participation in a PDMP would be required only when such participation is not restricted based on State law or regulation based on their State of licensure and is in accordance with Federal statutes and regulations; and (5) employment, or a contractual obligation to treat patients in a setting that has the ability to accept third-party payment for costs in providing health services, including written billing, credit and collection policies and procedures, or Federal health benefits.

The elements were identified as common to many high-quality practice settings, which includes both private practices as well as federally qualified health centers and community mental health centers, and therefore worthy of replication. The elements would be expected to be common to OTPs, and OTPs currently in operation but not providing MAT under 21 U.S.C. 823(g)(2). Taken together, this would facilitate additional opportunities to expand access to MAT. Another consideration in the selection of these elements was the need to limit the expansion of group practices formed for the sole purpose of pooling the individual practitioner limits to maximize revenue but which fail to

offer a full continuum of services. HHS sought comment on additional, alternate pathways by which a practitioner could become eligible to apply for a higher patient limit.

The comments and HHS responses are set forth below.

Comment: HHS received a small number of comments expressing concerns that a qualified practice setting does not include a mandate to have trained substance use disorder counseling staff on site or available by an affiliation agreement. One commenter also recommended requiring a set ratio of addiction counselors in qualified practice settings. HHS also received a small number of comments recommending that HHS implement a requirement that provides for waived practitioners to hire behavioral health providers as part of their practice or have a formalized agreement with outside providers to offer these services.

Response: HHS has carefully considered the required elements of a qualified practice setting and has balanced the benefits of ensuring quality services and preventing diversion with the costs of being too restrictive. A requirement to have substance use disorder counseling or other behavioral health providers on staff on site or available by an affiliation agreement could limit the number of entities that would meet the requirements of a qualified practice setting and therefore not sufficiently increase access to treatment. A specific set ratio of addiction counselors in a qualified practice setting may also restrict the number of entities which would meet the definition of qualified practice setting and limit the impact of the rule.

Comment: HHS received a small number of comments noting that the narrow definition of a qualified practice setting makes it difficult for rural physicians or physicians in underserved settings to meet these qualifications.

Response: HHS believes that entities such as federally qualified health centers, community mental health centers, OTPs, and certain private practices which exist in rural and other underserved areas can meet the definition of a qualified practice setting.

Comment: One comment recommended that HHS require third-party accreditation for qualified practice settings via the Commission on Accreditation of Rehabilitation Facilities (CARF) or the Joint Commission on Accreditation of Health Care Organizations (JCAHO).

Response: Requiring accreditation of qualified practice settings could create a barrier for individual practitioners who have a waiver to prescribe

buprenorphine and have an interest in applying for the higher patient limit. HHS believes the burden imposed on these practitioners would be unreasonable and is not justified. Accordingly, HHS has not made any changes to the rule based on this comment.

Comment: One commenter also encouraged pharmacists to enter into collaborative practice agreements with physicians and other prescribers as part of a qualified practice setting.

Response: HHS encourages collaborative relationships between physicians and pharmacists, but declines to require it as a specific requirement as part of the definition of qualified practice setting.

Comment: HHS received a comment suggesting that skilled nursing homes and long-term residency facilities be added to the list of settings in which buprenorphine induction and maintenance can occur.

Response: Any facility that meets the requirements of a qualified practice setting will be considered a qualified practice setting.

Comment: One commenter suggested any medical facility offering MAT should offer both buprenorphine and Vivitrol®.

Response: HHS supports the full array of services, including medications, that comprise evidence-based MAT, but this requirement is beyond its scope.

Comment: HHS received a comment expressing concerns that the rule will consolidate the use of medication in large treatment centers, which will lead to increased prices for patients.

Response: HHS expects that the practitioners who obtain a waiver to prescribe to up to 275 patients as well as additional practitioners who decide to obtain a waiver for 30 or 100 patients either in an effort to eventually obtain a 275 patient limit or because they feel more confident that treatment capacity in the community is sufficient to keep them from being overwhelmed by demand, will increase access to MAT at both individual practices as well as among practitioners affiliated with treatment centers. HHS does not have information to assess how this will impact patient prices for care.

After-Hours Coverage

Comment: HHS received a comment recommending that all practitioners who prescribe MAT should have after-hours coverage, regardless of the size of the practice.

Response: Adopting the approach urged by the commenter, which would apply to all practitioners prescribing MAT regardless of their authorized

patient limit, is beyond the scope of the rule.

Health Information Technology (Health IT)

Comment: HHS received a small number of comments requesting clarification about what exactly constitutes a qualifying use of health IT. Specifically, the commenter asked whether the definition of “meaningful use” under the Medicare regulations would apply, and whether a program specifically designed for medical use would be required or if a practitioner could simply maintain a spreadsheet of all enrolled patients.

Response: The rule requires that practitioners use health IT like electronic health records or health information exchanges only if such records are otherwise required to be used in the practitioner’s practice setting. The rule does not create a new requirement to use electronic health records.

Comment: HHS received a comment stating that electronic health records are not as efficient as paper reporting.

Response: HHS disagrees. Some of the specific benefits associated with electronic health records include the ability to access patient charts remotely, the receipt of notifications about potential medical errors, the receipt of important reminders about providing preventive care and meeting clinical guidelines, and the ability to communicate directly with patients. All of these benefits enable practitioners to make well-informed, safe, and timely treatment decisions and ultimately provide higher-quality care.

Prescription Drug Monitoring Programs (PDMPs)

Comment: HHS received a small number of comments expressing concerns about the requirement to check PDMPs. These comments noted that not all States have operational PDMPs and questioned the extent to which PDMPs benefit patients.

Response: HHS supports PDMPs as a tool to address opioid use disorders and notes that at the time of the proposed rule, there were 49 States with operational PDMPs. The rule requires the use of a PDMP where a program is operational and its use is permitted/required in accordance with State law.

Comment: Several comments stated that providers should be incentivized to use PDMPs. One commenter recommended that the final rule require regular review of the PDMP for patients receiving buprenorphine and documentation of the reviews in the patient’s chart. Another commenter

suggested a mandatory review of State PDMPs on each visit to make certain that buprenorphine/naloxone is filled appropriately and no other narcotics are being prescribed.

Response: HHS understands this comment to refer to all patients who may be prescribed buprenorphine. HHS appreciates these comments; but the suggestions fall beyond the scope of this rule.

Comment: One comment requested that HHS provide assistance to States in developing and improving prescription drug monitoring programs.

Response: Providing assistance to States in developing and improving PDMPs is outside the scope of the rule, but HHS does have several programs that have provided this assistance to States in the past and has a program at CDC that currently does so. More information can be found here—<http://www.cdc.gov/drugoverdose/pdmp/states.html>.

Comment: One commenter stated that registration with a State prescription database should be a requirement for all waived physicians, not just the ones with the higher limit.

Response: Imposing requirements on practitioners treating patients for all waived practitioners is beyond the scope of this rule.

Provision of Behavioral Health Services

Comment: HHS received a comment requesting clarification about how a qualified practice is required to provide access to case management services and whether providing the phone number for other providers would satisfy this requirement.

Response: The intent of the requirement is that a practitioner have services available on site or have a referring relationship to case management or counseling services that allows for warm hand-offs of the patient and ongoing care coordination, not just the ability to provide a phone number.

Comment: HHS received numerous comments about the need for comprehensive psychosocial or case management treatment and team-based care along with buprenorphine.

Response: HHS agrees that comprehensive behavioral support services are a critical component of the effective delivery of MAT, including buprenorphine-based MAT. The standard of care² includes the provision

of behavioral health support services and HHS encourages all practitioners who are authorized to prescribe buprenorphine to ensure that their patients receive these services.

Comment: HHS received a small number of comments in favor of raising the patient limit without requiring formal counseling. One commenter stated that many patients feel that attending less formal counseling that is not delivered by licensed or certified health care professionals such as Narcotics Anonymous meetings are counterproductive.

Response: HHS believes that in order to ensure quality care, providing behavioral health support services is a key component to delivering effective MAT and encourages all practitioners prescribing covered medications to ensure that their patients receive it. The selection of behavioral health support services is a clinical decision to be made between the practitioner and the patient.

Comment: HHS received a small number of comments requesting that it provide a clearer definition of the format of referral to behavioral health providers. One commenter requested that HHS issue guidance that clearly defines the format of referral agreements. One comment requested that HHS define the format of referral to behavioral health services to require active referring rather than just the capacity to refer. Similarly, another commenter recommended that providers with a waiver to prescribe buprenorphine be required to include a Letter of Agreement with an organization for counseling services.

Response: HHS believes that limiting the referral to a specific format may be unduly restrictive and have unintended consequences. As noted earlier, HHS declines to require a specific written agreement as part of the behavioral health services component of the qualified practice setting definition, but may provide further guidance with respect to example referral agreements at a later date.

Comment: HHS received a comment asking whether a peer recovery support specialist would be considered capable of meeting the requirements for providing behavioral health services.

Response: Peer recovery support services are one possible behavioral health service. The selection of specific psycho-social interventions is a clinical decision to be made between the practitioner and the patient.

Comment: HHS received a comment noting that current guidelines for concurrent psychosocial treatment with buprenorphine are not enforced and, as

a result, raising the patient limit may not effectively increase access to care.

Response: The enforcement of concurrent psychosocial treatment with buprenorphine exceeds the scope of this rule.

Third-Party Payment

Comment: HHS received numerous comments expressing concerns with the requirement that practitioners prescribe in a setting that accepts third-party payment.

Response: This requirement was created to minimize the public health and safety risks, such as diversion, that are associated with dispensing or prescribing medications that are not supported by an appropriate medical diagnosis and assessment of medical need. Such risks are often associated with “cash only: entities that do not accept any third-party payment for services. Using third-party payment provides a record that buprenorphine has been provided to an individual and thus allows for more accountability, lowering the risk of diversion. However, not everyone who needs treatment has a third-party payer (e.g., insurance or Medicaid coverage). Thus, to avoid creating more barriers to treatment for these individuals, this regulation would not require third-party payment for all patients by practitioners operating at the higher patient limit and instead would only require that the provider be authorized and capable of billing third-party payers as an indication of their level of accountability. Moreover, with increasing coverage of substance use disorder treatment through private insurance and Medicaid programs in many States, substance use disorder treatment providers should have additional incentives to qualify and engage in third-party billing.

Comment: HHS received a comment requesting clarification on whether a practice would need to accept all third-party payment sources, including Medicare and Medicaid. The commenter also asked whether a practitioner can require payment in cash but provide billing information for the patient to submit to their insurance for reimbursement.

Response: Practitioners who qualify for the higher patient limit by practicing in a qualified practice setting must be able to accept third-party payments. However, the intention of the requirement is not that the practitioner must accept only third-party payments or must accept all third-party payment sources. Rather, the practitioner in a qualified practice setting must accept at least some third-party payment systems. The practitioner in a qualified practice

²² Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004

setting cannot have a “cash only” business.

Comment: HHS received a comment recommending that physicians be incentivized to care for Medicaid patients by not counting a certain number of Medicaid patients towards their higher limit.

Response: This issue is beyond the scope of this rule.

Comment: HHS received several comments stating that the requirement to accept third-party payments should be expanded to include all individuals with the higher patient limit, not just those using the “qualified practice setting” exception.

Response: The elements of a qualified practice setting are intended to provide practitioners who have not qualified for the higher patient limit as a result of possessing additional credentialing as defined in § 8.2 with the necessary specialty training to prevent diversion and provide quality services. HHS declines to incorporate this approach into the rule.

Diversion Control Plan

Comment: HHS received numerous comments about the need for formal diversion mitigation strategies, such as wrapper counts, drug testing, enforcement of the parity law for treatment, and the use of more efficient and lower dose, dual therapy preparations.

Response: HHS agrees that a diversion plan is important. The final rule requires that providers who receive the higher patient limit attest to having such a plan. The specifics of the diversion plan will be left to the individual practitioner.

Comment: HHS received a comment recommending that physicians obtain a written agreement from each patient stating that the patient: Will receive an initial assessment and treatment plan; will be subject to medication adherence and substance use monitoring; and understands all available treatment options, including all FDA-approved drugs for treatment of opioid use disorder and their potential risks and benefits.

Response: HHS supports the intent of the comment but these issues are related to provider-patient relationships and therefore beyond the scope of this rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.615 without modification.

Subpart F—Process To Request a Higher Patient Limit of 275 (§ 8.620)

HHS proposed § 8.620 to describe the process to request a patient limit of 200. Similar to the waiver process for the 30 and 100 patient limits, the process would begin with filing a form, in this case, a Request for Patient Limit Increase. A proposed draft of the Request for Patient Limit Increase was posted along with the NPRM and has been submitted to the Office of Management and Budget for final review. The higher patient limit would carry with it greater responsibility for behavioral health services, care coordination, diversion control, and continuity of care in emergencies and for transfer of care in the event that the practitioner does not request renewal of the higher patient limit or the practitioner’s renewal request is denied. The new Request for Patient Limit Increase process would require providers to affirm that they would meet these requirements. HHS proposed definitions of “behavioral health services,” “diversion control plan,” “emergency situation,” “nationally recognized evidence-based guidelines,” and “practitioner incapacity” in § 8.2 to assist practitioners in understanding what is expected of them in making these attestations. These responsibilities would be aligned with the standards of ethical medical and business practice and are not expected to be burdensome to practitioners. Single State Authorities, State Opioid Treatment Authorities and other resources/entities exist to help in the development of patient placement in the event that transfer to other addiction treatment would be required, for example, if a practitioner chose to no longer practice at the higher patient limit. HHS proposed that practitioners approved at the higher limit would also be required to reaffirm their ongoing eligibility to fulfill these requirements every 3 years as described in § 8.640.

The comments and our responses are set forth below.

Comment: HHS received a comment expressing the following concerns about the Request for Patient Limit Increase form: Question 7A9 assumes that physicians have an “original” 100 patients, and additional patients above the 100 patient level who would need to be transferred elsewhere in the event that a physician’s renewal request for the higher patient limit is denied. However, the commenter noted that it is unrealistic to assume that a physician would be treating the exact same original 100 patients three years, or even

one year, after being approved to treat more than 100 patients.

Response: The patient level refers to those patients the practitioner is treating at the time the request is denied. It is the practitioner’s responsibility to review his or her case load and identify which patients over the 100 patient limit he or she will notify.

Comment: A commenter noted that Question 8 requires physicians to certify that they will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination. The commenter requests information about the purpose of this certification, as it appears to be a significant restriction on a physician’s ability to practice medicine and prescribe other medications as needed.

Response: The certification check box on the Request for Patient Limit Increase is to ensure that waived practitioners certify that they are using only medications covered under 21 U.S.C. 823(g)(2)(C). Patients for whom a practitioner does not dispense or prescribe covered medications should not be counted against the patient limit. This does not mean that practitioners are prohibited from prescribing medications to treat conditions other than a substance use disorder among their office-based opioid treatment with buprenorphine patients.

Comment: HHS received a comment recommending that it consider the impact of the 42 CFR part 2 substance use disorder treatment confidentiality provisions on patients who do not share their substance use records with their other providers.

Response: The appropriate sharing of patient information is important. As such, HHS included an attestation that practitioners receiving a waiver to treat up to 275 patients provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act and implementing regulations and 42 CFR part 2.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.620 without modification.

Subpart F—How Will a Patient Request for a Higher Limit Be Processed (§ 8.625)

HHS proposed § 8.625 to describe how SAMHSA will process a Request for Patient Limit Increase. The process

for requesting a higher patient limit would be processed similarly to how the current 30 or 100 patient waiver is processed, with one difference. Whereas the lower patient limit waivers are not time limited, the waiver for the higher limit would have a term not to exceed 3 years with the option for renewal. Thus, a practitioner would be required to submit a new Request for Patient Limit Increase every 3 years if he or she desired to continue treating up to the higher patient limit. In addition, we proposed, among other things, that if SAMHSA denied a practitioner's Request for Patient Limit Increase on the basis of deficiencies that could be resolved, SAMHSA would allow a designated time period for resolving such deficiencies. We also proposed that, if such deficiencies are not resolved during the designated time period, SAMHSA would deny the practitioner's Request for Patient Limit Increase. It should be noted that DEA has independent enforcement authority and this rule in no way affects that authority or changes the way in which DEA and SAMHSA interact with respect to waivers.

After considering this process, the Department has made a minor modification to § 8.625(c) by replacing the word "will" with the word "may" in the last sentence of this paragraph. This modification gives SAMHSA the flexibility to approve a practitioner's Request for Patient Limit Increase, if, for example, relevant deficiencies are resolved to the satisfaction of SAMHSA shortly after the expiration of the designated time period.

The comments and HHS responses are set forth below.

Comment: HHS received a comment recommending that the length of the term to prescribe buprenorphine should gradually increase to a term of 3 years. The commenter stated that initially it should be a 1-year term, then a 2-year term, and then a 3-year term thereafter.

Response: HHS has sought to strike the right balance between encouraging practitioners to apply for the higher patient limit and ensuring that they are providing high quality care. HHS believes that asking practitioners to submit a Request for Patient Limit Increase more frequently than every 3 years would create an unnecessary burden and act as a deterrent to requesting the higher limit.

Comment: HHS received one comment suggesting that, rather than using a 3-year term, the highest patient limit should be based on a periodic review of the practice and its outcome statistics.

Response: HHS does not have the administrative capacity to conduct a periodic review of all waived practitioners' outcome statistics and other aspects of their practices beyond its anticipated oversight activities to ensure compliance with the rule.

Comment: HHS received a comment suggesting that the turn-around time for approving waiver requests be shortened from 45 to 30 days.

Response: HHS appreciates the commenters desire to shorten the time frame within which SAMHSA would process a Patient Request for a Higher Limit; however, due to staff and resource limitations, HHS believes the 45 day time period is a balanced approach for ensuring requests are turned around in an appropriate time frame to meet both the practitioner and SAMHSA's needs. HHS notes that it views this timeframe as a maximum, not a minimum, and will endeavor to process these requests quickly.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comment HHS received, HHS is finalizing the provisions as proposed in § 8.625 with the exception of the word change noted in § 8.625(c).

Subpart F—What must practitioners do in order to maintain their approval to treat up to 275 patients under § 8.625 (§ 8.630)

HHS proposed § 8.630 to describe the conditions for maintaining a waiver for each 3-year period for which waivers are valid, including maintenance of all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b). Compliance with the requirements specified in § 8.620 would have to be continuous.

HHS did not receive any comments specific to § 8.630.

Summary of Regulatory Changes

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions as proposed in § 8.630 without modification.

Subpart F—RESERVED (§ 8.635)

HHS proposed § 8.635 to describe the reporting requirements for practitioners whose Request for Patient Limit Increase is approved under § 8.625. HHS requested comments on whether the proposed reporting periods and deadline could be combined with other, existing reporting requirements in a way that would make reporting less burdensome for practitioners. HHS

proposed the following reporting requirements:

- a. The average monthly caseload of patients receiving buprenorphine-based MAT, per year
- b. Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:
 1. Treatment initiation
 2. Change in clinical status
- c. Percentage of patients who had a prescription drug monitoring program query in the past month
- d. Number of patients at the end of the reporting year who:
 1. Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery
 2. Are not being seen by the provider due to referral by the provider to a more or less intensive level of care
 3. No longer desire to continue use of buprenorphine
 4. Are no longer receiving buprenorphine for reasons other than 1–3.

The comments and HHS responses are set forth below.

HHS received a number of comments on these requirements. Many commenters expressed concern that the reporting requirements were burdensome and could decrease practitioners' interest in reaching the higher patient limit. Some commenters said that the reporting requirements would not ensure the appropriate level of behavioral health care. There were other concerns that the requirements were not consistent between practitioners who had waivers to treat up to 100 patients and practitioners with the higher patient limit. In addition, there was confusion about the periodicity of the reporting requirements. Overall, many commenters requested clarity.

