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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3140; Directorate Identifier 2015–NM–063–AD; Amendment 39–18385; AD 2016–02–05]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model BD–100–1A10 (Challenger 300) airplanes. This AD was prompted by multiple reports of a short circuit between the heater element and the metal sheath of the pitot-static probe heater. This AD requires replacement of the left and right pitot-static probes with newly redesigned left and right pitot-static probes. We are issuing this AD to prevent degradation of the heating ability of the pitot-static probe heater, resulting in erroneous airspeed indication during flight in icing conditions and consequent reduced controllability of the airplane.

DATES: This AD becomes effective March 8, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 8, 2016.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-3140;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* 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–2015–3140.

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model BD–100–1A10 (Challenger 300) airplanes. The NPRM published in the **Federal Register** on July 31, 2015 (80 FR 45617).

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2015–04, dated March 17, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model BD–100–1A10 (Challenger 300) airplanes. The MCAI states:

> There have been several reports where the pitot-static probe heater came on and remained on regardless of the heater control selected position. Investigation determined that the root cause is a short circuit between the heater element and the metal sheath. If not corrected, this condition may degrade the heating, resulting in erroneous Airspeed Indication when flying in icing condition [and consequent reduced controllability of the airplane].
>
> This [Canadian] AD mandates the replacement of the pitot-static probes with a redesigned probe which will prevent this failure mode.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-3140-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 45617, July 31, 2015) or on the determination of the cost to the public.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (80 FR 45617, July 31, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 45617, July 31, 2015).

Related Service Information Under 1 CFR Part 51

Bombardier issued Service Bulletin 100–34–38, dated January 9, 2014. The service information describes procedures for replacement of the left and right pitot-static probes with newly redesigned left and right pitot-static probes, part numbers 0856WC3 and 0856WC4 respectively. 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 126 airplanes of U.S. registry.

We also estimate that it will take about 12 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 about $13,468 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $1,825,488, or $14,488 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.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-3140;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–02–05 Bombardier, Inc.: Amendment 39–18385. Docket No. FAA–2015–3140; Directorate Identifier 2015–NM–063–AD.

(a) Effective Date

This AD becomes effective March 8, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model BD–100–1A10 (Challenger 300) airplanes, certificated in any category, serial numbers 20003 through 20500 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by multiple reports of a short circuit between the heater element and the metal sheath of the pitot-static probe heater. We are issuing this AD to prevent degradation of the heating ability of the pitot-static probe heater, resulting in erroneous airspeed indication during flight in icing conditions and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Replacement of Left and Right Pitot-Static Probes

Within 24 months after the effective date of this AD, replace the left and right pitot-static probes with newly designed pitot-static probes, part numbers (P/N) 0856WC3 and 0856WC4 respectively, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 100–34–38, dated January 9, 2014.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install a pitot-static probe, P/N 0856WC1 or 0856WC2, on any airplane.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

(2) *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, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2015–04, dated March 17, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-3140-0002.*

(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 this AD specifies otherwise.

(i) Bombardier Service Bulletin 100–34–38, dated January 9, 2014.

(ii) Reserved.

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

(4) You may 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 January 20, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–01741 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–2068; Directorate Identifier 2016–SW–002–AD; Amendment 39–18387; AD 2016–02–06]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Bell Helicopter Textron Canada Limited (Bell) Model 429 helicopters. This AD requires inspecting each tail rotor (T/R) pitch link (link) bearing bore for corrosion and pitting and either replacing the T/R link or applying sealant. This AD also requires a recurring inspection of the sealant and repeating the inspections for corrosion and pitting if any sealant is missing. This AD is prompted by an incident in which a helicopter experienced an in-flight failure of a T/R link. These actions are intended to detect corrosion or pitting and to prevent failure of a T/R link and subsequent loss of control of the helicopter.

DATES: This AD becomes effective February 2, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of February 2, 2016.