HHS proposed to include reporting requirements as part of its approach to increasing access to MAT while ensuring that patients receive the full array of services that comprise evidence-based MAT and minimizing the risk that the medications provided for treatment are misused or diverted. HHS appreciates the comments received and, in light of them, has decided to delay finalizing this section of the proposed rule and to publish elsewhere in this issue of **Federal Register** a Supplemental Notice of Proposed Rulemaking on the reporting requirements proposed in § 8.635 of the

NPRM. As explained in the Supplemental Notice of Proposed Rulemaking published elsewhere in this issue of the **Federal Register**, HHS will consider the public comments on this Supplemental Notice as well as comments already received on the March 30, 2016 NPRM in finalizing the reporting requirements. We expect to finalize the reporting requirements expeditiously following the receipt of additional public comment.

Summary of Regulatory Changes

HHS is reserving § 8.635

Subpart F—Process for Renewing Patient Limit Increase Approval (§ 8.640)

We proposed § 8.640 to describe the process for a practitioner renewing his or her approval for the higher patient limit. In order for a practitioner to renew an approval, he or she would have to submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of the approval term.

The comments and HHS responses are set forth below.

Comment: HHS received several comments recommending that the renewal request be synchronized with the renewal of the DEA registration in an effort to reduce administrative burdens.

Response: HHS agrees that coordination among Federal agencies is beneficial and will work with DEA to synchronize these forms to the extent possible.

Comment: HHS received a comment stating that the current certification and recertification process should be retained and that additional recertification requirements are unnecessary. The commenter also stated that the DEA registration renewal process, as well as the regular oversight of waived physicians conducted by SAMHSA, is sufficient to ensure safety and proper prescribing practices and that a duplicative recertification process will only discourage participation by providers.

Response: HHS believes that due to the fact that practitioners with the higher patient limit will now be able to treat up to almost 3 times as many patients as prior to the rule, additional requirements related to renewing the practitioner's Request for Patient Limit Increase is prudent to ensure high quality care and minimize diversion.

Comment: HHS received a comment stating that the 90 day timeline for receiving approval is too long. The commenter also stated that language

should be added regarding when a response to a request should be provided and what one does when the response does not come by the stated time.

Response: HHS believes the commenter was confused with respect to the 90 day time period. The NPRM indicated that "Practitioners who intend to continue to treat up to 200 patients beyond their current 3 year approval term must submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of their approval term." It does not state that SAMHSA has 90 days to process the renewal request. In addition, the proposed rule states that "If SAMHSA does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until SAMHSA reaches a final decision." Thus, the preamble of the proposed rule discusses what happens if the response from SAMHSA is not obtained by a certain date.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.640 without modification.

Subpart F—Responsibilities of Practitioners Who Do Not Submit a Renewal Request for Patient Limit Increase or Whose Renewal Request Is Denied (§ 8.645)

HHS proposed § 8.645 to describe the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase or whose renewal request is denied. Under § 8.620(b)(7), practitioners would notify all patients affected above the 100 patient limit that the practitioner would no longer be able to provide MAT services using covered medications and would make every effort to transfer patients to other addiction treatment.

Summary of Regulatory Changes

HHS did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, HHS is finalizing the provisions as proposed in § 8.645 without modification.

Subpart F—Suspension or Revocation of a Practitioner's Patient Limit Increase Approval (§ 8.650)

HHS proposed § 8.650 to describe under what circumstances SAMHSA

would suspend or revoke a practitioner's patient limit increase of 200. If SAMHSA had reason to believe that immediate action would be necessary to protect public health or safety, SAMHSA would suspend the practitioner's patient limit increase of 200. If SAMHSA determined that the practitioner had made misrepresentations in his or her Request for Patient Limit Increase, or if the practitioner no longer satisfied the requirements of this subpart, or he or she had been found to have violated the CSA pursuant to 21 U.S.C. 824(a), SAMHSA would revoke the practitioner's patient limit increase of 200. It should be noted that DEA has independent enforcement authority and this rule in no way affects that authority or changes the way in which DEA and SAMHSA interact with respect to waivers.

The comments and HHS responses are set forth below.

Comment: HHS received a comment that practitioners who perform poorly on outcome and quality measures should be limited to 100 patients or less, or even have their waiver revoked if outcomes and quality are extremely poor.

Response: HHS believes allowing for suspension or revocation when SAMHSA determines that a practitioner no longer satisfies the requirements of the rule is appropriate and commensurate with ensuring that patients receive quality care. Additionally, such requirements relating to practitioners who have waivers to treat up to 30 and 100 patients are beyond the scope of this rule.

Comment: HHS received a comment requesting that we add an appeals mechanism for physicians to dispute erroneous determinations of not being in compliance with requirements for the patient limit increase.

Response: HHS declines to set forth a specific appeal mechanism in the rule, but notes that practitioners are able to re-apply if their Request for Patient Limit Increase is denied.

Summary of Regulatory Changes

The proposed language under § 8.650 provided only one circumstance under which SAMHSA could suspend a practitioner's Patient Limit Increase approval, and three instances under which SAMHSA could revoke this approval. After further consideration, HHS has modified the language in § 8.650 in an effort to allow the Secretary to suspend or revoke a practitioner's Request for Patient Limit Increase approval on the basis of any of

the criteria identified in this section to provide additional flexibility. For the reasons set forth in the proposed rule and considering the comments received, HHS is finalizing the remaining provisions of this section as proposed in the NPRM.

Subpart F—Practitioner Patient Limit Increase During Emergency Situations (§ 8.655)

HHS proposed § 8.655 to describe the process, including the information and documentation necessary, for a practitioner with an approved 100 patient limit to request approval to temporarily treat up to 200 patients in an emergency situation. The intention of this provision is to help assure continuity of care for patients whose care might otherwise be abruptly terminated due to the death or disability of their practitioner. This provision would also help communities respond rapidly to a sudden increase in demand for medication-assisted treatment. Sudden increases in demand for treatment may be experienced when there is a local disease outbreak associated with drug use, or when a natural or human-caused disaster either displaces persons in treatment from their practitioner or program or destroys program infrastructure. The emergency provision generally would not be intended to correct poor resource deployment due to lack of planning. The emergency provision of the proposed rule would only be considered if other options for addressing the increased demand for medication-assisted treatment could not address the situation.

HHS proposed that the practitioner must provide information and documentation that: (1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the emergency qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit; (2) identifies a period of time in which the higher patient limit should apply, and provides a rationale for the period of time requested; and (3) describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to the higher patient limit expires. Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an

immediate increase in the higher patient limit. If, after consultation with the governmental authorities, SAMHSA determines that a practitioner's request under this section should be granted, SAMHSA will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months. A practitioner wishing to receive an extension of the approval period granted must submit a request to SAMHSA at least 30 days before the expiration of the six month period and certify that the emergency situation continues. Except as provided in this section and § 8.650, requirements in other sections under subpart F do not apply to practitioners receiving waivers in this section.

The comments and HHS responses are set forth below.

Comment: HHS received a comment that the governmental authority, not the physician, should make a request to temporarily treat the higher patient limit in emergency situations.

Response: The waiver authorized under 21 U.S.C. 823(g)(2) may be granted to practitioners who dispense or prescribe covered medications to patients. Therefore, only practitioners may request a temporary patient limit increase under emergency situations. However, along with working with practitioners, SAMHSA will consult, to the extent possible, with governmental authorities to address emergency situations.

Comment: HHS received a comment recommending that it focus resources on creating sustainable, expanded treatment capacity to relieve those physicians impacted by the emergency request who may not be qualified or have the infrastructure to treat over 100 patients per the proposed rule.

Response: HHS agrees with the commenter that sustainable, expanded treatment capacity is the goal for all practitioners who experience emergency situations. By granting an extension of the six-month emergency provision, this will allow practitioners with a waiver to treat up to 100 patients, with up to a year of experience with prescribing covered medications, and will better position them to apply for a Request for Patient Limit Increase.

Comment: HHS received a small number of comments asking how quickly providers will be notified about whether they are approved to increase their patient limit during an emergency, with one commenter requesting that this information be included in the final rule. Another commenter recommended that providers receive a response within 48 to 72 hours.

Response: Every effort will be made to assure prompt decision-making and communication regarding requests to increase a practitioner's patient limit in response to an emergency. Given the wide variety of situations, number of stakeholders and decision-makers involved, and range of acuity of possible emergency situations, a specific deadline will not be established in the final rule.

Comment: HHS received a comment that the application process for an emergency should be simplified.

Response: HHS believes the application process outlined in the rule is necessary to ensure public safety and welfare. Furthermore, HHS believes that there is a compelling reason to require an application process given that the practitioner could be taking on almost 3 times as many patients without the necessary training or qualified practice setting supports.

Comment: HHS received a comment recommending that the State Opioid Treatment Authority or Single State Agency determine whether physicians can assure continuous access to care in the event of practitioner incapacity or emergency and whether physicians will be able to notify all patients that they are no longer able to provide buprenorphine, in the event that the request for the higher patient limit is not renewed or the renewal request is denied.

Response: HHS cannot address this issue within the scope of this rule.

Comment: HHS received a comment stating that emergency provisions should be explicitly expanded to include exemption from the patient limit for categories of patients in immediate need of treatment where no other practitioner is available. The comment specifically mentioned pregnant women with an opioid use disorder, and persons with a recent non-fatal opioid overdose.

Response: The patient limit applies to practitioners and not patients; therefore, the circumstances related to the availability of practitioners with waivers must dictate the emergency, not the circumstances of individual patients.

Comment: HHS received a comment recommending that practitioners be able to treat an unlimited number of patients during an emergency.

Response: HHS does not believe that this approach is warranted at this time.

Comment: HHS received several comments describing a need for a clearer definition of emergency situations.

Response: HHS' intent is to reserve this option for true emergency situations. Recognizing that no two

emergencies look the same, HHS envisions that this option for a temporary higher patient limit could be triggered when a waived practitioner dies or becomes physically or mentally incapacitated or whose waiver is suspended or revoked. Other possible scenarios include: Unforeseen displacement of a large population of individuals in need of medication-assisted treatment due to disaster; outbreak of acute infections that are blood borne or otherwise associated with injection drug use such as HIV. In all cases the emergency increase of a practitioner's patient limit is meant to be temporary. The affected community and practitioner(s) should plan to definitively meet the need for treatment and resolve the emergency by expanding all forms of MAT and meeting criteria for the higher patient limit via non-emergency criteria at the earliest possible date.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule, and considering the comments received, HHS is finalizing the provisions as proposed in § 8.655 without modification.

III. Information Collection Requirements

The NPRM called for new collections of information under the Paperwork Reduction Act of 1995. The final rule calls for the most of the same collections of information as the NPRM. As defined in implementing regulations, "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. In this section, we first identify and describe the types of information applicants and waived practitioners must collect and report, and then we provide an estimate of the total annual burden. The estimate covers the employees' time for reviewing and posting the collections required.

Title: Medication Assisted Treatment for Opioid Use Disorders.

OMB Control Number: 0930-03XX.

Summary of the Collection of Information: The final rule estimates up to six categories of information collection, each of which is described in the following analysis:

A. Approval, 42 CFR 8.620(a) through (c): In order for a practitioner to receive approval for a patient limit of 275, a practitioner must meet all of the

requirements specified in § 8.610 and submit a Request for Patient Limit Increase to SAMHSA that includes all of the following:

- Completed 3-page Request for Patient Limit Increase Form, a draft of which was posted in the public docket along with the NPRM;
- Statement certifying that the practitioner:
 - Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders;
 - Will provide patients with necessary behavioral health services as defined in § 8.2 or will provide such services through an established formal agreement with another entity to provide behavioral health services;
 - Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule and part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;
 - Will use patient data to inform the improvement of outcomes;
 - Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;
 - Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in § 8.2; and
 - Will notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment.

B. Diversion Control Plan, 42 CFR 8.12(c)(2): Creating and maintaining a diversion control plan is one of the requirements that practitioners must attest to before they are approved to treat at the higher limit. This plan is not required to be submitted to SAMHSA.

C. Renewal, 42 CFR 8.640: Describes the process for a practitioner renewing his or her approval for the higher patient limit. In order for a practitioner to renew an approval, he or she must

submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under § 8.620 at least 90 days before the expiration of the approval term.

D. Patient Notice, 42 CFR 8.645: Describes the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase or whose renewal request is denied. Practitioners who do not renew their Request for Patient Limit Increase or whose renewal request is denied must notify all patients above the 100 patient limit that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment. The Patient Notice is a model notice to guide practitioners in this situation when they notify their patients.

E. Emergency Provisions, 42 CFR 8.655: Describes the process for practitioners with a current waiver to prescribe up to 100 patients, and who are not otherwise eligible to treat up to 275 patients, to request a temporary increase to treat up to 275 patients in order to address emergency situations as defined in § 8.2. To initiate this process, the practitioner shall provide information and documentation that: (1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit; (2) Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and (3) Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires. If a practitioner wishes to receive an extension of the approval period granted under this section, he or she must submit a request to SAMHSA at least 30 days before the expiration of the 6-month period, and certify that the emergency situation as defined in § 8.2 necessitating an increased patient limit continues.

Annual burden estimates for these requirements are summarized in the following table:

42 CFR citation	Purpose of submission	Number of respondents	Responses/respondent	Burden/response (hr.)	Total burden (hrs.)	Hourly wage cost (\$)	Total wage cost (\$)
8.620(a) through (c)	Request for Patient Limit Increase.	517	1	.5	259	93.74	24,232
8.12(c)(2)	Diversion Control Plan	517	1	.5	259	93.74	24,232
8.640	Renewal Request for a Patient Limit Increase.	0	1	.5	0	93.74	0
8.645	Patient Notice	0	1	3	0	93.74	0
8.655(d)	Request for a Temporary Patient Increase for an Emergency.	10	1	3	30	64.47	1,934
Total	2,394	4,598	50,398

Note that these estimates differ from those found in the RIA because the estimates here are wage cost estimates while the estimates in the RIA are resource cost estimates which incorporate costs associated with overhead and benefits.

HHS received several comments regarding the Collection of Information.

One commenter wanted to include in the Request for Patient Limit Increase information that required the implementation of random tablet/film counts and urine screens. Another commenter wanted mandatory Point-of-Care Urine Drug Screens on each visit to document the presence of buprenorphine/naloxone and the absence of other opioids. HHS also received a comment recommending that drug testing be included as part of treatment with buprenorphine and thus noted in the information that would be collected in the Request for Patient Limit Increase.

HHS believes that drug screens are likely part of a practitioner's diversion control plan and part of the data that will inform the practitioner's ability to help the patient achieve better outcomes. Thus, HHS is not revising the information to be collected as part of the Request for Patient Limit Increase.

HHS received a comment recommending that pharmacists be included in the pool of practitioners to which a release of information should be considered.

HHS believes it may be appropriate to release certain information to pharmacists if the patient provides consent. HHS declines to require that pharmacists be included in the pool of practitioners to which information may be released.

IV. Regulatory Impact Analysis

A. Introduction

HHS has examined the impact of this final rule under Executive Order 12866 on Regulatory Planning and Review

(September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act of 1980 (Pub. L. 96-354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Order 12866 directs 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 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. HHS expects that this final rule will have an annual effect on the economy of \$100 million or more in at least 1 year and therefore is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. HHS anticipates that the final rule will not have a significant economic impact on a substantial

number of small entities. We provide supporting analysis in section F.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$146 million, using the most current (2015) implicit price deflator for the gross domestic product. HHS expects this final rule to result in expenditures that would exceed this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. HHS has determined that the final rule does not contain policies that would have substantial direct effects 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 changes in the rule represent the Federal Government regulating its own program. Accordingly, HHS concludes that the final rule does not contain policies that have federalism implications as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

B. Summary of the Final Rule

Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)) allows individual practitioners to dispense and prescribe Schedule III, IV, or V controlled substances that have been approved by the FDA specifically for use in

maintenance and detoxification treatment without obtaining the separate registration required by 21 CFR 1301.13(e) and imposes a limit on the number of patients a practitioner may treat at any one time.

Section 303(g)(2)(B)(iii) of the CSA allows qualified practitioners who file an initial NOI to treat a maximum of 30 patients at a time. After one year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. To qualify, the practitioner must be a physician, possess a valid license to practice medicine, be a registrant of the DEA, have the capacity to refer patients for appropriate counseling and other appropriate ancillary services, and have completed required training. The training requirement may be satisfied in several ways: one may hold board certification in addiction psychiatry from the American Board of Medical Specialties or addiction medicine from the American Osteopathic Association; hold an addiction certification from the American Society of Addiction Medicine (ASAM); complete an 8-hour training provided by an approved organization; have participated as an investigator in one or more clinical trials leading to the approval of a medication that qualifies to be prescribed under 21 U.S.C. 823(g)(2); or complete other training or have such other experience as the State medical licensing board or Secretary of HHS considers to demonstrate the ability of the practitioner to treat and manage persons with opioid use disorder.

Pursuant to 21 U.S.C. 823(g)(2)(B)(iii), the Secretary is authorized to promulgate regulations that change the total number of patients that a practitioner may treat at any one time.

The laws pertaining to the utilization of buprenorphine were last revised approximately ten years ago at a time when the extent of the opioid public health crisis was less well-documented. The purpose of the final rule is to expand access to MAT with buprenorphine while encouraging practitioners administering buprenorphine to ensure their patients can receive the full array of services that comprise evidence-based MAT and to minimize the risk of drug diversion. The final rule revises the highest patient limit from 100 patients per practitioner with an existing waiver (waivered practitioner) to 275 patients for practitioners who meet certain criteria in addition to those established in statute. Practitioners who have had a waiver to treat 100 patients for at least one year could obtain approval to treat up to 275 patients if they meet the

requirements defined in this final rule and after submitting a Request for Patient Limit Increase to SAMHSA. Practitioners approved to treat up to 275 patients will also be required to accept greater responsibility for providing behavioral health services and care coordination, and ensuring quality assurance and improvement practices, diversion control, and continuity of care in emergencies. The higher limit also requires regularly reaffirming the practitioner's ongoing eligibility and participating in data reporting and monitoring as required by SAMHSA. In addition, practitioners in good standing with a current waiver to treat up to 100 patients (*i.e.*, the practitioner has filed a NOI and satisfied all required criteria) may request approval to treat up to 275 patients in specific emergency situations for a limited time period specified in the rule. We anticipate that qualifying emergency situations will occur very infrequently. As a result, we do not anticipate that this provision will contribute significantly to the impact of this final rule. SAMHSA will review all emergency situation requests, to the extent practicable, in consultation with appropriate governmental authorities before such requests are granted. Finally, the final rule defines patient limit in such a way that firmly ties the individual patient to the prescribing practitioner of record rather than to the covering practitioner at a given moment. This will enable waived practitioners to provide reciprocal cross-coverage of patients for brief periods, such as weekends or vacations, without being considered to be in excess of their respective individual limits. This will help to ensure continuity of care in select situations, and we expect that this will primarily affect the timing of treatment rather than the quantity of treatment. As a result, we do not anticipate that the changes related to cross-coverage will contribute significantly to the impact of this final rule, and we do not estimate associated costs and benefits.

C. Need for the Rule

The United States is facing an unprecedented increase in prescription opioid misuse, heroin use, and opioid-related overdose deaths. In 2014, 18,893 overdose deaths involved prescription opioids and 10,574 involved heroin.³

³ Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014. Atlanta, GA: Center for Disease Control and Prevention. Available at http://www.cdc.gov/nchs/data/health_policy/AADR_

Underlying many of these deaths is an untreated opioid use disorder.^{4 5 6} In 2014, more than 2.2 million people met diagnostic criteria for an opioid use disorder.⁷

Beyond the increase in overdose deaths, the health and economic consequences of opioid use disorders are substantial. In 2011, the most recent year data are available, an estimated 660,000 emergency department visits were due to the misuse or abuse of prescription opioids, heroin, or both.⁸ A recent analysis estimated the costs associated with emergency department and hospital inpatient care for opioid abuse-related events in the United States was more than \$9 billion per year.⁹ The societal costs of prescription opioid abuse, dependence, and misuse in the United States in 2011 were estimated at \$55.7 billion annually, not including societal costs related to heroin use.¹⁰

Beginning around 2006, the United States started to experience a significant increase in the rate of hepatitis C virus infections. The available epidemiology indicates this increase is largely due to the increased injection of prescription opioids and heroin.^{11 12} In addition, in 2015, a large outbreak of HIV in a small rural community in Indiana was linked to injection of prescription opioids, primarily injection of the prescription opioid oxycodone. Over 80 percent

drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

⁴ Johnson EM, Lanier WA, Merrill RM, et al. Unintentional Prescription opioid-related overdose deaths: description of decedents by next of kin or best contact. *Utah, 2008–2009.* *J Gen Intern Med.* 2013;28(4):522–529.

⁵ Hall AJ, Logan JE, Toblin RL, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA.* 2008;300(22):2613–2620.

⁶ Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011;305(13):1315–1321.

⁷ Jones CM. Unpublished analysis of the 2014 National Survey on Drug Use and Health Public Use File. 2015.

⁸ Id.

⁹ Chandwani HS, Strassels SA, Rascati KL, Lawson KA, Wilson JP. Estimates of charges associated with emergency department and hospital inpatient care for opioid abuse-related events. *J Pain Palliat Care Pharmacother.* 2013;27(3):206–13.

¹⁰ Birnbaum HG, White AG, Schiller M, Waldman T, et al. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Med.* 2011;12(4):657–67.

¹¹ Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006–2012. *Clin Infect Dis* 2014;59:1411–9.

¹² Zibbell JE, Iqbal K, Patel RC, Suryaprasad A, et al. Increases in hepatitis C virus infection related to injection drug use related to injection drug use among persons aged ≤30 years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012. *MMWR Morb Mortal Wkly Rep.* 2015;64(17):453–8.

of the 135 cases, as of April 2015, identified in the outbreak were co-infected with hepatitis C virus.¹³ The infectious disease consequences associated with opioid injection have been found to account for a significant proportion of the economic burden and disability associated with opioid use disorders.¹⁴

There is robust literature documenting the effectiveness and cost-effectiveness of the use of buprenorphine in the treatment of opioid use disorder. Buprenorphine has been shown to increase treatment retention and to reduce opioid use, relapse risk, and risk behaviors that transmit HIV and hepatitis.^{15 16 17 18 19 20} Reductions in opioid-related mortality have been shown for buprenorphine.^{21 22 23}

¹³ Conrad C, Bradley HM, Broz D, et al. Community outbreak of HIV infection linked to injection drug use of oxycodone—Indiana, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(16): 443–4.

¹⁴ Degenhardt L, Whiteford HA, Ferrari AJ, Charlson FJ, et al. Global burden of disease attributable to illicit drug use and dependence: findings from the Global Burden of Disease Study 2010. *Lancet* 2013;382(9904):1564–74.

¹⁵ Clark RE, Baxter JD, Aweh G, O'Connell E, et al. Risk factors for relapse and higher costs among Medicaid members with opioid dependence or abuse: opioid agonists, comorbidities, and treatment history. *J Subst Abuse Treat.* 2015;57:75–80.

¹⁶ Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev.* 2014 Feb 6;2:CD002207. doi: 10.1002/14651858.CD002207.pub4.

¹⁷ Kraus ML, Alford DP, Kotz MM, et al. Statement of the American Society of Addiction Medicine consensus panel on the use of buprenorphine in office-based treatment of opioid addiction. *J Addict Med.* 2011;5(4):254–263.

¹⁸ Bonhomme J, Shim RS, Gooden R, Tyus D, Rust G. Opioid addiction and abuse in primary care practice: a comparison of methadone and buprenorphine as treatment options. *J Natl Med Assoc.* 2012;104(7–8):342–350.

¹⁹ Tsui JJ, Evans JL, Lum PJ, Hahn JA, Page K. Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA Intern Med.* 2014;174(12):1974–1981.

²⁰ Woody GE, Bruce D, Korhuis PT, Chhatre S, et al. HIV risk reduction with buprenorphine-naloxone or methadone: findings from a randomized trial. *J Acquir Immune Defic Syndr.* 2015;68(5):554–61.

²¹ Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.* Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

²² Schwartz RP, Gryczynski J, O'Grady KE, et al. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995–2009. *Am J Public Health.* 2013;103(5):917–922.

²³ Carrieri MP, Amass L, Lucas GM, Vlahov D, Wodak A, Woody GE. Buprenorphine use: the international experience. *Clin Infect Dis.* 2006;43(suppl 4):S197–S215.

Despite these well-documented benefits, buprenorphine treatment for opioid use disorder is significantly underutilized and often does not incorporate the full scope of recommended clinical practices that make up evidence-based MAT. Generally, there is significant unmet need for MAT treatment among individuals with opioid use disorders.²⁴ There is also substantial geographic variation in the capacity to prescribe buprenorphine. Research suggests that 10 percent of the population live in areas where there is a limited number of practitioners eligible to prescribe buprenorphine or in counties that have no practitioners with a waiver to prescribe buprenorphine.²⁵ These are primarily rural counties and areas located in the middle of the country.²⁶ Only about 5 percent of practitioners currently authorized to treat up to the 100 patient limit are located in rural counties.²⁷

Evidence suggests that utilization of buprenorphine is limited directly by the existence of treatment limits. Practitioners currently providing MAT with buprenorphine under 21 U.S.C. 823(g)(2) report that being limited to treating not more than 100 patients at a time is a barrier to expanding treatment.^{28 29 30} A recent survey by ASAM found that among the 1,309 respondents (approximately 35 percent of ASAM's membership), comprising a range of addiction stakeholders, including those working in OTPs and outpatient or office-based practice

²⁴ Jones CM, Campopiano M, Baldwin G, McCance-Katz E. National and state treatment need and capacity for opioid agonist medication-assisted treatment. *Am J Public Health* 2015;105(8):e55–63.

²⁵ Rosenblatt RA, Andrilla CH, Catlin M, Larson EH. Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *Ann Fam Med.* 2015 Jan–Feb;13(1):23–6. doi: 10.1370/afm.1735.

²⁶ Dick AW, Pacula RL, Gordon AJ, Sorbero M, et al. Growth in buprenorphine waivers for physicians increased potential access to opioid agonist treatment, 2002–11. *Health Affairs* 2015;34(6):1028–1034.

²⁷ Stein BD, Pacula RL, Gordon AJ, Burns RM, et al. Where is buprenorphine dispensed to treat opioid use disorders? The role of private offices, opioid treatment programs, and substance abuse treatment facilities in urban and rural counties. *Milbank Quarterly* 2015;93(3):56561–583.

²⁸ Molfenter T, Sherbeck C, Zehner M, Starr S. Buprenorphine Prescribing Availability in a Sample of Ohio Specialty Treatment Organizations. *J Addict Behav Ther Rehabil.* 2015;4(2). pii: 1000140.

²⁹ Molfenter T, Sherbeck C, Zehner M, Quanbeck A, et al. Implementing buprenorphine in addiction treatment: payer and provider perspectives in Ohio. *Subst Abuse Treat Prev Policy.* 2015;10:13. doi: 10.1186/s13011-015-0009-2.

³⁰ Substance Abuse and Mental Health Services Administration. (2006). *The SAMHSA Evaluation of the Impact of the DATA Waiver Program.* Retrieved from http://www.buprenorphine.samhsa.gov/FOR_FINAL_summaryreport_colorized.pdf.

settings, 544, or 41.6 percent, were currently treating more than 80 patients, and 796, or 60.8 percent, reported there was demand for treatment in excess of the current 100 patient limit under the Drug Addiction Treatment Act of 2000 (Pub. L. 106–310).³¹ Increasing the number of patients that a single practitioner can treat with buprenorphine, then, could have a direct impact on buprenorphine capacity and utilization.

In addition to direct barriers to treating additional patients imposed by the patient limit, there are indirect barriers to expanding treatment capacity. In particular, increases in a practitioner's ability to expand his or her patient base will allow the practitioner to take advantage of economies of scale to increase the practice's efficiency. For example, a practitioner with a larger practice is more likely to be able to afford to hire specialized support staff, which allows the practitioner to reduce time spent on tasks best suited for another individual. This may help to enable the provision of the full complement of ancillary services that make up evidence-based MAT. Increasing a practitioner's maximum capacity for treatment has the potential to make treating patients with buprenorphine more economically feasible, with the likelihood of increasing capacity to prescribe buprenorphine.

The statutory change implemented in 2007 that increased the limit on the number of buprenorphine patients a practitioner could treat from 30 to 100, after having a 30 patient limit for 1 year, was associated with a significant increase in the use of buprenorphine.³² In 2007, when practitioners were first able to treat up to 100 patients, nearly 25 percent of eligible practitioners submitted a NOI to treat 100 patients (1,937 practitioners out of 7,887 practitioners).³³ The findings from the ASAM survey discussed above and additional information indicate there is sufficient demand from both providers and patients to raise the patient limit. In addition, based on the experience in 2007, it is expected that some proportion of eligible practitioners will respond to the final rule by submitting a Request for Patient Limit Increase to treat up to 275 patients.

³¹ American Society of Addiction Medicine. 2015. Available at: <http://www.asam.org/magazine/read/article/2015/12/08/addiction-specialists-weigh-in-on-the-data-2000-patient-limits>.

³² Stein *supra* note 27.

³³ Jones, *supra* note 24.

D. Analysis of Benefits and Costs

a. Increased Ability for Waivered Practitioners To Treat Patients With Buprenorphine-Based MAT

This final rule directly expands opportunities for physicians who currently treat or who may treat patients with buprenorphine, as they will now have the potential to treat up to 275 patients with buprenorphine. We believe that this may translate to a financial opportunity for these physicians, depending on the costs associated with treating these additional patients.

Relatedly, this final rule may increase the value of the waiver to treat opioid use disorder under 21 U.S.C. 823(g)(2). The final rule requires practitioners to have a waiver to treat 100 patients for 1 year and to have additional credentialing as defined in § 8.2 or to practice in a qualified practice setting as defined in the rule in order to request approval to treat up to 275 patients. If getting to the 275-patient limit provides sufficient benefits to practitioners, this final rule may also increase incentives for other practitioners to apply for the lower patient limit waivers, insofar as they are milestones towards the 275-patient limit. In addition, this rule may also make it more valuable for practitioners to have additional credentialing as defined in § 8.2, or to practice in a qualified practice setting. The final rule, then, may increase the number of practitioners in these categories and thus the number of practitioners eligible for the 275-patient limit in the future.

b. Increased Treatment for Patients

Permitting practitioners to treat up to 275 patients will only be successful if it results in practitioners serving additional patients. As discussed previously, there are many reasons to expect this to happen as a result of the publication of this final rule. In addition, we expect that other factors could amplify the impact of the changes in the rule. First, following the implementation of the Affordable Care Act, health insurance coverage has expanded dramatically in the United States. The uninsured rate among adults age 18–64 declined from 22.3 percent in 2010 to 12.7 percent during the first 6 months of 2015.³⁴ Further, the Affordable Care Act expanded coverage includes populations who may be at

high-risk for opioid use disorders that previously did not have sufficient access to health insurance coverage.³⁵ Second, parity protections from the Mental Health Parity and Addiction Equity Act and the Affordable Care Act will include coverage for mental health and substance use disorder treatment that is comparable to medical and surgical coverage in many types of insurance policies. Insurance coverage and cost of treatment have previously been cited as important reasons that individuals seeking treatment have not used buprenorphine.^{36 37 38 39} A final rule to extend parity protections to Medicaid managed care plans was released earlier this year. These changes in health insurance coverage should improve access to substance use disorder treatment, including buprenorphine.

c. Increased Time To Treat Patients

Lack of practitioner time to treat patients with opioid use disorder, which includes a patient exam, medication consultation, counseling, and other appropriate treatment services, and lack of behavioral health staff to provide these treatment services, are additional barriers to providing MAT with buprenorphine in the office-based setting.^{40 41} These barriers could be addressed by leveraging the time and skills of clinical support staff, such as nurses and clinical social workers. For example, in Massachusetts and Vermont, nurses provide screening, intake, education, and other ancillary services for patients treated with buprenorphine. This enables practitioners to treat additional patients and to provide the requisite

psychosocial services.^{42 43 44} However, in order to afford a nurse or other clinician dedicated to providing evidence-based treatment for an opioid use disorder, practitioners need a minimum volume of patients. Allowing practitioners to treat up to 275 patients at a time could be a step towards supporting practitioners that seek to hire nurses and other clinical staff to reduce practitioners' time requirements and to provide the comprehensive services of high-quality MAT with buprenorphine. This impact of leveraging non-physicians to facilitate expanded access to buprenorphine has been demonstrated in both Vermont and Massachusetts.^{45 46}

Discussions with stakeholders about approaches to expanding access to MAT, including the use of buprenorphine-based MAT, suggest that expanding the patient limit in general will result in increased efficiencies in treating opioid use disorder patients. It will allow treating practitioners to provide the physician-appropriate services consistent with their waiver. It will provide more efficient supportive care, not related to prescribing or administering buprenorphine-containing products, by allowing the treating practitioner to supervise this care, which can be provided by physician assistants, nurse practitioners, nurse case managers, and other behavioral health specialists.

d. Federal Costs Associated With Disseminating Information About the Rule

Following publication of this final rule, SAMHSA will work to educate providers about the requirements and opportunities for requesting and obtaining approval to treat up to 275 patients under 21 U.S.C. 823(g)(2). SAMHSA will prepare materials summarizing the changes as a result of

³⁵ Jones, *supra* note 7.

³⁶ Volkow ND, Frieden TR, Hyde PS, et al. Medication-assisted therapies—tackling the opioid-overdose epidemic. *New Eng J Med* 2014; 370(22):2063–6.

³⁷ Sohler NL, Weiss L, Egan JE, et al. Consumer attitudes about opioid addiction treatment: a focus group study in New York City. *J Opioid Manag.* 2013;9(2):111–119.

³⁸ Greenfield BL, Owens MD, Ley D. Opioid use in Albuquerque, New Mexico: a needs assessment of recent changes and treatment availability. *Addict Sci Clin Pract.* 2014;9:10. doi: 10.1186/1940-0640-9-10.

³⁹ American Society of Addiction Medicine. State Medicaid coverage and authorization requirements for opioid dependence medications. 2013. Available at: <http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>.

⁴⁰ Hutchinson E, Catlin M, Andrilla CH, Baldwin LM, Rosenblatt RA. Barriers to primary care physicians prescribing buprenorphine. *Ann Fam Med.* 2014 Mar–Apr;12(2):128–33.

⁴¹ DeFlavio JR, Rolin SA, Nordstrom BR, Kazal LA Jr. Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians. *Rural Remote Health.* 2015;15:3019. Epub 2015 Feb 4.

⁴² Alford D, LaBelle C, Richardson J, O'Connell J, et al. Treating homeless opioid dependent patients with buprenorphine in an office-based setting. *Society of General Internal Medicine.* 2007; 22: 171–176.

⁴³ LaBelle, C. Nurse Care Manager Model. <http://buprenorphine.samhsa.gov/presentations/LaBelle.pdf>.

⁴⁴ State of Vermont: Concept for Medicaid Health Home Program http://hcr.vermont.gov/sites/hcr/files/VT_SPA_Concept_Paper_final_CMS_10_02_12.pdf.

⁴⁵ LaBelle CT, Han SC, Bergeron A, Samet JH. Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Statewide Implementation of the Massachusetts Collaborative Care Model in Community Health Centers. *J Subst Abuse Treat.* 2016;60:6–13.

⁴⁶ Vermont Department of Health. The effectiveness of Vermont's System of Opioid Addiction Treatment. 2015. Available at: <http://legislature.vermont.gov/assets/Legislative-Reports/Opioid-system-effectiveness-1.14.15.pdf>.

³⁴ Centers for Disease Control and Prevention. Health insurance coverage: early release of estimates from the National Health Interview Survey, January–June 2015. Available at: http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur_201511.pdf.

this final rule, and provide these materials to practitioners potentially affected by the rulemaking upon its publication. SAMHSA has already established channels for disseminating information about rule changes to stakeholders; it is estimated that preparing and disseminating these materials will cost approximately \$40,000, based upon experience soliciting public comment on past rules and publications such as the Federal Opioid Treatment Program Standards.

e. Practitioners Costs To Evaluate the Policy Change

We expect that practitioners potentially affected by this policy change will process the information and decide how to respond. In particular, they will likely evaluate the requirements and opportunities associated with the ability to treat up to 275 patients, and decide whether or not it is advantageous to pursue approval to treat up to 275 patients and make any necessary changes to their practice, such as obtaining additional credentialing as defined in § 8.2, or the ability to treat patients in a qualified practice setting.

We estimate that practitioners may spend an average of thirty minutes processing the information and deciding what action to take. According to the U.S. Bureau of Labor Statistics,⁴⁷ the average hourly wage for a physician is \$93.74. After adjusting upward by 100 percent to account for overhead and benefits, we estimate that the per-hour cost of a physician's time is \$187.48. Thus, the cost per practitioner to process this information and decide upon a course of action is estimated to be \$93.74. SAMHSA will disseminate

information to an estimated 50,000 practitioners, which includes practitioners with a waiver to prescribe buprenorphine (*i.e.*, approximately 30,000 practitioners as of December 2015) and those who are reached through SAMHSA's dissemination network (*i.e.*, 20,000 practitioners). For purposes of analysis we assume that 75 percent of these practitioners will review this information, and, as a result, we estimate that dissemination will result in a total cost of \$3.5 million.

f. Practitioner Costs To Submit a Request for Patient Limit Increase

Practitioners who want to treat up to 275 patients at a given time are required to submit a Request for Patient Limit Increase form to SAMHSA. The form is three pages in length. We estimate that the form takes a practitioner an average of 1 hour to complete the first time it is completed, implying a cost of \$187.48 per submission after adjusting upward by 100 percent to account for overhead and benefits. A draft Request for Patient Limit Increase form is available in the docket. We did not receive public comment on these assumptions when proposed, and as a result they remain unchanged from those appearing in the proposed rule. We do not have ideal information with which to estimate the number of practitioners who will submit a Request for Patient Limit Increase form in response to this final rule, and we therefore acknowledge uncertainty regarding the estimate of the total associated cost. However, based on the experience with the patient limit increase from 30 to 100 implemented in 2007,^{48,49} the results of the 2015 ASAM survey described earlier, public

comment, and discussions with stakeholders, and changes in qualifications necessary to request a waiver to treat up to 275 patients, we estimate that between 500 and 1,800 practitioners will request approval to treat up to 275 patients within the first year following publication of the final rule. This translates to between approximately 5 percent and 18 percent of eligible providers with the 100 patient limit requesting the higher patient limit in the first year. This is consistent with a public comment that indicated that 8 to 15 physicians (or 11 percent–21 percent) in Vermont would request the higher patient limit, as well as a recent study in Ohio which found among specialty treatment providers that 17 percent had turned away patients due to prescribing capacity limits.⁵⁰ In addition, our lower bound estimate of 5 percent is in line with an internal analysis by HHS that found approximately 5 percent of physicians with the 100 patient limit in 3 geographic diverse States were prescribing at or near their 100 patient limit. We estimate that between 100 and 300 additional practitioners will request approval to treat up to 275 patients in each of the subsequent 4 years. This would result in 600 to 2,100 practitioners in the second year, 700 to 2,400 practitioners in the third year, 800 to 2,700 in the fourth year, and 900 to 3,000 practitioners in the fifth year. We use the midpoint of each of these ranges to estimate costs and benefits in the first 5 years following publication of the final rule. This would result in a range of \$93,740 to \$337,464 in costs related to Request for Patient Limit Increase submissions in the first year.