We must receive comments on this AD by April 4, 2016.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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–2016–2068; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the Transport Canada AD, the incorporated by reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

We are adopting a new AD for Bell Model 429 helicopters with a T/R link part number (P/N) 429–012–112–101, –101FM, –103, or –103FM installed. This AD requires inspecting each T/R link bearing bore for any aluminum oxide corrosion and then cleaning the affected area of the T/R link and inspecting for any pitting. If there is any corrosion or any pitting, this AD requires replacing the T/R link. If there is no corrosion or pitting, this AD requires applying corrosion preventative sealant. This AD also requires a recurring inspection of the sealant, and repeating the inspection for corrosion and pitting if any sealant is missing.

This AD was prompted by AD No. CF–2016–01, dated January 5, 2016, issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition for Bell Model 429 helicopters. Transport Canada advises of an incident in which a T/R link on a Model 429 helicopter failed, causing vibration and difficulty controlling the helicopter. According to Transport Canada, the failure was caused by a crack that had initiated at a corrosion pit between the roll staked lip of the bearing and the beveled edge of the link. Transport Canada further states deficiencies in the application of corrosion resistant finishes to the link during manufacturing caused the corrosion.

This condition, if not detected, could result in failure of a link and loss of control of the helicopter. For these reasons, Transport Canada AD No. CF–2016–01 requires inspection of the T/R link and replacement of any link with corrosion. The Transport Canada AD also requires application of corrosion preventative sealant and re-identification of the T/R link.

FAA's Determination

This helicopter has been approved by the aviation authority of Canada and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in the Canadian AD. We are issuing this AD because we evaluated all information provided by Transport Canada and determined the unsafe condition exists and is likely to exist or

develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

Bell Helicopter issued Alert Service Bulletin 429–15–26, dated December 7, 2015 (ASB), which advises of receiving reports of corrosion on T/R links between the roll staked lip of bearing P/N 429–312–107–103 and the beveled edge of T/R link P/N 429–012–112–101/–103. The ASB specifies, within 10 flight hours or before March 7, 2016, an inspection with 10X magnification of all 8 T/R link bearing bores between the roll staked lip of the bearing outer race and the link bearing bore for corrosion. If there is corrosion, the ASB specifies replacing the link. If there is no corrosion, the ASB specifies cleaning the area and performing a second inspection with 10X magnification. If there is corrosion, the ASB specifies replacing the link. If there is no corrosion, the ASB specifies removing the torque stripe, cleaning the area, and applying corrosion preventative sealant. The ASB also specifies re-identifying the P/Ns as 429–012–112–101FM and 429–012–112–103FM. Further, the ASB specifies, at intervals of 50 flight hours after the initial actions, an inspection of the sealant and reapplication if the sealant is damaged.

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.

AD Requirements

This AD requires, within 10 hours time-in-service (TIS), without first cleaning the T/R link bearing bores, using 10X or higher magnification to inspect each T/R link bearing bore for any aluminum oxide corrosion extruding from between the roll staked lip of the bearing outer race and the link bearing bore. If there is any aluminum oxide corrosion, this AD requires replacing the T/R link before further flight. If there is no corrosion, this AD requires cleaning the T/R link bearing bores and inspecting for any pitting. If there is any pitting, this AD requires replacing the T/R link before further flight. If there is no pitting, this AD requires applying corrosion preventative sealant. Within 50 hours TIS and thereafter at intervals not to exceed 50 hours TIS, this AD requires inspecting the corrosion preventative sealant of each T/R link by using 10X or higher magnification. If the corrosion preventative sealant is missing, this AD requires performing the inspections for any aluminum oxide corrosion and pitting.