	Number of requests for patient limit increase	Cost (\$)
Year 1	1,150	215,600
Year 2–5	200	37,500
Total	1,950	365,600

g. Practitioner Costs To Resubmit a Request for Patient Limit Increase

After approval, a practitioner would need to be resubmit a Request for Patient Limit Increase every 3 years to maintain his or her waiver to treat up to 275 patients. A practitioner would use

the same 3-page Request for Patient Limit Increase used for an initial waiver request. We estimate that this will take 30 minutes because practitioners will be more familiar with the Request for Patient Limit Increase. Consistent with the physician wage estimate above, we

estimate that resubmissions will require a practitioner an average of 30 minutes to complete, implying a cost of \$93.74 per resubmission. To calculate costs associated with resubmission, we assume that all physicians who submit a Request for Patient Limit Increase will

⁴⁷ U.S. Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Retrieved from: http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

⁴⁸ Arfken CL, Johanson CE, Menza SD, Schuster CR. Expanding treatment capacity for opioid

dependence with office-based treatment with buprenorphine: national surveys of physicians. *J Subst Abuse Treat.* 2010;39(2):96–104.

⁴⁹ Jones, *supra* note 24.

⁵⁰ Molfenter T, Sherbeck C, Zehner M, Starr S. Buprenorphine prescribing availability in a sample of Ohio specialty treatment organizations. *J Addict Behav Ther Rehabil.* 2015;4(2): doi:10.4172/2324–9005.1000140.

submit a renewal 3 years later. Our estimates are summarized in the table below.

	Number of renewals	Cost (\$)
Year 1–3 (renewals not necessary)	0	0
Year 4	1,150	108,000
Year 5	200	19,000
Total	1,350	127,000

h. Private-Sector Costs Associated With Newly Applying for Any Waiver

Practitioners may also be interested in the ability to eventually treat up to 275 patients, and may make changes toward achieving that goal. As discussed previously, these changes may increase the number of practitioners who apply for a waiver to treat 30 or 100 patients. This would require practitioners to complete the required training, possess a valid license to practice medicine, be a registrant of DEA, and have the capacity to refer patients for appropriate counseling and other appropriate ancillary services. In addition, these changes could increase the number of practitioners who seek additional credentialing as defined in § 8.2 or meet the requirements for practicing in a qualified practice setting as outlined in the final rule. This would likely include practice experience requirements, fees and time associated with preparing for and taking an exam, time and fees for continuing medical education requirements, and payment of certification fees. We lack information to estimate the number of practitioners who will change behavior along these dimensions, and did not receive this information through the public comment process. Thus, we do not provide estimates of costs and benefits.

i. Federal Costs Associated With Processing New 275-Patient Limit Waivers

In addition to the costs associated with practitioners seeking approval for the higher patient limit, costs will be incurred by SAMHSA and DEA in order to process the additional Requests for Patient Limit Increase generated by the final rule. For purposes of analysis, and based on contractor estimates, SAMHSA estimates that it will pay a contractor \$100 to process each waiver. As discussed previously, we estimate that between 500 and 1,800 practitioners will request approval to treat up to 275 patients within the first year of the rule, and between 100 and 300 additional practitioners will request approval to treat up to 275 patients in each of the subsequent 4 years. In addition, we

estimate that physicians will resubmit 500 to 1,800 renewals in year 4, and 100 to 300 renewals in year 5. As a result, we estimate costs to SAMHSA to process these waivers of \$50,000–\$180,000 in year 1, \$10,000–\$30,000 in year 2, \$10,000–\$30,000 in year 3, \$60,000–\$210,000 in year 4, and \$20,000–\$60,000 in year 5 following publication of the final rule. We estimate that DEA will allocate the equivalent of 1 FTE at the GS–11 level to process the additional requests coming to DEA for issuance of a new DEA number designating the physician as eligible to prescribe buprenorphine for the treatment of opioid use disorder as a result of this final rule. We estimate the associated cost is \$144,238, which we arrive at by multiplying the salary of a GS–11 employee at step 5, which is \$72,219 in 2015, by two to account for overhead and benefits.

j. Costs and Benefits of New Treatment

Once requests to treat up to 275 patients generated by the final rule are processed, approved practitioners would be able to increase the number of patients they treat with buprenorphine. These patients, then, could utilize additional medical services that are consistent with the expectations for high-quality, evidence-based MAT in the rule. We estimate the cost for buprenorphine and these additional medical services, including behavioral health and psychosocial services, as a result of the final rule to total \$4,349 per patient per year, as described below.

This estimate was derived using claims data from the 2009–2014 Truven Health MarketScan® database. According to the MarketScan® data, the annual cost of buprenorphine prescriptions and ancillary psychosocial services received totaled \$3,500 for individuals with private insurance and \$3,410 for individuals with Medicaid. Specifically, the average annual cost of buprenorphine prescriptions was \$2,100 for commercial insurance based on receipt of an average of seven buprenorphine prescriptions annually and \$2,600 for Medicaid based on receipt of an average of 10

buprenorphine prescriptions annually. We use estimates from commercial insurance and Medicaid in order to capture the range of costs per patient across different insurance programs. However, we note that the rule will impact patients with and incur costs to not only commercial insurance and Medicaid but also other public and private insurers.

According to the MarketScan® data, approximately 69 percent of Medicaid patients and 45 percent of privately insured patients received an outpatient psychosocial service related to substance use disorder in addition to their buprenorphine prescription. The average number of visits among those who received any psychosocial service was eight for privately insured patients at an average cost of \$3,000 per year and 10 for Medicaid patients at an average cost of \$1,100 per year. We assumed that the quality of care would increase among patients treated by practitioners with the 275-patient limit due to the extra oversight and quality of care requirements in the final rule. Specifically, we assumed that 80 percent of patients would receive outpatient psychosocial services.

The cost of providing MAT with buprenorphine, including prescriptions, ancillary, and psychosocial services, is estimated at \$4,590 for commercial insurance and \$3,525 for Medicaid beneficiaries. Based on data from IMS Health, it is estimated that approximately 18 percent of individuals receiving MAT with buprenorphine are Medicaid enrollees. Thus, we arrived at the estimated average cost for individuals new to the treatment system as a result of the final rule to be \$4,350 per patient per year.

The total resource costs associated with additional treatment is the product of additional treatment costs per person and the number of people who will receive additional treatment as a result of the final rule. For purposes of analysis, we assume that each practitioner who requests approval to treat up to 275 patients will treat between 20 and 50 additional patients each year. This is based on the

experience with the increase from the 30 patient limit to the 100 patient limit and taking into account the increase in demand for buprenorphine treatment since that statutory change.^{51 52} In addition, we have adjusted the upper bound of this range in line with the shift to the availability of a waiver to treat up to 275 rather than 200 patients. We note that in that case, there were no new costs imposed on practitioners beyond those associated with additional treatment, whereas in this final rule there are new costs beyond those

associated with additional treatment. However, applying this assumption would result in an estimated range of 10,000 to 90,000 additional patients treated in the first year; and an additional 2,000 to 15,000 patients in each subsequent year. To estimate costs associated with this increase in the number of patients, we assume that, on average, each physician will treat the equivalent of 35 full-time patients (*i.e.*, some patients might receive fewer services and others might receive more, but for cost estimates we assume it

averages out to the equivalent of 35 patients receiving the full spectrum of care). We use these ranges to estimate costs and benefits of the rule. Based on this information, we estimate the treatment costs associated with new patients receiving treatment with buprenorphine as a result of this final rule will be between \$43.5 million and \$391 million in the first year with a central estimate of \$175 million, and an additional \$8.7 million to \$65.2 million in each subsequent year with a central estimate of \$30.4 million.⁵³

	Additional people receiving treatment, relative to baseline	Treatment costs (millions)
Year 1	40,250	\$175
Year 2	47,250	205
Year 3	54,250	236
Year 4	61,250	266
Year 5	68,250	297

Evidence suggests that the benefits associated with additional buprenorphine utilization are likely to exceed their cost. One study estimates the costs and Quality Adjusted Life Year (QALY) gains associated with long-term office-based treatment with buprenorphine-naloxone for clinically stable opioid-dependent patients compared to no treatment. The authors estimate total treatment costs over 2 years of \$7,700 and an associated 0.22 QALY gain compared to no treatment in their base case.^{54 55} Following a food safety rule recently published by FDA,⁵⁶ we use a value of \$1,260 per quality-adjusted life day. This implies a value of \$460,215 (\$1,260 * 365.25) per QALY, which we use to monetize the health benefits here. As a result, we estimate average annual benefits ranges of \$51,000 per person who achieves 6

months of clinical stability. Evidence suggests a 43.3 percent completion rate for a six month treatment course.⁵⁷ For other individuals, we estimate they experience half of the annual health benefits, equivalent to 0.055 QALYs. In addition, based on an internal analysis of data from the National Survey on Drug Use and Health, we estimate that 20 percent of new patients impacted by this rule will have received some form of non-medication-assisted treatment for opioid use disorder in the past year and 80 percent of patients will be new to treatment.⁵⁸ For the 20 percent of patients switching to buprenorphine from other non-MAT interventions, we adjust their estimated health benefit downward by 15 percent to account for benefits derived from non-MAT interventions prior to initiating buprenorphine treatment. As a result,

we estimate monetized health benefits of \$1,416 million in the first year, with estimated monetized health benefits rising by \$246 million in each subsequent year as more individuals receive treatment as a result of the rule. These monetized health benefits are summarized below. We also explore the sensitivity of these results to our assumptions regarding the health benefits related to treatment in our section on sensitivity analysis. HHS believes that the public will also experience benefits that go beyond the health benefits quantified and monetized here. These benefits include reductions in costs associated with criminal justice system interactions. While these are important benefits of this rule, HHS does not quantify the rule's effects along these dimensions.

	Additional people receiving treatment, relative to baseline	Monetized health benefits (millions)
Year 1	40,250	\$1,416
Year 2	47,250	1,662
Year 3	54,250	1,909

⁵¹ Arfken, *supra* note 48.

⁵² Jones, *supra* note 24.

⁵³ As noted subsequently, some individuals newly receiving MAT would have accessed non-MAT interventions in the absence of this rule. Accounting for this would reduce the estimates of rule-induced costs.

⁵⁴ Schackman BR, Leff JA, Polsky D, Moore BA, Fiellin DA. Cost-Effectiveness of Long-Term Outpatient Buprenorphine-Naloxone Treatment for Opioid Dependence in Primary Care. *Journal of General Internal Medicine*. 2012;27(6):669–676. doi:10.1007/s11606-011-1962-8.

⁵⁵ These results omit lost utility associated with the illegal consumption of heroin or other opioids. Such omission is consistent with Zerby, R.O. Is Cost-Benefit Analysis Legal? Three Rules. *Journal of Policy Analysis and Management* 17(3): 419–456, 1998.

⁵⁶ This RIA can be found here: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf>.

⁵⁷ Fiellin DA, Pantalon MV, Chawarski MC, Moore BA, Sullivan LE, O'Connor PG, Schottenfeld RS. Counseling plus Buprenorphine—Naloxone

Maintenance Therapy for Opioid Dependence. *New England Journal of Medicine*. 2006; 355:365–374. doi: 10.1056/NEJMoa055255

⁵⁸ Given that data from the National Survey on Drug Use and Health indicate only a minority of patients with substance use disorder treatment need actually recognize that need and seek treatment, we note that 20 percent likely represents the lower bound of the portion of new MAT recipients who would have received some form of non-MAT treatment in the absence of the rule, thus leading to some tendency in the benefits to be overestimated.

	Additional people receiving treatment, relative to baseline	Monetized health benefits (millions)
Year 4	61,250	2,155
Year 5	68,250	2,431

k. Potential for Diversion

While we expect many benefits associated with this final rule, it is possible that there would be unintended negative consequences. First, prior research looked at Utah statewide increases in buprenorphine use and the number of reported unintentional pediatric exposures, and found that as buprenorphine use increased between 2002 and 2011, the number of unintentional pediatric exposures in the State increased.⁵⁹ Thus, it is possible that the increased utilization of buprenorphine as a result of this final rule without appropriate patient counseling and action to ensure the safe use, storage, and disposal of buprenorphine, may lead to an increase in unintentional pediatric exposures. In addition, there has been an increase in diversion of buprenorphine as use of the product has increased. According to the National Forensic Laboratory Information System (NFLIS)—a system used to track diversion—buprenorphine is the third most common narcotic analgesic reported in NFLIS, with 15,209 cases reported in 2014. This represents 12.4 percent of all narcotic analgesic cases in NFLIS in 2014.⁶⁰

It is important to note that studies have found that the motivation to divert buprenorphine is often associated with lack of access to treatment or using the medication to manage withdrawal—as opposed to diversion for the medication’s psychoactive effect.^{61 62} Thus, the overall effect of this rulemaking on diversion is not clear given that the increased utilization of buprenorphine could affect the opportunity for diversion, but also

could, in some cases, reduce diversion because of improved access to high-quality, evidence-based buprenorphine treatment.

Moreover, to reduce the risk of diversion, one of the additional requirements placed on providers who seek the 275-patient limit is implementation of a diversion control plan. However, it is possible that State and local law enforcement could incur additional costs if diversion increases as a result of this final rule. We do not have sufficient information to estimate the extent to which these unintended consequences could occur, and did not receive any through public comment.

l. Practitioner Reporting Requirements

As discussed elsewhere in the preamble, HHS has decided to issue concurrently a Supplemental Notice of Proposed Rulemaking to seek additional comments on the proposed reporting requirements and is therefore delaying the finalization of the reporting requirements proposed in § 8.635 of the NPRM. At this time, we lack the information necessary to estimate the costs associated with future reporting requirements, and as a result do not estimate them here.

m. Costs Associated With Waiver Requests in Emergencies

Under the final rule, practitioners in good standing with a current waiver to treat up to 100 patients may request temporary approval to treat up to 275 patients in specific emergency situations. As discussed previously, we anticipate that qualifying emergency situations will occur very infrequently.

We estimate that practitioners will request ten of these waivers in each year. We estimate that requesting this waiver would require approximately 1 hour of physician time and 2 hours of administrative time, and responding to the request would require resources approximately equivalent to responding the three Requests for Patient Limit Increase submissions, which is \$300. As a result, we estimate that this requirement is associated with costs of approximately \$7,000 in each year following publication of the final rule.

n. Summary of Impacts

The final rule’s impacts will take place over a long period of time. As discussed previously, we expect the existence of the waiver to treat up to 275 patients will increase the desirability of waivers to treat 30 and 100 patients. This implies that more practitioners will work toward fulfilling the requirements associated with receiving these waivers. Further, this may make practitioners early in their career more likely to choose addiction medicine or addiction psychiatry as their specialty. All of this implies that the final rule will have a growing impact on capacity to prescribe buprenorphine as time passes. Since the lack of capacity to treat patients using buprenorphine is a barrier to its utilization, this suggests that the final rule will lead to growing increases in the utilization of buprenorphine, and growing increases in the associated positive health and economic effects.

The following table presents these costs and benefits over the first 5 years of the final rule.

ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES

	Present value over 5 years by discount rate (millions of 2014 dollars)		Annualized value over 5 years by discount rate (millions of 2014 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
BENEFITS				
Quantified Benefits	8,935	8,228	1,894	1,875

⁵⁹ Centers for Disease Control and Prevention. Buprenorphine prescribing practices and exposures reported to a poison center—Utah, 2002–2011. MMWR 2012;61:997–1001.

⁶⁰ Drug Enforcement Administration. National Forensic Laboratory Information System. 2014

Annual Report. Available at: <https://www.nflis.deadiversion.usdoj.gov/Reports.aspx>.

⁶¹ Lofwall MR, Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug Alcohol Depend. 2012;126(3):379–83.

⁶² Genberg BL, Gillespie M, Schuster CR, Johanson CE, et al. Prevalence and correlates of street-obtained buprenorphine use among current and former injectors in Baltimore, Maryland. Addict Behav. 2013;38(12):2868–73.

ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES—Continued

COSTS	3 Percent	7 Percent	3 Percent	7 Percent
	Quantified Costs	1,109	1,022	235

E. Sensitivity Analysis

The total estimated benefits of the changes here are sensitive to assumptions regarding the number of practitioners who will seek a waiver to treat up to 275 patients as a result of the final rule, the number of individuals who will receive MAT as a result of the final rule, the average per-person health benefits associated with this additional treatment, and the dollar value of these health improvements. We estimate that 500 to 1,800 practitioners will apply for a waiver to treat up to 275 patients in the first year, and 100 to 300 practitioners will apply for a waiver to treat up to 275 patients in subsequent years following publication of the final rule, with central estimates at the midpoint of each range. For alternative estimates in these ranges using a 3 percent discount rate, all else equal, we estimate annualized benefits ranging from \$855 million to \$2,934 million and annualized costs ranging from \$107 million to \$364 million.

We estimate that practitioners who receive a waiver to treat up to 275 patients will treat between 20 and 50 additional patients each year, with a central estimate of an average of 35 additional patients. For alternative estimates of 20 to 50 additional patients per year, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$1,082 million to \$2,706 million and annualized costs ranging from \$135 million to \$336 million over the 5 years following implementation.

We estimate that individuals who receive MAT as a result of the final rule will experience average health improvements equivalent to approximately 0.08 QALYs. For alternative estimates of these health improvements between 0.04 and 0.12 QALYs, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$991 million to \$2,973 million over the 5 years following implementation. To estimate

the dollar value of health benefits, we use a value of approximately \$460,000 per QALY. For alternative values per QALY between \$300,000 and \$600,000, all else equal, we estimate annualized benefits using a 3 percent discount rate ranging from \$1,235 million to \$2,469 million over the 5 years following implementation.

Alternative assumptions along these four dimensions, when varied together, using a 3 percent discount rate, imply annualized benefit estimates ranging from \$167 million to \$8,576 million and annualized cost estimates ranging from \$61 million to \$519 million. We note that, in all scenarios discussed in this section, annualized benefits substantially exceed annualized costs. There are, however, uncertainties not reflected in this sensitivity analysis, which might lead to net benefits results that are smaller or larger than the range of estimates summarized in the following table.

LOW, HIGH, AND PRIMARY BENEFIT AND COST ESTIMATES

BENEFITS	Annualized value over 5 years 3 percent discount rate (millions of 2014 dollars)		
	Low	Primary	High
Quantified Benefits	167	1,894	8,576
COSTS	Low	Primary	High
	Quantified Costs	61	235

F. Analysis of Regulatory Alternatives

We carefully considered the option of not pursuing regulatory action. However, existing evidence indicates that opioid use disorder and its related health consequences is a substantial and increasing public health problem in the United States, and it can be addressed by increasing access to effective treatment. As discussed previously, the lack of sufficient access to treatment is directly affected by the existing limit on the number of patients each practitioner with a waiver can currently treat using buprenorphine, and removing this barrier to access is very likely to increase the provision of this treatment. Finally, the provision of MAT with buprenorphine provides tremendous benefits to the individual who

experiences health gains associated with treatment, as well as to society which bears smaller costs associated with the negative effects of opioid use disorders. These benefits are expected to greatly exceed the costs associated with increases in treatment. As a result, we expect the benefits of this regulatory action to exceed its costs.

We also considered allowing practitioners waived to treat up to 100 patients to apply for the higher prescribing limit without having to meet the additional credentialing as defined in § 8.2 or qualified practice setting requirements as defined in the final rule. One important objective of this final rule is to expand access while mitigating the risks associated with expanded access. In addition, the effects

of this rule are difficult to project, leading us to adopt a measured approach to increasing access. Given the complexity of the condition, the increased potential for diversion associated with a higher prescribing limit, and the need to ensure high quality care, it was determined that addition specialist physicians and those with the infrastructure and capacity to deliver the full complement of services recommended by clinical practice guidelines would be best suited to balance these concerns.

Finally, we considered the alternative of having no reporting requirement for physicians with the 275-patient limit. Although this alternative would reduce the 1 hour of physician time and 2 hours of administrative time estimated

for data reporting in our analysis, we did not pursue this alternative. The reporting requirements are intended to reinforce recommendations included in clinical practice guidelines on the delivery of high quality, effective, and safe patient care. Specifically, nationally-recognized clinical guidelines on office-based opioid treatment with buprenorphine suggest that optimal care include administration of the medication and the use of psychotherapeutic support services. They also recommend that physicians and practices prescribing buprenorphine for the treatment of opioid use disorder in the outpatient setting take steps to reduce the likelihood of buprenorphine diversion. Each of these tenets is reflected in the reporting requirements.

G. Regulatory Flexibility Analysis

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. The categories of entities affected most by this final rule will be offices of practitioners and hospitals. We expect that the vast majority of these entities will be considered small based on the Small Business Administration size standards or non-profit status, and assume here that all affected entities are small. According to SAMHSA data, as of March 2016, there were 32,123 practitioners with a waiver to prescribe buprenorphine for the treatment of opioid use disorder. This group of practitioners is most likely to be impacted by the final rule, but we lack information on the total number of associated entities. We acknowledge that some practitioners with a waiver may provide services at multiple entities, many entities may employ multiple practitioners with a waiver, and some entities currently unaffiliated with these practitioners will be impacted by this final rule. As a result, we estimate that approximately 32,123 small entities will be affected by this final rule.

HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. As discussed above, the final rule imposes a small burden on entities. This burden is primarily associated with processing information disseminated by SAMHSA, opting to completing the waiver process to treat additional patients, and submitting information after receiving a waiver to treat 275 patients, which are estimated

to take a maximum of 4 hours per practitioner in any given year. This represents less than 1 percent of hours worked for an individual working full-time. Further, this final rule does not require practitioners to undertake these burdens, as this rulemaking does not require practitioners to seek a waiver to treat 275 patients. As a result, we anticipate that this final rule will not have a significant impact on a substantial number of small entities.

List of Subjects in 42 CFR Part 8

Health professions, Methadone, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HHS amends 42 CFR part 8 as follows:

PART 8—MEDICATION ASSISTED TREATMENT FOR OPIOID USE DISORDERS

■ 1. The authority citation for part 8 continues to read as follows:

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290bb–2a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

■ 2. Revise the heading of part 8 as set forth above.

■ 3. Amend part 8 as follows:

■ a. Remove the word “opiate” and add the word “opioid” in its place wherever it appears; and

■ b. Remove the phrases “opioid addiction” and “Opioid addiction” and add in their places the phrases “opioid use disorder” and “Opioid use disorder”, respectively, wherever they appear.

■ 4. Revise the heading to subpart A to read as follows:

Subpart A—General Provisions

■ 5. Revise § 8.1 to read as follows:

§ 8.1 Scope.

(a) Subparts A through C of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid use disorders. The regulations also establish the Secretary’s standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid use disorder must first obtain from the Secretary or, by delegation, from the

Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary’s standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary’s standards for treatment of opioid use disorder with an opioid agonist treatment medication.

(b) The regulations in subpart F of this part establish the procedures and requirements that practitioners who are authorized to treat up to 100 patients pursuant to a waiver obtained under section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)), must satisfy in order to treat up to 275 patients with medications covered under section 303(g)(2)(C) of the CSA.

■ 6. Amend § 8.2 as follows:

■ a. Revise the definitions of “Accreditation body” and “Accreditation body application”;

■ b. Add, in alphabetical order, the definitions of “Additional Credentialing,” “Approval term,” and “Behavioral health services”;

■ c. Add, in alphabetical order, the definitions of “Covered medications,” “Dispense,” “Diversion control plan,” and “Emergency situation”;

■ d. Revise the definition of “Interim maintenance treatment”;

■ e. Add, in alphabetical order, the definitions of “Medication-Assisted Treatment (MAT),” “Nationally recognized evidence-based guidelines,” and “Opioid dependence”;

■ f. Remove the definition of “Opioid treatment”;

■ g. Revise the definitions of “Opioid treatment program”;

■ h. Add, in alphabetical order, the definitions of “Opioid program treatment certification,” “Opioid use disorder,” and “Opioid use disorder treatment”;

■ i. Revise the definition of “Patient”;

■ j. Add, in alphabetical order, the definitions of “Patient limit,” “Practitioner,” and “Practitioner incapacity”; and

■ k. Remove the definition of “Registered opioid treatment program”.

The revisions and additions read as follows:

§ 8.2 Definitions.

* * * * *

Accreditation body means a body that has been approved by SAMHSA in this part to accredit opioid treatment programs using opioid agonist treatment medications.

Accreditation body application means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body.

* * * * *

Additional Credentialing means board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties or certification by the American Osteopathic Academy of Addiction Medicine, the American Board of Addiction Medicine, or the American Society of Addiction Medicine.

Approval term means the 3 year period in which a practitioner is approved to treat up to 275 patients that commences when a practitioner's Request for Patient Limit Increase is approved in accordance with § 8.625.

Behavioral health services means any non-pharmacological intervention carried out in a therapeutic context at an individual, family, or group level.

Interventions may include structured, professionally administered interventions (e.g., cognitive behavior therapy or insight oriented psychotherapy) delivered in person, interventions delivered remotely via telemedicine shown in clinical trials to facilitate medication-assisted treatment (MAT) outcomes, or non-professional interventions.

* * * * *

Covered medications means the drugs or combinations of drugs that are covered under 21 U.S.C. 823(g)(2)(C).

* * * * *

Dispense means to deliver a controlled substance to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled substance.

Diversion control plan means a set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly.

Emergency situation means that an existing State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for medication-assisted treatment as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as practitioner incapacity; natural or human-caused disaster; an outbreak associated with drug use; and

result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

* * * * *

Interim maintenance treatment means maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

* * * * *

Medication-Assisted Treatment (MAT) means the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder.

Nationally recognized evidence-based guidelines means a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions.

* * * * *

Opioid dependence means repeated self-administration that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

* * * * *

Opioid treatment program or "OTP" means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1).

Opioid treatment program certification means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards described in § 8.12.

Opioid use disorder means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opioid-induced problems.

Opioid use disorder treatment means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to an opioid use disorder. This term includes a range of services including detoxification

treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

Patient for purposes of subparts B through E of this part, means any individual who receives maintenance or detoxification treatment in an opioid treatment program. For purposes of subpart F of this part, patient means any individual who is dispensed or prescribed covered medications by a practitioner.

Patient limit means the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time.

Practitioner means a physician who is appropriately licensed by the State to dispense covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).

Practitioner incapacity means the inability of a practitioner as a result of an involuntary event to physically or mentally perform the tasks and duties required to provide medication-assisted treatment in accordance with nationally recognized evidence-based guidelines.

* * * * *

■ 7. Amend § 8.3 by revising the introductory text of paragraph (b) to read as follows:

§ 8.3 Application for approval as an accreditation body.

* * * * *

(b) *Application for initial approval.* Electronic copies of an accreditation body application form [SMA-167] shall be submitted to: <http://buprenorphine.samhsa.gov/pls/bwns/waiver>.

Accreditation body applications shall include the following information and supporting documentation:

* * * * *

Subpart C [Redesignated as Subpart D]

■ 8. Redesignate subpart C, consisting of §§ 8.21 through 8.34, as subpart D and revise the heading to read as follows:

Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

Subpart B [Redesignated as Subpart C]

■ 9. Redesignate subpart B, consisting of §§ 8.11 through 8.15, as subpart C and revise the heading to read as follows:

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

- 10. Add a heading for new subpart B to read as follows:

Subpart B—Accreditation of Opioid Treatment Programs

§§ 8.3, 8.4, 8.5, and 8.6 [Transferred to Subpart B]

- 11. Transfer §§ 8.3, 8.4, 8.5, and 8.6 to new subpart B.

Subpart E [Reserved]

- 12. Add reserved subpart E.
- 13. Add subpart F, consisting of §§ 8.610 through 8.655, to read as follows:

Subpart F—Authorization To Increase Patient Limit to 275 Patients

Sec.

- 8.610 Which practitioners are eligible for a patient limit of 275?
- 8.615 What constitutes a qualified practice setting?
- 8.620 What is the process to request a patient limit of 275?
- 8.625 How will a Request for Patient Limit Increase be processed?
- 8.630 What must practitioners do in order to maintain their approval to treat up to 275 patients?
- 8.635 [Reserved]
- 8.640 What is the process for renewing a practitioner's Request for Patient Limit Increase approval?
- 8.645 What are the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase, or whose renewal request is denied?
- 8.650 Can SAMHSA's approval of a practitioner's Request for Patient Limit Increase be suspended or revoked?
- 8.655 Can a practitioner request to temporarily treat up to 275 patients in emergency situations?

Subpart F—Authorization To Increase Patient Limit to 275 Patients

§ 8.610 Which practitioners are eligible for a patient limit of 275?

The total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C. 823(g)(2)(B)(iii) is 275 if:

- (a) The practitioner possesses a current waiver to treat up to 100 patients under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) and has maintained the waiver in accordance with applicable statutory requirements without interruption for at least one year since the practitioner's notification of intent

(NOI) under section 303(g)(2)(B) to treat up to 100 patients was approved;

- (b) The practitioner:
 - (1) Holds additional credentialing as defined in § 8.2; or
 - (2) Provides medication-assisted treatment (MAT) utilizing covered medications in a qualified practice setting as defined in § 8.615;
 - (c) The practitioner has not had his or her enrollment and billing privileges in the Medicare program revoked under § 424.535 of this title; and
 - (d) The practitioner has not been found to have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a).

§ 8.615 What constitutes a qualified practice setting?

A qualified practice setting is a practice setting that:

- (a) Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
- (b) Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
- (c) Uses health information technology (health IT) systems such as electronic health records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information;
- (d) Is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law. PDMP means a statewide electronic database that collects designated data on substances dispensed in the State. For practitioners providing care in their capacity as employees or contractors of a Federal government agency, participation in a PDMP is required only when such participation is not restricted based on their State of licensure and is in accordance with Federal statutes and regulations;
- (e) Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

§ 8.620 What is the process to request a patient limit of 275?

In order for a practitioner to receive approval for a patient limit of 275, a practitioner must meet all of the requirements specified in § 8.610 and

submit a Request for Patient Limit Increase to SAMHSA that includes all of the following:

- (a) Completed Request for Patient Limit Increase form;
- (b) Statement certifying that the practitioner:
 - (1) Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders;
 - (2) Will provide patients with necessary behavioral health services as defined in § 8.2 or through an established formal agreement with another entity to provide behavioral health services;
 - (3) Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule (45 CFR part 160 and 45 CFR part 164, subparts A and E) and 42 CFR part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;
 - (4) Will use patient data to inform the improvement of outcomes;
 - (5) Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;
 - (6) Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in § 8.2; and
 - (7) Will notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment;
- (c) Any additional documentation to demonstrate compliance with § 8.610 as requested by SAMHSA.

§ 8.625 How will a Request for Patient Limit Increase be processed?

(a) Not later than 45 days after the date on which SAMHSA receives a practitioner's Request for Patient Limit Increase as described in § 8.620, or renewal Request for Patient Limit Increase as described in § 8.640, SAMHSA shall approve or deny the request.

(1) A practitioner's Request for Patient Limit Increase will be approved if the practitioner satisfies all applicable requirements under §§ 8.610 and 8.620. SAMHSA will thereafter notify the

practitioner who requested the patient limit increase, and the Drug Enforcement Administration (DEA), that the practitioner has been approved to treat up to 275 patients using covered medications. A practitioner's approval to treat up to 275 patients under this section will extend for a term not to exceed 3 years.

(2) SAMHSA may deny a practitioner's Request for Patient Limit Increase if SAMHSA determines that:

(i) The Request for Patient Limit Increase is deficient in any respect; or
(ii) The practitioner has knowingly submitted false statements or made misrepresentations of fact in the practitioner's Request for Patient Limit Increase.

(b) If SAMHSA denies a practitioner's Request for Patient Limit Increase (or renewal), SAMHSA shall notify the practitioner of the reasons for the denial.

(c) If SAMHSA denies a practitioner's Request for Patient Limit Increase (or renewal) based solely on deficiencies that can be resolved, and the deficiencies are resolved to the satisfaction of SAMHSA in a manner and time period approved by SAMHSA, the practitioner's Request for Patient Limit Increase will be approved. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the designated time period, the Request for Patient Limit Increase may be denied.

§ 8.630 What must practitioners do in order to maintain their approval to treat up to 275 patients?

(a) A practitioner whose Request for Patient Limit Increase is approved in accordance with § 8.625 shall maintain all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b), during the practitioner's 3-year approval term. Failure to do so may result in SAMHSA withdrawing its approval of a practitioner's Request for Patient Limit Increase.

(b) [Reserved]

§ 8.635 [Reserved]

§ 8.640 What is the process for renewing a practitioner's Request for Patient Limit Increase approval?

(a) Practitioners who intend to continue to treat up to 275 patients beyond their current 3 year approval term must submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined under

§ 8.620 at least 90 days before the expiration of their approval term.

(b) If SAMHSA does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until SAMHSA reaches a final decision.

§ 8.645 What are the responsibilities of practitioners who do not submit a renewal Request for Patient Limit Increase, or whose renewal request is denied?

Practitioners who are approved to treat up to 275 patients in accordance with § 8.625, but who do not renew their Request for Patient Limit Increase, or whose renewal request is denied, shall notify, under § 8.620(b)(7) in a time period specified by SAMHSA, all patients affected above the 100 patient limit, that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment.

§ 8.650 Can SAMHSA's approval of a practitioner's Request for Patient Limit Increase be suspended or revoked?

(a) SAMHSA, at any time during a practitioner's 3 year approval term, may suspend or revoke its approval of a practitioner's Request for Patient Limit Increase under § 8.625 if it is determined that:

- (1) Immediate action is necessary to protect public health or safety;
- (2) The practitioner made misrepresentations in the practitioner's Request for Patient Limit Increase;
- (3) The practitioner no longer satisfies the requirements of this subpart; or
- (4) The practitioner has been found to have violated the CSA pursuant to 21 U.S.C. 824(a).

(b) [Reserved]

§ 8.655 Can a practitioner request to temporarily treat up to 275 patients in emergency situations?

(a) Practitioners with a current waiver to prescribe up to 100 patients and who are not otherwise eligible to treat up to 275 patients under § 8.610 may request a temporary increase to treat up to 275 patients in order to address emergency situations as defined in § 8.2 if the practitioner provides information and documentation that:

(1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an

emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit;

(2) Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and

(3) Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires.

(b) Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an immediate increase in the higher patient limit.

(c) If SAMHSA determines that a practitioner's request under this section should be granted, SAMHSA will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months.

(d) If a practitioner wishes to receive an extension of the approval period granted under this section, he or she must submit a request to SAMHSA at least 30 days before the expiration of the six month period, and certify that the emergency situation as defined in § 8.2 necessitating an increased patient limit continues. Prior to taking action on a practitioner's extension request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an extension of an increase in the higher patient limit.

(e) Except as provided in this section and § 8.650, requirements in other sections under subpart F of this part do not apply to practitioners receiving waivers in this section.

Dated: June 30, 2016.

Kana Enomoto,

Principal Deputy Administrator, Substance Abuse and Mental Health Services Administration.

Approved: June 30, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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Part IV

Department of Education

Applications for New Awards; Promise Neighborhoods Program—
Implementation Grant Competition; Notices

DEPARTMENT OF EDUCATION**Applications for New Awards; Promise Neighborhoods Program—Implementation Grant Competition**

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information:
 Promise Neighborhoods Program—Implementation Grant Competition.
 Notice inviting applications for new awards for fiscal year (FY) 2016.
 Catalog of Federal Domestic Assistance (CFDA) Number: 84.215N (Implementation).

DATES: *Applications Available:* July 8, 2016.

Deadline for Notice of Intent to Apply: July 25, 2016.

Date of Pre-Application Webinars:
 The Promise Neighborhoods team intends to hold Pre-Application Webinars to provide technical assistance to interested applicants. Detailed information regarding these Webinar times will be provided on the Promise Neighborhoods' Web site at <http://www2.ed.gov/programs/promiseneighborhoods/index.htm>.

Deadline for Transmittal of Applications: September 6, 2016.

Deadline for Intergovernmental Review: November 7, 2016.

Note: Due to a scheduled systems shutdown, applicants will not be able to submit applications for the Promise Neighborhoods competition between 9:00 p.m. on Wednesday, July 20, 2016 until 6:00 a.m. on Monday, July 25, 2016 and from 9:00 p.m. on Wednesday, July 27, 2016 until 6:00 a.m. on Monday, August 1, 2016.

Full Text of Announcement**I. Funding Opportunity Description**

Purpose of Program: The Promise Neighborhoods program is carried out under the legislative authority of the Fund for the Improvement of Education (FIE), title V, part D, subpart 1, sections 5411 through 5413 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (20 U.S.C. 7243–7243b). FIE supports nationally significant programs to improve the quality of elementary and secondary education at the State and local levels and to help all children meet challenging State academic content and student academic achievement standards.

On December 10, 2015, the President signed into law the Every Student Succeeds Act (ESSA), Public Law 114–95, which reauthorized the ESEA.

Beginning in FY 2017, the ESEA, as amended by the ESSA, will serve as the statutory authority for future Promise Neighborhoods competitions.

The purpose of the Promise Neighborhoods program is to significantly improve the educational and developmental outcomes of children and youth in our most distressed communities and to transform those communities by—

(1) Identifying and increasing the capacity of eligible organizations (as defined in this notice) that are focused on achieving results for children and youth throughout an entire neighborhood;

(2) Building a complete continuum of cradle-through-college-to-career solutions (continuum of solutions) (as defined in this notice) of both education programs and family and community supports (both as defined in this notice), with great schools at the center. All strategies in the continuum of solutions must be accessible to children with disabilities (CWD) (as defined in this notice) and English learners (ELs) (as defined in this notice);

(3) Integrating programs and breaking down agency “silos” so that solutions are implemented effectively and efficiently across agencies;

(4) Developing the local infrastructure of systems and resources needed to develop, implement, and sustain effective interventions to improve education outcomes and enhance family and community well-being across the broader region beyond the initial neighborhood; and

(5) Learning about the overall impact of the Promise Neighborhoods program and about the relationship between particular strategies in Promise Neighborhoods and student outcomes, including through an evaluation of the program, particular elements within the continuum of solutions, or both.

Background

The vision of the Promise Neighborhoods program is that all children and youth living in our most distressed communities have access to great schools and strong systems of family and community support that will prepare them to attain an excellent education and successfully transition to college and a career.

A Promise Neighborhood is both a place and a strategy. A place eligible to become a Promise Neighborhood is a geographic area¹ that is distressed, often facing inadequate access to high-quality

early learning programs and services, with struggling schools, low high school and college graduation rates, high rates of unemployment, high rates of crime, and indicators of poor health. These conditions contribute to and intensify the negative outcomes associated with children and youth living in poverty.