Differences Between This AD and the Transport Canada AD

This AD only applies to helicopters with certain link P/Ns installed. The Transport Canada AD does not specify link P/Ns. This AD requires inspecting the bearing bores for any pitting after cleaning the T/R link, while the Transport Canada AD requires inspecting for corrosion after cleaning the T/R link. This AD requires inspecting the sealant with 10X or higher magnification, while the Transport Canada AD does not specify any magnification. This AD does not require re-identifying the P/N of the link, whereas the Transport Canada AD does. As part of the recurring inspection of the corrosion preventative sealant, if the sealant is missing, this AD requires repeating the inspections for aluminum oxide corrosion and pitting to ensure part integrity before reapplying sealant. The Transport Canada AD only specifies reapplying sealant if the sealant is damaged.

Costs of Compliance

We estimate that this AD affects 73 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. We estimate the cost of labor at $85 per work-hour.

Inspecting the set of T/R links (eight bearings) for corrosion will take about one work-hour for an estimated cost of $85 per helicopter and $6,205 for the U.S. fleet. Cleaning and inspecting the set of T/R links for pitting will take about one work-hour for an estimated cost of $85 per helicopter. Replacing a T/R link will require no additional work-hours after inspection and required parts cost $2,739 for an estimated replacement cost of $2,739 per T/R link. Removing the torque stripe, cleaning, and applying sealant to the set of T/R links will take about one work-hour with a negligible parts cost for an estimated cost of $85 per helicopter. Inspecting the sealant on a set of T/R links will take about one work-hour for an estimated cost of $85 per helicopter and $6,205 for the U.S. fleet per inspection cycle.

According to Bell Helicopter's service information 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 by Bell Helicopter. Accordingly, we have included all costs in our cost estimate.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the unsafe condition can adversely affect control of the helicopter, and certain required corrective actions must be accomplished within 10 hours TIS.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for public comment before issuing this AD are impracticable and contrary to the public interest and that good cause exists for making this amendment effective in less than 30 days.

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, I certify that this AD:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–02–06 Bell Helicopter Textron Canada Limited: Amendment 39–18387; Docket No. FAA–2016–2068; Directorate Identifier 2016–SW–002–AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters with a tail rotor (T/R) pitch link (link) part number (P/N) 429–012–112–101, –101FM, –103, or –103FM installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a T/R link. This condition could result in loss of T/R flight control and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective February 2, 2016.

(d) Compliance

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

(e) Required Actions

(1) For T/R link P/N 429–012–112–101 and 429–012–112–103, within 10 hours time-in-service (TIS):

(i) Remove each T/R link assembly. Prior to cleaning the T/R link bearing bores, using 10X or higher power magnification, inspect each T/R link bearing bore for aluminum oxide corrosion extruding from between the roll staked lip of the bearing outer race and the link bearing bore. Aluminum oxide corrosion appears as a white crystalline material in contrast with the black finish and any accumulated soot. An example of this corrosion is shown in Figure 1 of Bell Helicopter Alert Service Bulletin 429–15–26, dated December 7, 2015 (ASB 429–15–26).

(ii) If there is any aluminum oxide corrosion, replace the T/R link before further flight.

(iii) If there is no aluminum oxide corrosion, clean each T/R link bearing bore with isopropyl alcohol and inspect for pitting.

(A) If there is any pitting, replace the T/R link before further flight.

(B) If there is no pitting, apply corrosion preventative sealant by following the Accomplishment Instructions, paragraph 5. of Part I, of ASB 429–15–26.

(2) For all T/R links listed in paragraph (a) of this AD, within 50 hours TIS and thereafter at intervals not to exceed 50 hours TIS, using 10X or higher power magnification, inspect each T/R link bearing bore for missing corrosion preventative sealant. If any corrosion preventative sealant is missing, perform the actions in paragraph (e)(1)(i) through (e)(1)(iii) of this AD before further flight.

(3) Do not install T/R link P/N 429–012–112–101 or –103 on any helicopter before complying with the actions in paragraph (e)(1) of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

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

(g) Additional Information

The subject of this AD is addressed in Transport Canada AD CF–2016–01, dated January 5, 2016. You may view the Transport Canada AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–2068.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail Rotor System.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Bell Helicopter Alert Service Bulletin 429–15–26, dated December 7, 2015.