Children and youth who are from low-income families and grow up in neighborhoods of concentrated poverty face educational and life challenges above and beyond the challenges faced by children who are from low-income families who grow up in neighborhoods without a high concentration of poverty. A Federal evaluation of the reading and mathematics outcomes of elementary students in 71 schools in 18 districts and 7 States found that even when controlling for individual student poverty, there is a significant negative association between school-level poverty and student achievement.² The evaluation found that students have lower academic outcomes when a higher percentage of their same-school peers qualify for free and reduced-priced lunch (FRPL) compared to when a lower percentage of their same-school peers qualify for FRPL. The compounding effects of neighborhood poverty continue later in life. Another study found that for children with similar levels of family income, growing up in a neighborhood where the number of families in poverty was between 20 and 30 percent increased the chance of downward economic mobility—moving down the income ladder relative to their parents—by more than 50 percent compared with children who grew up in neighborhoods with under 10 percent of families in poverty.³ Furthermore, the effects of poverty and distressed neighborhoods are closely connected to children's long-term economic and social mobility. One recent study found that there is a wide variety across cities in the likelihood of children moving from the bottom quintile of earners to the top quintile over the course of their lifetimes.⁴ This implies that the

² M Lacour, LD Tissington (July 2011). The effects of poverty on academic achievement. Educational Research and Reviews. Available online at www.academicjournals.org/article/article1379765941_Lacour%20and%20Tissington.pdf.

³ Sharkey, Patrick. “Neighborhoods and the Black-White Mobility Gap.” Economic Mobility Project: An Initiative of The Pew Charitable Trusts, 2009.

⁴ “Socioeconomic Mobility in the United States: New Evidence and Policy Lessons,” Raj Chetty in *Shared Prosperity in America's Communities*, Edited by Susan M. Wachter and Lei Ding, pg 13, 2016. Available online at: <https://books.google.com/books?hl=en&lr=&id=84uTCwAAQBAJ&oi=fnd&pg=PA7&dq=chetty&ots=kHLEtwQhgH&sig=>

¹ For the purpose of this notice, the Department uses the terms “geographic area” and “neighborhood” interchangeably.

magnitude of the impact of growing up in a distressed neighborhood varies by region, thereby suggesting that it is particularly important to focus attention and resources on addressing a unique set of needs within specific distressed communities. Researchers also identify school quality as one of the key factors in upward mobility, which suggests that we can improve children's likelihood of success by improving the schools in their communities.⁵ Although education can improve mobility, there are often complex institutional and contextual barriers that prevent communities from making comprehensive improvements.

A Promise Neighborhood strategy addresses the complex, interconnected issues in the distressed community it serves. Promise Neighborhoods are led by organizations that work to ensure that all children and youth in the target geographic area have access to services that lead to improved educational and developmental outcomes from cradle-to-career; are based on the best available evidence and designed to learn about the impact of approaches, for which there is less evidence; are linked and integrated seamlessly; and include education programs as well as programs that provide family and community supports. Promise Neighborhoods enable children and youth within targeted distressed communities to participate in the full range of cradle-to-career supports that are necessary for them to realize their potential. Our expectation is that over time, a greater proportion of the neighborhood residents receive these supports, and that ultimately neighborhood indicators show significant progress. For this reason, each Promise Neighborhood must demonstrate several core features: (1) Significant need in the neighborhood; (2) a strategy to build a continuum of solutions with strong schools at the center; and (3) the organizational and relational capacity to achieve results.

In developing strategies to build a continuum of solutions, communities face the challenge of implementing a comprehensive suite of interconnected services that ensure continuous engagement with community members. Since its inception in 2010, the Promise Neighborhoods program has supported planning and implementation efforts in 47 communities across the country. In particular, the experiences of the 12 Promise Neighborhoods implementation grantees provide valuable information about the conditions that are most

critical for successful implementation of a Promise Neighborhoods strategy. To date, Promise Neighborhoods grantees have provided meaningful service coordination across a range of public and private entities; in so doing, they are building out the ongoing community-based infrastructure necessary to coordinate supports and transform outcomes over time. These successes have helped validate the core value of a comprehensive neighborhood approach.

While they have had success in many areas, Promise Neighborhoods grantees have struggled to collect the full range of data necessary to effectively employ comprehensive case and longitudinal data management systems and conduct meaningful evaluation activities. Such data systems are critical to effectively coordinating a range of services for high-need students and their families within a Promise Neighborhood. In order to address this challenge, we encourage applicants to carefully consider the data-related expectations for Promise Neighborhood grantees outlined in this notice, and in particular, to commit to establishing the conditions for effective data management at the onset of the grant period.

In order to help all applicants understand how to effectively set up and utilize appropriate data systems that are critical to grantee success, the Department's applicant outreach materials and Webinars associated with this year's competition—all of which will be made publicly available on our Web site—will discuss effective practices for data collection and management. In addition, recognizing the prior difficulties associated with collecting and managing data related to Promise Neighborhoods, the Department has developed recommended data collection and management strategies for Promise Neighborhoods grantees. These recommendations are intended to guide Promise Neighborhoods grantees in meeting the program's data expectations. This document is available on the Department's Web site at: <http://www2.ed.gov/programs/promiseneighborhoods/resources.html>.

There are four competitive preference priorities for this competition. Given the Promise Neighborhoods program's focus on coordinating education and community services, this competition prioritizes applicants that are focused on driving greater collaboration within their communities through the competitive preference priorities. Building on prior Promise Neighborhoods grantees' work to enhance high-quality early learning

opportunities, this year's competition includes a competitive preference priority intended to improve coordination among early learning providers and ensure alignment between early learning systems and elementary education systems. We continue to recognize and highlight solutions for catalyzing change in distressed communities through the Neighborhood Revitalization Initiative (NRI). Thus, we prioritize applicants or an applicant's partner who received a Choice or HOPE VI grant from the U.S. Department of Housing and Urban Development (HUD) via a competitive preference priority focused on Quality Affordable Housing. The NRI is a place-based approach to help neighborhoods in distress transform themselves into neighborhoods of opportunity. Additional information pertaining to the NRI may be found at <https://www.whitehouse.gov/administration/eop/oua/initiatives/neighborhood-revitalization>.

In addition, we also include a competitive preference priority that gives preference to applicants working in designated Promise Zones.⁶ This competitive preference priority recognizes that Promise Zones represent a network of commitment and collaboration between local public and private sector partners to address community members' interrelated needs within high-poverty regions, and such coordination may better enable the successful implementation of a Promise Neighborhoods grant. The 22 Promise Zones that have been designated as of June 6, 2016 are located in Atlanta, Georgia; Camden City, New Jersey; the Choctaw Nation of Oklahoma; East Indianapolis, Indiana; Evansville, Indiana; Nashville, Tennessee; Los Angeles, California; the Lowlands of South Carolina; Minneapolis, Minnesota; North Hartford, Connecticut; Philadelphia, Pennsylvania; Pine Ridge, South Dakota; Sacramento, California; San Antonio, Texas; San Diego, California; South Los Angeles, California; Southeast Florida Regional Planning Commission; Southeastern Kentucky; St. Louis, Missouri; Spokane Tribe of Indians, Washington; Turtle Mountain Band of Chippewa Indians,

⁶ Promise Zones are high-poverty urban, rural, and tribal communities that the Federal government will partner with and invest in to accomplish the following goals: Create jobs, leverage private investment, increase economic activity, expand educational opportunities, and reduce violent crime. Each designated Promise Zone will be asked to identify a set of outcomes they will pursue to revitalize their communities, develop a strategy supporting those outcomes, and realign resources accordingly.

srRfcE3Kj-cMvOSmpYrhtWfEXe4#v=onepage&q=raj%20chettychetty&f=false.

⁵ Ibid.

Rolette County, North Dakota; and Roosevelt Roads, Puerto Rico.

As Promise Neighborhoods grantees implement comprehensive transformation plans in their communities, we expect them to build out the full continuum of cradle through college to career solutions. We emphasize the importance of robust strategies for the college and career portion of the Promise Neighborhoods pipeline and for this reason, we include a fourth competitive preference priority for applicants that choose to prioritize postsecondary or technical education and career development. In proposing strategies, we encourage applicants to be mindful of the importance of ensuring that all students and their families have an opportunity to benefit from the services and supports provided.

Priorities: This competition includes three absolute priorities and four competitive preference priorities. Absolute Priority 1, Absolute Priority 2, Absolute Priority 3, and Competitive Preference Priority 2 are from the Promise Neighborhoods notice of final priorities, requirements, definitions, and selection criteria published in the **Federal Register** on July 6, 2011 (76 FR 39590) (2011 Promise Neighborhoods NFP). Competitive Preference Priority 1 and Competitive Preference Priority 4 are from the notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 10, 2014 (79 FR 73425) (Supplemental Priorities). Competitive Preference Priority 3 is from the Promise Zones notice of final priority published in the **Federal Register** on March 27, 2014 (79 FR 17035) (2014 Promise Zones NFP) (Promise Zones NFP).

Absolute Priorities: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities.

Note: Applicants must indicate in their application whether they are applying under Absolute Priority 1, Absolute Priority 2, or Absolute Priority 3. If an applicant applies under Absolute Priority 2 or Absolute Priority 3 and is deemed ineligible, it still may be considered for funding under Absolute Priority 1. For applications addressing Absolute Priority 1, Absolute Priority 2, and Absolute Priority 3, the Secretary prepares a rank order of applications for each absolute priority based solely on the evaluation of their quality according to the selection criteria.

Each of the three absolute priorities constitutes its own funding category. Assuming that applications in each

funding category are of sufficient quality, the Secretary intends to award grants under each absolute priority. These priorities are:

Absolute Priority 1—Submission of Promise Neighborhood Plan.

To meet this priority, an applicant must submit a plan to create a Promise Neighborhood. The plan must describe the need in the neighborhood, a strategy to build a continuum of solutions, and the applicant's capacity to achieve results. Specifically, an applicant must—

(1) Describe the geographically defined area (neighborhood) to be served and the level of distress in that area based on indicators of need (as defined in this notice) and other relevant indicators. The statement of need in the neighborhood must be based, in part, on results of a comprehensive needs assessment and segmentation analysis (as defined in this notice). Applicants may propose to serve multiple, non-contiguous geographically defined areas. In cases where target areas are not contiguous, the applicant must explain its rationale for including non-contiguous areas;

(2) Describe the applicant's strategy for building a continuum of solutions over time that addresses neighborhood challenges as identified in the needs assessment and segmentation analysis. The applicant must also describe how it has built community support for and involvement in the development of the plan. The continuum of solutions must be based on best available evidence including, where available strong or moderate evidence (as defined in this notice), and be designed to significantly improve educational outcomes and to support the healthy development and well-being of children and youth in the neighborhood. The strategy must be designed to ensure that over time, a greater proportion of children and youth in the neighborhood who attend the target school or schools have access to a complete continuum of solutions, and must ensure that over time, a greater proportion of children and youth in the neighborhood who do not attend the target school or schools have access to solutions within the continuum of solutions. The strategy must also ensure that, over time, students not living in the neighborhood who attend the target school or schools have access to solutions within the continuum of solutions.

The success of the applicant's strategy to build a continuum of solutions will be based on the results of the project, as measured against the project indicators as defined in this notice and described in Table 1 and Table 2. In its strategy,

the applicant must propose clear and measurable annual goals during the grant period against which improvements will be measured using the indicators. The strategy must—

(a) Identify each solution that the project will implement within the proposed continuum of solutions, and must include—

(i) High-quality early learning programs and services designed to improve outcomes across multiple domains of early learning (as defined in this notice) for children from birth through third grade;

(ii) Ambitious, rigorous, and comprehensive education reforms that are linked to improved educational outcomes for children and youth in preschool through the 12th grade. Public schools served through the grant may include persistently lowest-achieving schools (as defined in this notice) or low-performing schools (as defined in this notice) that are not also persistently lowest-achieving schools. An applicant (or one or more of its partners) may serve an effective school or schools (as defined in this notice) but only if the applicant (or one or more of its partners) also serves at least one low-performing school (as defined in this notice) or persistently lowest-achieving school (as defined in this notice). An applicant must identify in its application the public school or schools it would serve and describe the current status of reforms in the school or schools, including, if applicable, the type of intervention model being implemented. In cases where an applicant operates a school or partners with a school that does not serve all students in the neighborhood, the applicant must partner with at least one additional school that also serves students in the neighborhood. An applicant proposing to work with a persistently lowest-achieving school must include in its strategy one of the four school intervention models (turnaround model, restart model, school closure, or transformation model) described in Appendix C of the Race to the Top (RTT) notice inviting applications for new awards for FY 2010 that was published in the **Federal Register** on November 18, 2009 (74 FR 59836, 59866).

An applicant proposing to work with a or low-performing school must include in its strategy ambitious, rigorous, and comprehensive interventions to assist, augment, or replace schools, which may include implementing one of the four school intervention models, or may include another model of sufficient ambition, rigor, and comprehensiveness to

significantly improve academic and other outcomes for students. An applicant proposing to work with a low-performing school must include in its strategy an intervention that addresses the effectiveness of teachers and leaders and the school's use of time and resources, which may include increased learning time (as defined in this notice);

Note regarding school reform strategies: So as not to penalize an applicant for proposing to work with an LEA that has implemented rigorous reform strategies prior to the publication of this notice, an applicant is not required to propose a new reform strategy in place of an existing reform strategy in order to be eligible for a Promise Neighborhoods implementation grant. For example, an LEA might have begun to implement improvement activities that meet many, but not all, of the elements of a transformation model of school intervention. In this case, the applicant could propose, as part of its Promise Neighborhood strategy, to work with the LEA as the LEA continues with its reforms.

(iii) Programs that prepare students to be college- and career-ready; and

(iv) Family and community supports (as defined in this notice).

To the extent feasible and appropriate, the applicant must describe, in its plan, how the applicant and its partners will leverage and integrate high-quality programs, related public and private investments, and existing neighborhood assets into the continuum of solutions. An applicant must also include in its application an appendix that summarizes the evidence supporting each proposed solution and describes how the solution is based on the best available evidence, including, where available, strong or moderate evidence (as defined in this notice). An applicant must also describe in the appendix how and when—during the implementation process—the solution will be implemented; the partners that will participate in the implementation of each solution (in any case in which the applicant does not implement the solution directly); the estimated per-child cost, including administrative

costs, to implement each solution; the estimated number of children, by age, in the neighborhood who will be served by each solution and how a segmentation analysis was used to target the children and youth to be served; and the source of funds that will be used to pay for each solution. In the description of the estimated number of children to be served, the applicant must include the percentage of all children of the same age group within the neighborhood proposed to be served with each solution, and the annual goals required to increase the proportion of children served to reach scale over time.

An applicant must also describe in its plan how it will identify Federal, State, or local policies, regulations, or other requirements that would impede its ability to achieve its goals and how it will report on those impediments to the Department and other relevant agencies.

As appropriate, considering the time and urgency required to dramatically improve outcomes of children and youth in our most distressed neighborhoods and to transform those neighborhoods, applicants must establish both short-term and long-term goals to measure progress.

As part of the description of its strategy to build a continuum of solutions, the applicant must also describe how it will participate in, organize, or facilitate, as appropriate, communities of practice for Promise Neighborhoods;

(b) Establish clear, annual goals for evaluating progress in improving systems, such as changes in policies, environments, or organizations that affect children and youth in the neighborhood. Examples of systems change could include a new school district policy to measure the results of family and community support programs, a new funding resource to support the Promise Neighborhoods strategy, or a cross-sector collaboration at the city level to break down municipal agency “silos” and partner with local philanthropic organizations to drive achievement of a set of results; and

(c) Establish clear, annual goals for evaluating progress in leveraging

resources, such as the amount of monetary or in-kind investments from public or private organizations to support the Promise Neighborhoods strategy. Examples of leveraging resources are securing new or existing dollars to sustain and scale up what works in the Promise Neighborhood or integrating high-quality programs in the continuum of solutions. Applicants may consider, as part of their plans to scale up their Promise Neighborhood strategy, serving a larger geographic area by partnering with other applicants to the Promise Neighborhoods program from the same city or region;

(3) Explain how it used its needs assessment and segmentation analysis to determine the children with the highest needs and explain how it will ensure that children in the neighborhood receive the appropriate services from the continuum of solutions. In this explanation of how it used the needs assessment and segmentation analysis, the applicant must identify and describe in its application the educational indicators and family and community support indicators that the applicant used to conduct the needs assessment. Whether or not the implementation grant applicant received a Promise Neighborhoods planning grant, the applicant must describe how it—

(a) Collected data for the educational indicators listed in Table 1 and used them as both program and project indicators;

(b) Collected data for the family and community support indicators in Table 2 and used them as program indicators; and

(c) Collected data for unique family and community support indicators, developed by the applicant, that align with the goals and objectives of the project and used them as project indicators or used the indicators in Table 2 as project indicators.

An applicant must also describe how it will collect at least annual data on the indicators in Tables 1 and 2; establish clear, annual goals for growth on indicators; and report those data to the Department.

TABLE 1—EDUCATION INDICATORS AND RESULTS THEY ARE INTENDED TO MEASURE

Indicator	Result
—Number and percentage of children from birth to kindergarten entry who have a place where they usually go, other than an emergency room, when they are sick or in need of advice about their health.	Children enter kindergarten ready to succeed in school.

TABLE 1—EDUCATION INDICATORS AND RESULTS THEY ARE INTENDED TO MEASURE—Continued

Indicator	Result
—Number and percentage of three-year-olds and children in kindergarten who demonstrate at the beginning of the program or school year age-appropriate functioning across multiple domains of early learning (as defined in this notice) as determined using developmentally appropriate early learning measures (as defined in this notice).	
—Number and percentage of children, from birth to kindergarten entry, participating in center-based or formal home-based early learning settings or programs, which may include Early Head Start, Head Start, child care, or preschool.	
—Number and percentage of students at or above grade level according to State mathematics and reading or language arts assessments in at least the grades required by the ESEA (3rd through 8th and once in high school).	Students are proficient in core academic subjects.
—Attendance rate of students in 6th, 7th, 8th, and 9th grade	Students successfully transition from middle school grades to high school.
—Graduation rate (as defined in this notice)	Youth graduate from high school.
—Number and percentage of Promise Neighborhood students who graduate with a regular high school diploma, as defined in 34 CFR 200.19(b)(1)(iv), and obtain postsecondary degrees, vocational certificates, or other industry-recognized certifications or credentials without the need for remediation.	High school graduates obtain a postsecondary degree, certification, or credential.

TABLE 2—FAMILY AND COMMUNITY SUPPORT INDICATORS AND RESULTS THEY ARE INTENDED TO MEASURE

Indicator	Result
—Number and percentage of children who participate in at least 60 minutes of moderate to vigorous physical activity daily; and —Number and percentage of children who consume five or more servings of fruits and vegetables daily; or —possible third indicator, to be determined (TBD) by applicant.	Students are healthy.
—Number and percentage of students who feel safe at school and traveling to and from school, as measured by a school climate needs assessment (as defined in this notice); or —possible second indicator, TBD by applicant.	Students feel safe at school and in their community.
—Student mobility rate (as defined in this notice); or —possible second indicator, TBD by applicant.	Students live in stable communities.
—For children from birth to kindergarten entry, the number and percentage of parents or family members who report that they read to their child three or more times a week; —For children in the kindergarten through eighth grades, the number and percentage of parents or family members who report encouraging their child to read books outside of school; and —For children in the ninth through twelfth grades, the number and percentage of parents or family members who report talking with their child about the importance of college and career; or —possible fourth indicator TBD by applicant.	Families and community members support learning in Promise Neighborhood schools.
—Number and percentage of students who have school and home access (and percentage of the day they have access) to broadband internet (as defined in this notice) and a connected computing device; or —possible second indicator TBD by applicant.	Students have access to 21st century learning tools.

Note: The indicators in Tables 1 and 2 are not intended to limit an applicant from collecting and using data for additional indicators. Examples of additional indicators are—

(i) The number and percentage of children who participate in high-quality learning activities during out-of-school hours or in the hours after the traditional school day ends;

(ii) The number and percentage of students who are suspended or receive discipline referrals during the year;

(iii) The share of housing stock in the geographically defined area that is rent-protected, publicly assisted, or targeted for redevelopment with local, State, or Federal funds; and

(iv) The number and percentage of children who are homeless or in foster care and who have an assigned adult advocate.

Note: While the Department believes there are many programmatic benefits of collecting data on every child in the proposed neighborhood, the Department

will consider requests to collect data on only a sample of the children in the neighborhood for some indicators so long as the applicant describes in its application how it would ensure the sample would be representative of the children in the neighborhood.

(4) Describe the experience and lessons learned, and describe how the applicant will build the capacity of its management team and project director in all of the following areas:

(a) Working with the neighborhood and its residents, including parents and families that have children or other members with disabilities or ELs, as well as with the schools described in paragraph (2) of this priority; the LEA in which the school or schools are located; Federal, State, and local government leaders; and other service providers.

(b) Collecting, analyzing, and using data for decision-making, learning, continuous improvement, and accountability. The applicant must describe—

(i) Progress towards developing, launching, and implementing a longitudinal data system that integrates student-level data from multiple sources in order to measure progress on educational and family and community support indicators for all children in the neighborhood, disaggregated by the subgroups listed in section 1111(b)(3)(C)(xiii) of the ESEA;

(ii) How the applicant has linked or made progress to link the longitudinal data system to school-based, LEA, and State data systems; made the data accessible to parents, families, community residents, program partners, researchers, and evaluators while abiding by Federal, State, and other privacy laws and requirements; and managed and maintained the system;

(iii) How the applicant has used rapid-time (as defined in this notice) data in prior years and, how it will continue to use those data once the Promise Neighborhood strategy is implemented, for continuous program improvement; and

(iv) How the applicant will document the implementation process, including by describing lessons learned and best practices.

(c) Creating and strengthening formal and informal partnerships, for such purposes as providing solutions along the continuum of solutions and committing resources to sustaining and scaling up what works. Each applicant must submit, as part of its application, a memorandum of understanding, signed by each organization or agency with which it would partner in implementing the proposed Promise Neighborhood. The memorandum of understanding must describe—

(i) Each partner's financial and programmatic commitment; and

(ii) How each partner's existing vision, theory of change (as defined in this notice), theory of action (as defined in this notice), and current activities align with those of the proposed Promise Neighborhood; and

(d) The governance structure proposed for the Promise Neighborhood, including a system for holding partners

accountable, how the eligible entity's governing board or advisory board is representative of the geographic area proposed to be served (as defined in this notice), and how residents of the geographic area would have an active role in the organization's decision-making.

(e) Integrating funding streams from multiple public and private sources from the Federal, State, and local level. Examples of public funds include Federal resources from the U.S. Department of Education, such as the 21st Century Community Learning Centers program and title I of the ESEA, and from other Federal agencies, such as the U.S. Departments of Health and Human Services, Housing and Urban Development, Justice, Labor, and Treasury.

(5) Describe the applicant's commitment to work with the Department, and with a national evaluator for Promise Neighborhoods or another entity designated by the Department, to ensure that data collection and program design are consistent with plans to conduct a rigorous national evaluation of the Promise Neighborhoods program and of specific solutions and strategies pursued by individual grantees. This commitment must include, but need not be limited to—

(a) Ensuring that, through memoranda of understanding with appropriate entities, the national evaluator and the Department have access to relevant program and project data sources (e.g., administrative data and program and project indicator data), including data on a quarterly basis if requested by the Department;

(b) Developing, in consultation with the national evaluator, an evaluation strategy, including identifying a credible comparison group (as defined in this notice); and

(c) Developing, in consultation with the national evaluator, a plan for identifying and collecting reliable and valid baseline data for both program participants and a designated comparison group of non-participants.

Absolute Priority 2—Promise Neighborhoods in Rural Communities.

To meet this priority, an applicant must propose to implement a Promise Neighborhood strategy that (1) meets all of the requirements in Absolute Priority 1; and (2) serves one or more rural communities only.

Absolute Priority 3—Promise Neighborhoods in Tribal Communities.

To meet this priority, an applicant must propose to implement a Promise Neighborhood strategy that (1) meets all of the requirements in Absolute Priority

1; and (2) serves one or more Indian tribes (as defined in this notice).

Competitive Preference Priorities: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award two additional points to applications that meet Competitive Preference Priority 1, two additional points for applications that meet Competitive Preference Priority 2, two additional points for applications that meet Competitive Preference Priority 3, and two additional points for applications that meet Competitive Preference Priority 4. Applicants may address more than one of the competitive preference priorities. Therefore, an applicant must identify in the project narrative section of its application the priority or priorities it wishes the Department to consider for purposes of earning the competitive preference priority points.

Note: The Department will not review or award points under any competitive preference priority for an application that fails to clearly identify the competitive preference priority or priorities it wishes the Department to consider for purposes of earning the competitive preference priority points.

These priorities are:

Competitive Preference Priority 1—Improving Early Learning Development and Outcomes (0 or 2 points).

Projects that are designed to improve early learning and development outcomes across one or more of the essential domains of school readiness (as defined in this notice) for children from birth through third grade (or for any age group within this range) through a focus on improving the coordination and alignment among early learning and development systems and between such systems and elementary education systems, including coordination and alignment in engaging and supporting families and improving transitions for children along the birth-through-third grade continuum, in accordance with applicable privacy laws.

Competitive Preference Priority 2—Quality Affordable Housing (0 or 2 points).

To meet this priority, an applicant must propose to serve geographic areas that were the subject of an affordable housing transformation pursuant to a Choice Neighborhoods or HOPE VI grant awarded by the U.S. Department of Housing and Urban Development during FY 2009 or later years. To be eligible under this priority, the applicant must either: (1) Be able to demonstrate that it

has received a Choice Neighborhoods or HOPE VI grant; or (2) provide, in its application, a memorandum of understanding between it and a partner that is a recipient of a Choice Neighborhoods or HOPE VI grant. The memorandum must indicate a commitment on the part of the applicant and partner to coordinate implementation and align resources to the greatest extent practicable.

Competitive Preference Priority 3—Promise Zones (0 or 2 points).

This priority is for projects that are designed to serve and coordinate with a federally designated Promise Zone.

Note: As a participant in the Administration's Promise Zone Initiative, the Department is cooperating with the Departments of Housing and Urban Development, the Department of Agriculture (USDA), and nine other Federal agencies to support comprehensive revitalization efforts in 20 high-poverty urban, rural, and tribal communities across the country. Each application for Promise Neighborhoods funds that is accompanied by a Certification of Consistency with Promise Zone Goals and Implementation (HUD Form 50153) signed by an authorized representative of the lead organization of a Promise Zone designated by HUD or USDA supporting the application will receive two point. An application for Promise Neighborhoods grant funds that is not accompanied by a signed certification (HUD Form 50153) will receive zero points. To view the list of designated Promise Zones and lead organizations please go to www.hud.gov/promisezones. The certification form is available at portal.hud.gov/hudportal/documents/huddoc?id=HUD_Form_50153.pdf.

Competitive Preference Priority 4—High School and Transition to College (0 or 2 points).

Increasing the number and proportion of high-need students (as defined in this notice) who are academically prepared for, enroll in, or complete on time college, other postsecondary education, or other career and technical education.

Definitions

The definitions of “large sample,” “logic model,” “multi-site sample,” “moderate evidence of effectiveness,” “relevant outcomes,” “strong theory,” and “What Works Clearinghouse (WWC) Evidence Standards” are from 34 CFR 77.1. The definitions of “essential domains of school readiness,” “high-minority school,” “high-need students,” and “regular high school diploma” are from the Supplemental Priorities. All other definitions are from the 2011

Promise Neighborhoods NFP. We may apply these definitions in any year in which this program is in effect.

The following definitions apply to this program:

Children with disabilities or *CWD* means individuals who meet the definition of child with a disability in 34 CFR 300.8, infant or toddler with a disability in 34 CFR 300.25, handicapped person in 34 CFR 104.3(j), or disability as it pertains to an individual in 42 U.S.C. 12102.

Community of practice means a group of grantees that agrees to interact regularly to solve a persistent problem or improve practice in an area that is important to them and the success of their projects. Establishment of communities of practice under Promise Neighborhoods will enable grantees to meet, discuss, and collaborate with each other regarding grantee projects.

Continuum of cradle-through-college-to-career solutions or *continuum of solutions* means solutions that—

- (1) Include programs, policies, practices, services, systems, and supports that result in improving educational and developmental outcomes for children from cradle through college to career;
- (2) Are based on the best available evidence, including, where available, strong or moderate evidence (as defined in this notice);
- (3) Are linked and integrated seamlessly (as defined in this notice); and
- (4) Include both education programs and family and community supports.

Credible comparison group includes a comparison group formed by matching project participants with non-participants based on key characteristics that are thought to be related to outcomes. These characteristics include, but are not limited to: (1) Prior test scores and other measures of academic achievement (preferably the same measures that will be used to assess the outcomes of the project); (2) demographic characteristics, such as age, disability, gender, English proficiency, ethnicity, poverty level, parents' educational attainment, and single- or two-parent family background; (3) the time period in which the two groups are studied (*e.g.*, the two groups are children entering kindergarten in the same year as opposed to sequential years); and (4) methods used to collect outcome data (*e.g.*, the same test of reading skills administered in the same way to both groups).

Developmentally appropriate early learning measures means a range of assessment instruments that are used in

ways consistent with the purposes for which they were designed and validated; appropriate for the ages and other characteristics of the children being assessed; designed and validated for use with children whose ages, cultures, languages spoken at home, socioeconomic status, abilities and disabilities, and other characteristics are similar to those of the children with whom the assessments will be used; used in conformance with the recommendations of the National Research Council reports on early childhood;⁷ and used in compliance with the measurement standards set forth by the American Educational Research Association (AERA), the American Psychological Association (APA), and the National Council for Measurement in Education (NCME) in the 1999 Standards for Educational and Psychological Testing.

Education programs means programs that include, but are not limited to—

- (1) High-quality early learning programs or services designed to improve outcomes across multiple domains of early learning for young children. Such programs must be specifically intended to align with appropriate State early learning and development standards, practices, strategies, or activities across as broad an age range as birth through third grade so as to ensure that young children enter kindergarten and progress through the early elementary school grades demonstrating age-appropriate functioning across the multiple domains;
- (2) For children in preschool through the 12th grade, programs, inclusive of related policies and personnel, that are linked to improved educational outcomes. The programs—
 - (a) Must include effective teachers and effective principals;
 - (b) Must include strategies, practices, or programs that encourage and facilitate the evaluation, analysis, and use of student achievement, student growth (as defined in this notice), and other data by educators, families, and other stakeholders to inform decision-making;
 - (c) Must include college- and career-ready standards, assessments, and practices, including a well-rounded

⁷ One example of these reports is referenced here. National Research Council (2008). *Early Childhood Assessment: Why, What, and How*. Committee on Developmental Outcomes and Assessments for Young Children, C.E. Snow and S.B. Van Hemel, Editors. Board on Children, Youth, and Families, Board on Testing and Assessment, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Available at: www.nap.edu/catalog.php?record_id=12446.

curriculum, instructional practices, strategies, or programs in, at a minimum, core academic subjects as defined in section 9101(11) of the ESEA, that are aligned with high academic content and achievement standards and with high-quality assessments based on those standards; and

(d) May include creating multiple pathways for students to earn regular high school diplomas (e.g., using schools that serve the needs of over-aged, under-credited, or other students with an exceptional need for flexibility regarding when they attend school or the additional supports they require; awarding credit based on demonstrated evidence of student competency; or offering dual-enrollment options); and

(3) Programs that prepare students for college and career success, which may include programs that—

(a) Create and support partnerships with community colleges, four-year colleges, or universities and that help instill a college-going culture in the neighborhood;

(b) Provide dual-enrollment opportunities for secondary students to gain college credit while in high school;

(c) Provide, through relationships with businesses and other organizations, apprenticeship opportunities to students;

(d) Align curricula in the core academic subjects with requirements for industry-recognized certifications or credentials, particularly in high-growth sectors;

(e) Provide access to career and technical education programs so that individuals can attain the skills and industry-recognized certifications or credentials for success in their careers;

(f) Help college students, including CWD and ELs from the neighborhood to transition to college, persist in their academic studies in college, graduate from college, and transition into the workforce; and

(g) Provide opportunities for all youth (both in and out of school) to achieve academic and employment success by improving educational and skill competencies and providing connections to employers. Such activities may include opportunities for on-going mentoring, supportive services, incentives for recognition and achievement, and opportunities related to leadership, development, decision-making, citizenship, and community service.

Effective school means a school that has—

(1) Significantly closed the achievement gaps between subgroups of students (as identified in section

1111(b)(3)(C)(xiii) of the ESEA) within the school or district; or

(2)(a) Demonstrated success in significantly increasing student academic achievement in the school for all subgroups of students (as identified in section 1111(b)(3)(C)(xiii) of the ESEA) in the school; and (b) made significant improvements in other areas, such as graduation rates (as defined in this notice) or recruitment and placement of effective teachers and effective principals.

Eligible organization means an organization that:

(1) Is representative of the geographic area proposed to be served;

(2) Is one of the following:

(a) A nonprofit organization that meets the definition of a nonprofit under 34 CFR 77.1(c), which may include a faith-based nonprofit organization.

(b) An institution of higher education as defined by section 101(a) of the Higher Education Act of 1965, as amended.

(c) An Indian tribe (as defined in this notice);

(3) Currently provides at least one of the solutions from the applicant's proposed continuum of solutions in the geographic area proposed to be served; and

(4) Operates or proposes to work with and involve in carrying out its proposed project, in coordination with the school's LEA, at least one public elementary or secondary school that is located within the identified geographic area that the grant will serve.

English learners or *ELs* means individuals who meet the definition of limited English proficient, as defined in section 9101(25) of the ESEA.

Essential domains of school readiness means the domains of language and literacy development, cognition and general knowledge (including early mathematics and early scientific development), approaches toward learning (including the utilization of the arts), physical well-being and motor development (including adaptive skills), and social and emotional development.

Family and community supports means:

(1) Child and youth health programs, such as physical, mental, behavioral, and emotional health programs (e.g., home visiting programs; Early Head Start; programs to improve nutrition and fitness, reduce childhood obesity, and create healthier communities);

(2) Safety programs, such as programs in school and out of school to prevent, control, and reduce crime, violence, drug and alcohol use, and gang activity; programs that address classroom and

school-wide behavior and conduct; programs to prevent child abuse and neglect; programs to prevent truancy and reduce and prevent bullying and harassment; and programs to improve the physical and emotional security of the school setting as perceived, experienced, and created by students, staff, and families;

(3) Community stability programs, such as programs that—

(a) Increase the stability of families in communities by expanding access to quality, affordable housing, providing legal support to help families secure clear legal title to their homes, and providing housing counseling or housing placement services;

(b) Provide adult education and employment opportunities and training to improve educational levels, job skills and readiness in order to decrease unemployment, with a goal of increasing family stability;

(c) Improve families' awareness of, access to, and use of a range of social services, if possible at a single location;

(d) Provide unbiased, outcome-focused, and comprehensive financial education, inside and outside the classroom and at every life stage;

(e) Increase access to traditional financial institutions (e.g., banks and credit unions) rather than alternative financial institutions (e.g., check cashers and payday lenders);

(f) Help families increase their financial literacy, financial assets, and savings; and

(g) Help families access transportation to education and employment opportunities;

(4) Family and community engagement programs that are systemic, integrated, sustainable, and continue through a student's transition from K–12 school to college and career. These programs may include family literacy programs and programs that provide adult education and training and opportunities for family members and other members of the community to support student learning and establish high expectations for student educational achievement; mentorship programs that create positive relationships between children and adults; programs that provide for the use of such community resources as libraries, museums, television and radio stations, and local businesses to support improved student educational outcomes; programs that support the engagement of families in early learning programs and services; programs that provide guidance on how to navigate through a complex school system and how to advocate for more and improved learning opportunities; and programs

that promote collaboration with educators and community organizations to improve opportunities for healthy development and learning; and

(5) 21st century learning tools, such as technology (e.g., computers and mobile phones) used by students in the classroom and in the community to support their education. This includes programs that help students use the tools to develop knowledge and skills in such areas as reading and writing, mathematics, research, critical thinking, communication, creativity, innovation, and entrepreneurship.

Graduation rate means the four-year or extended-year adjusted cohort graduation rate as defined by 34 CFR 200.19(b)(1).

Note: This definition is not meant to prevent a grantee from also collecting information about the reasons why students do not graduate from the target high school, e.g., dropping out or moving outside of the school district for non-academic or academic reasons.

High-minority school means a school as that term is defined by a local educational agency, which is consistent with its State Teacher Equity Plan, as required by section 1111(b)(8)(c) of the ESEA. The applicant must provide the definition(s) of high-minority schools used in its application.

High-need students means students who are at risk of educational failure or otherwise in need of special assistance and support, such as students who are living in poverty, who attend high-minority schools (as defined in this notice), who are far below grade level, who have left school before receiving a regular high school diploma (as defined in this notice), who are at risk of not graduating with a diploma on time, who are homeless, who are in foster care, who have been incarcerated, who have disabilities, or who are English learners.

Increased learning time means using a longer school day, week, or year to significantly increase the total number of school hours. This strategy is used to redesign the school's program in a manner that includes additional time for (a) instruction in core academic subjects as defined in section 9101(11) of the ESEA; (b) instruction in other subjects and enrichment activities that contribute to a well-rounded education, including, for example, physical education, service learning, and experiential and work-based learning opportunities that are provided by partnering, as appropriate, with other organizations; and (c) teachers to collaborate, plan, and engage in professional development within and across grades and subjects.

Indian tribe means any Indian or Alaska Native tribe, band, nation, pueblo, village or community that the Secretary of the Interior acknowledges to exist as an Indian tribe, 25 U.S.C. 479a and 479a-1 or any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601, *et seq.*, that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. The term "Indian" means a member of an Indian tribe.

Indicators of need means currently available data that describe—

(1) Education need, which means—
(a) All or a portion of the neighborhood includes or is within the attendance zone of a low-performing school that is a high school, especially one in which the graduation rate (as defined in this notice) is less than 60 percent or a school that can be characterized as low-performing based on another proxy indicator, such as students' on-time progression from grade to grade; and
(b) Other indicators, such as significant achievement gaps between subgroups of students (as identified in section 1111(b)(3)(C)(xiii) of the ESEA) within a school or LEA, high teacher and principal turnover, or high student absenteeism; and

(2) Family and community support need, which means—

(a) Percentages of children with preventable chronic health conditions (e.g., asthma, poor nutrition, dental problems, obesity) or avoidable developmental delays;
(b) Immunization rates;
(c) Rates of crime, including violent crime;
(d) Student mobility rates;
(e) Teenage birth rates;
(f) Percentage of children in single-parent or no-parent families;
(g) Rates of vacant or substandard homes, including distressed public and assisted housing; or
(h) Percentage of the residents living at or below the Federal poverty threshold.

Large sample means an analytic sample of 350 or more students (or other single analysis units), or 50 or more groups (such as classrooms or schools) that contain 10 or more students (or other single analysis units).

Linked and integrated seamlessly, with respect to the continuum of solutions, means solutions that have common outcomes, focus on similar milestones, support transitional time periods (e.g., the beginning of kindergarten, the middle grades, or

graduation from high school) along the cradle-through-college-to-career continuum, and address time and resource gaps that create obstacles for students in making academic progress.

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (i.e., the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the relationships among the key components and outcomes, theoretically and operationally.

Low-performing schools means schools receiving assistance through title I of the ESEA, that are in corrective action or restructuring in the State, as determined under section 1116 of the ESEA, and the secondary schools (both middle and high schools) in the State that are equally as low-achieving as these Title I schools and are eligible for, but do not receive Title I funds.

Note: A State that received ESEA flexibility was not required to identify schools in corrective action or restructuring under Section 1116 of the ESEA; rather, the State identified priority and focus schools. Moreover, with the enactment of the ESSA, and State, beginning in the 2017–2018 school year, will no longer identify schools in corrective action or restructuring under section 1116 of the ESEA or identify schools as priority and focus schools under ESEA flexibility. Therefore, consistent with Section 5(c)(2) of the ESSA, ED will allow applicants to consider the following schools as low-performing schools: (1) Elementary and secondary schools identified, at the time of submission of an application under this competition, as in need as in need of corrective action or restructuring under the ESEA, as authorized amended by the NCLB; (2), elementary and secondary schools identified, at the time of submission of an application under this competition, as a priority or focus school by a State under ESEA flexibility; and, (3) secondary (both middle and high schools) in a State that are, at the time of submission of an application under this competition, equally as low-achieving as these Title I schools above and are eligible for, but do not receive, Title I funds.

Moderate evidence means evidence from previous studies with designs that can support causal conclusions (i.e., studies with high internal validity) but have limited generalizability (i.e., moderate external validity) or from studies with high external validity but moderate internal validity.

Neighborhood assets means—

(1) Developmental assets that allow residents to attain the skills needed to be successful in all aspects of daily life (e.g., educational institutions, early learning centers, and health resources);

(2) Commercial assets that are associated with production, employment, transactions, and sales (e.g., labor force and retail establishments);

(3) Recreational assets that create value in a neighborhood beyond work and education (e.g., parks, open space, community gardens, and arts organizations);

(4) Physical assets that are associated with the built environment and physical infrastructure (e.g., housing, commercial buildings, and roads); and

(5) Social assets that establish well-functioning social interactions (e.g., public safety, community engagement, and partnerships with youth, parents, and families).

Persistently lowest-achieving school means, as determined by the State—

(1) Any school receiving assistance through Title I that is in improvement, corrective action, or restructuring and that—

(a) Is among the lowest-achieving five percent of Title I schools or the lowest-achieving five Title I schools in the State, whichever number of schools is greater; or

(b) Is a high school that has had a graduation rate, that is less than 60 percent over a number of years.

Note: The Department will also consider any school a persistently lowest-achieving school that, at the time of submission of an application under this competition, meets the definition of “lowest-performing schools” set out in the Secretary’s Final Supplemental Priorities and Definitions for Discretionary Grant Programs (Supplemental Priorities), 79 FR 73425 (Dec. 10, 2014). The definition of “lowest-performing schools” in the Supplemental Priorities is as follows:

Lowest-performing schools means—

For a State with an approved request for flexibility under the Elementary and Secondary Education Act of 1965, as amended (ESEA), Priority Schools or Tier I and Tier II Schools that have been identified under the School Improvement Grants program. For any other State, Tier I and Tier II Schools that have been identified under the School Improvement Grants program. 79 FR 73425, 73454 (Dec. 10, 2014).

We are providing this flexibility because a State that received ESEA flexibility was not required to identify schools in corrective action or restructuring under the ESEA; but

rather, the State identified priority and focus schools. Moreover, consistent with final regulations issued under the School Improvement Grants program (80 FR 7223), the definition of Tier I and Tier II Schools includes persistently lowest-achieving schools.

Program indicators are indicators that the Department will use only for research and evaluation purposes and for which an applicant is not required to propose solutions.

Project indicators are indicators for which an applicant proposes solutions intended to result in progress on the indicators.

Public officials means elected officials (e.g., council members, aldermen and women, commissioners, State legislators, Congressional representatives, members of the school board), appointed officials (e.g., members of a planning or zoning commission, or of any other regulatory or advisory board or commission), or individuals who are not necessarily public officials, but who have been appointed by a public official to serve on the Promise Neighborhoods governing board or advisory board.

Rapid-time, in reference to reporting and availability of locally-collected data, means that data are available quickly enough to inform current lessons, instruction, and related education programs and family and community supports.

Regular high school diploma means the standard high school diploma that is awarded to students in the State and that is fully aligned with the State’s academic content standards or a higher diploma and does not include a General Education Development credential, certificate of attendance, or any alternative award.

Relevant outcome means the student outcome(s) (or the ultimate outcome if not related to students) the proposed process, product, strategy, or practice is designed to improve; consistent with the specific goals of a program.

Representative of the geographic area proposed to be served means that residents of the geographic area proposed to be served have an active role in decision-making and that at least one-third of the eligible entity’s governing board or advisory board is made up of—

(1) Residents who live in the geographic area proposed to be served, which may include residents who are representative of the ethnic and racial composition of the neighborhood’s residents and the languages they speak;

(2) Residents of the city or county in which the neighborhood is located but who live outside the geographic area

proposed to be served, and who are low-income (which means earning less than 80 percent of the area’s median income as published by the Department of Housing and Urban Development);

(3) Public officials (as defined in this notice) who serve the geographic area proposed to be served (although not more than one-half of the governing board or advisory board may be made up of public officials); or

(4) Some combination of individuals from the three groups listed in paragraphs (1), (2), and (3) of this definition.

Rural community means a neighborhood that—

(1) Is served by an LEA that is currently eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title VI, Part B of the ESEA. Applicants may determine whether a particular LEA is eligible for these programs by referring to information on the following Department Web sites. For the SRSA program: <http://www2.ed.gov/programs/reapsrsa/eligible10/index.html>. For the RLIS program: <http://www2.ed.gov/programs/reaprlisp/eligible10/index.html>; or

(2) Includes only schools designated with a school locale code of 42 or 43. Applicants may determine school locale codes by referring to the following Department Web site: <http://nces.ed.gov/ccd/schoolsearch/>.

School climate needs assessment means an evaluation tool that measures the extent to which the school setting promotes or inhibits academic performance by collecting perception data from individuals, which could include students, staff, or families.

Segmentation analysis means the process of grouping and analyzing data from children and families in the geographic area proposed to be served according to indicators of need (as defined in this notice) or other relevant indicators.

Note: The analysis is intended to allow grantees to differentiate and more effectively target interventions based on what they learn about the needs of different populations in the geographic area.

Strong evidence means evidence from studies with designs that can support causal conclusions (i.e., studies with high internal validity), and studies that in total, include enough of the range of participants and settings to support scaling up to the State, regional, or national level (i.e., studies with high external validity).

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model.

Student achievement means—

(1) For tested grades and subjects:

(a) A student's score on the State's assessments under the ESEA; and, as appropriate,

(b) Other measures of student learning, such as those described in paragraph (2) of this definition, provided they are rigorous and comparable across classrooms and programs.

(2) For non-tested grades and subjects: alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across classrooms.

Student growth means the change in achievement data for an individual student between two or more points in time. Growth may also include other measures that are rigorous and comparable across classrooms.

Student mobility rate is calculated by dividing the total number of new student entries and withdrawals at a school, from the day after the first official enrollment number is collected through the end of the academic year, by the first official enrollment number of the academic year.

Note: This definition is not meant to limit a grantee from also collecting information about why students enter or withdraw from the school, e.g., transferring to charter schools, moving outside of the school district for non-academic or academic reasons.

Theory of action means an organization's strategy regarding how, considering its capacity and resources, it will take the necessary steps and measures to accomplish its desired results.

Theory of change means an organization's beliefs about how its inputs, and early and intermediate outcomes, relate to accomplishing its long-term desired results.

Program Authority: 20 U.S.C. 7243–7243b.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79 81, 82, 84, 86, 97, 98, and 99. (b) The OMB Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative

Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2011 Promise Neighborhoods NFP. (e) The 2014 Promise Zones NFP. (f) The Supplemental Priorities.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: \$29,800,000.

These estimated available funds are only for Implementation grants under the Promise Neighborhoods program. Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY2017 from the list of unfunded applications from this competition.

Estimated Range of Awards: \$4,000,000 to \$6,000,000.

Estimated Average Size of Awards: \$5,000,000.

Maximum Award: \$6,000,000.

The maximum award amount is \$6,000,000 per 12-month budget period. We will not fund an annual budget exceeding \$6,000,000 per 12-month budget period.

Estimated Number of Awards: 3–5.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* An applicant must be an eligible organization (as defined in this notice). For purposes of *Absolute Priority 3—Promise Neighborhoods in Tribal Communities*, an eligible applicant is an eligible organization that partners with an Indian tribe or is an Indian tribe that meets the definition of an eligible organization.

2. *Cost-Sharing or Matching:* To be eligible for a grant under this competition, an applicant must demonstrate that it has established a commitment from one or more entities in the public or private sector, which may include Federal, State, and local public agencies, philanthropic organizations, private businesses, or individuals, to provide matching funds for the implementation process. An applicant for an implementation grant must obtain matching funds or in-kind donations equal to at least 100 percent of its grant award, except that an applicant proposing a project that meets

Absolute Priority 2—Promise Neighborhoods in Rural Communities or *Absolute Priority 3—Promise Neighborhoods in Tribal Communities* must obtain matching funds or in-kind donations equal to at least 50 percent of the grant award.

Eligible sources of matching include sources of funds used to pay for solutions within the continuum of solutions, such as Head Start programs, initiatives supported by the LEA, or public health services for children in the neighborhood. At least 10 percent of an implementation applicant's total match must be cash or in-kind contributions from the private sector, which may include philanthropic organizations, private businesses, or individuals.

Implementation applicants must demonstrate a commitment of matching funds in the applications. The applicants must specify the source of the funds or contributions and in the case of a third-party in-kind contribution, a description of how the value was determined for the donated or contributed goods or service. Applicants must demonstrate the match commitment by including letters in their applications explaining the type and quantity of the match commitment with original signatures from the executives of organizations or agencies providing the match. The Secretary may consider decreasing the matching requirement in the most exceptional circumstances, on a case-by-case basis.

An applicant that is unable to meet the matching requirement must include in its application a request to the Secretary to reduce the matching requirement, including the amount of the requested reduction, the total remaining match contribution, and a statement of the basis for the request. An applicant should review the Department's cost-sharing and cost-matching regulations, which include specific limitations, in 2 CFR 200.306 and the cost principles regarding donations, capital assets, depreciations and allowable costs, set out in subpart E of 2 CFR part 200.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office.

To obtain a copy via the Internet, use the following address: www.ed.gov/fund/grant/apply/grantapps/.

To obtain a copy from ED Pubs, write, fax, or call the following: Education Publications Center, P.O. Box 22207,

Alexandria, VA 22304. Telephone, toll free: 1-877-433-7827. FAX: (703) 605-6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1-877-576-7734.

You can contact ED Pubs at its Web site, also: www.EdPubs.gov or at its email address: edpubs@inet.ed.gov.

If you request an application from ED Pubs, be sure to identify this program as follows: CFDA number 84.215N. To obtain a copy from the program office, contact: Adrienne Hawkins, U.S.

Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202-5970.

Telephone: (202) 453-5638 or by email: PromiseNeighborhoods@ed.gov. If you use a TDD or TTY, call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2.a. Content and Form of Application Submission: Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Notice of Intent to Apply: July 25, 2016.

The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department of the applicant's intent to submit an application for funding by completing a Web-based form. When completing this form, applicants will provide (1) the applicant organization's name and address, and (2) information on the competitive preference priority or priorities under which the applicant intends to apply. Applicants may access this form online at <https://innovation.ed.gov/what-we-do/parental-options/promise-neighborhoods-pn/>. Applicants that do not complete this form may still apply for funding. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You are strongly encouraged to limit the application narrative to no more than 75 pages, using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.

- Double space (no more than three lines per vertical inch) all text in the application narrative. Text in charts, tables, figures, and graphs may be single-spaced.

- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

- Use one of the following fonts is strongly encouraged: Times New Roman, Courier, Courier New, or Arial.

- Include page numbers at the bottom of each page in your application narrative.

The suggested page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section.

2.b. Submission of Proprietary Information: Given the types of projects that may be proposed in applications for the Promise Neighborhoods program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define "business information" and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under "Other Attachments Form," please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. Submission Dates and Times: Applications Available: July 8, 2016. Deadline for Notice of Intent to Apply: July 25, 2016.

Date of Pre-Application Webinar: Promise Neighborhoods intends to hold Pre-Application Webinars to provide technical assistance to interested applicants. Detailed information regarding Pre-Application Webinar times will be provided on the Web site at <https://innovation.ed.gov/what-we-do/parental-options/promise-neighborhoods-pn/>.

Deadline for Transmittal of Applications: September 6, 2016. Applications for grants under this

competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements. Please note, due to a scheduled systems shutdown, applicants will not be able to submit applications for the Promise Neighborhoods competition between 9:00 p.m. on Wednesday, July 20, 2016 until 6:00 a.m. on Monday, July 25, 2016 and from 9:00 p.m. on Wednesday, July 27, 2016 until 6:00 a.m. on Monday, August 1, 2016.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: October 26, 2016.

4. Intergovernmental Review: This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. Funding Restrictions: We specify unallowable costs in 34 CFR 280.41. We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management: To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contract Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: <http://fedgov.dnb.com/webform>. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter in to the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at www.SAM.gov. To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a *SAM.gov* Tip Sheet, which you can find at: <http://www2.ed.gov/fund/grant/apply/sam-faqs.html>.

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: www.grants.gov/web/grants/register.html.

7. Other Submission Requirements: Applications for grants under Promise Neighborhoods must be submitted electronically unless you qualify for an exception to this requirement in

accordance with the instructions in this section.

a. Electronic Submission of Applications.

Applications for grants under Promise Neighborhoods, CFDA number 84.215N, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at www.Grants.gov. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the Promise Neighborhoods program at www.Grants.gov. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.215, not 84.215N).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.

- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for Promise Neighborhoods to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at www.G5.gov. In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: www.grants.gov/web/grants/applicants/apply-for-grants.html.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (e.g., Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.

- Your electronic application must comply with any page limit requirements described in this notice.

• After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number.

This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the *Grants.gov* System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1-800-518-4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202-5970. FAX: (202) 453-5638.

Your paper application must be submitted in accordance with the mail

or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215N), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.
- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
- (3) A dated shipping label, invoice, or receipt from a commercial carrier.
- (4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.
- (2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215N), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

1. Selection Criteria: The selection criteria are from 34 CFR 75.210 and the 2011 Promise Neighborhood NFP (76 FR 39590). All of the selection criteria are listed in this section and in the application package. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in determining the extent to which an applicant meets the criterion.

Points awarded under these selection criteria are in addition to any points an applicant earns under the competitive preference priorities in this notice. The maximum score that an application may receive under the competitive preference priorities and the selection criteria is 108 points.

(a) *Need for the Project (15 points).*

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers:

(1) The magnitude or severity of the problems to be addressed by the proposed project as described by indicators of need (as defined in this notice) and other relevant indicators identified in part by the needs assessment and segmentation analysis. (2011 Promise Neighborhoods NFP)

(2) The extent to which the geographically defined area has been described. (2011 Promise Neighborhoods NFP)

(3) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses. (34 CFR 75.210); and

(b) *Quality of Project Design (30 points).*

The Secretary reviews each application to determine the quality of the project design. In determining the

quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the applicant describes an implementation plan to create a complete continuum of solutions, including early learning through grade 12, college- and career-readiness, and family and community supports, without time and resource gaps, that will prepare all children in the neighborhood to attain an excellent education and successfully transition to college and a career, and that will significantly increase the proportion of students in the neighborhood that are served by the complete continuum to reach scale over time (2011 Promise Neighborhoods NFP);

(2) The extent to which the applicant documents that proposed solutions are based on the best available evidence including, where available, strong or moderate evidence (2011 Promise Neighborhoods NFP);

(3) The extent to which the applicant identifies existing neighborhood assets and programs supported by Federal, State, local, and private funds that will be used to implement a continuum of solutions (2011 Promise Neighborhoods NFP);

(4) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible (34 CFR 75.210); and

(5) The extent to which the proposed project is supported by strong theory (as defined in this notice). (34 CFR 75.210)

(c) *Quality of Project Services (20 points).*

The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of the project services, the Secretary considers:

(1) The likelihood that the services to be provided by the proposed project will lead to improvement in the achievement of students as measured against rigorous academic standards. (34 CFR 75.210)

(2) Creating formal and informal partnerships, including the alignment of the visions, theories of action, and theories of change described in its memorandum of understanding, and creating a system for holding partners accountable for performance in accordance with the memorandum of understanding. (2011 Promise Neighborhoods NFP);

(d) *Quality of the Management Plan (20 points).*

The Secretary considers the quality of the management plan for the proposed

project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) Working with the neighborhood and its residents; the schools described in paragraph (2)(b) of Absolute Priority 1; the LEA in which those schools are located; Federal, State, and local government leaders; and other service providers (2011 Promise Neighborhoods NFP).

(2) Collecting, analyzing, and using data for decision-making, learning, continuous improvement, and accountability, including whether the applicant has a plan to build, adapt, or expand a longitudinal data system that integrates student-level data from multiple sources in order to measure progress while abiding by privacy laws and requirements (2011 Promise Neighborhoods NFP); and

(e) *Adequacy of Resources (15 points).*

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers:

(1) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits (34 CFR 75.210).

(2) The extent to which the applicant demonstrates that it has the resources to operate the project beyond the length of the grant, including a multi-year financial and operating model and accompanying plan; the demonstrated commitment of any partners; evidence of broad support from stakeholders (e.g., LEAs, city government, other nonprofits) critical to the project's long-term success; or more than one of these types of evidence (34 CFR 75.210).

2. *Review and Selection Process:* The Department will screen applications submitted in accordance with the requirements in this notice, and will determine which applications have met eligibility and other statutory requirements.

The Department will use independent reviewers from various backgrounds and professions including: Pre-kindergarten-12 teachers and principals, college and university educators, researchers and evaluators, social entrepreneurs, strategy consultants, grant makers and managers, and others with community development and education expertise. The Department will thoroughly screen all reviewers for conflicts of interest to ensure a fair and competitive review process.

Reviewers will read, prepare a written evaluation, and score the applications assigned to their panel, using the

selection criteria provided in this notice.

For applications addressing Absolute Priority 1, Absolute Priority 2, and Absolute Priority 3, the Secretary prepares a rank order of applications for each absolute priority based solely on the evaluation of their quality according to the selection criteria. The Department may use more than one tier of reviews in determining grantees, including possible site visits for Implementation grant applicants. Additional information about the review process will be posted on the Department's Web site.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. Risk Assessment and Special Conditions: Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate

circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. Award Notices: If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Reporting: (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

4. Performance Measures: The Secretary has established the following performance indicator for Promise Neighborhoods: the percentage of implementation grantees that attain or exceed the annual goals that they establish and that are approved by the Secretary for—

- (a) Project indicators;
- (b) Improving systems; and
- (c) Leveraging resources.

All grantees will be required to submit annual performance reports documenting their contribution in assisting the Department in measuring the performance of the program against this indicator as well as other information requested by the Department.

5. Continuation Awards: In making a continuation award, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT:

Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202. Telephone: (202) 453-5638 or by email: PromiseNeighborhoods@ed.gov.

If you use a TDD or TTY, call the FRS, toll free, at 1-800-877-8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal**

Register by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Dated: July 1, 2016.

Nadya Chinoy Dabby,
Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2016-16130 Filed 7-7-16; 8:45 am]

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Federal Register

Vol. 81, No. 131

Friday, July 8, 2016

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World Wide Web

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H.R. 3114/P.L. 114-189

To provide funds to the Army Corps of Engineers to hire

veterans and members of the Armed Forces to assist the Corps with curation and historic preservation activities, and for other purposes. (July 6, 2016; 130 Stat. 613)
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