(ii) Reserved.

(3) For Bell Helicopter service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(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 Fort Worth, Texas, on January 22, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–01747 Filed 2–1–16; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1031

[CPSC Docket No. CPSC–2013–0034]

Commission Participation and Commission Employee Involvement in Voluntary Standards Activities

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The United States Consumer Product Safety Commission (''Commission'' or ''CPSC'') is issuing this final rule to amend the existing regulation on Commission participation and employee involvement in voluntary standards activities. Currently, Commission rules allow employees to participate in voluntary standard development groups on a non-voting basis and do not allow Commission employees to accept leadership positions in voluntary standard development groups. This final rule removes these restrictions and allows Commission employees to participate as voting members and to accept leadership positions in voluntary standard development groups, subject to prior approval by CPSC's Office of the Executive Director (''OEX'').

DATES: The final rule will become effective on March 3, 2016.

FOR FURTHER INFORMATION CONTACT: Patricia K. Adair, Supervisory Program Analyst, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301–504–7335; *padair@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

Many consumer products under the Commission's jurisdiction are covered by voluntary standards. Voluntary standards provide safety provisions addressing potential hazards associated with consumer products found in locations such as homes, schools, and recreational areas. Developing voluntary standards may involve multiple revisions to a standard within 1 year, or over multiple years. Voluntary standards development activities for consumer products within the Commission's jurisdiction are handled primarily by three standards development/coordinating organizations: ASTM International (previously called the American Society for Testing and Materials), the American National Standards Institute (''ANSI''), and Underwriters Laboratories Inc. (''UL''). Along with industry, consumer groups, and product safety experts, CPSC staff works with these and other organizations to coordinate the development of voluntary standards.

Currently, CPSC staff provides technical support to organizations that coordinate the development of voluntary standards. According to the CPSC's Voluntary Standards Activities FY 2014 Annual Report, CPSC staff provided technical support or monitored voluntary standards activities for 83 products in FY 2014. Staff participates in the voluntary standards development process by providing expert advice, technical assistance, and information, based on analyses of the numbers and causes of deaths, injuries, or incidents associated with a product. Staff may also conduct CPSC research, perform laboratory tests, and provide draft language for a voluntary standard.

The Commission's involvement and staff's participation in voluntary standards activities are governed by the Commission's rule at 16 CFR part 1031, Commission Participation and Commission Employee Involvement in Voluntary Standards Activities (''part 1031''). Part 1031 prohibits CPSC staff from voting and precludes staff from holding leadership positions in voluntary standards development groups. This final rule amends part 1031 to eliminate these prohibitions and allows CPSC staff to vote and hold leadership positions on an optional basis, provided that such activities have the prior approval of the CPSC's OEX.

A. Statutory and Regulatory Background

The Consumer Product Safety Act (''CPSA'') gives the Commission authority to promulgate mandatory safety standards for consumer products. 15 U.S.C. 2056(a)(1)(A). The Commission issued regulations in 1978, describing the extent and form of Commission involvement in the development of voluntary standards (43 FR 19216 (May 4, 1978)). Acknowledging the contribution that voluntary standards had made to reducing hazards associated with consumer products, the Commission stated its support for an effective voluntary standards program, finding that a proper combination of voluntary and mandatory standards can increase product safety better than either mandatory or voluntary activities alone.

In 1981, Congress amended the CPSA, the Federal Hazardous Substances Act (''FHSA''), and the Flammable Fabrics Act (''FFA''), to, among other things, mandate that the Commission give preference to voluntary standards, as opposed to promulgating mandatory standards, if the Commission determines that a voluntary standard would eliminate or adequately reduce an unreasonable risk of injury and there will likely be substantial compliance with the voluntary standard. 15 U.S.C. 2056(b), 15 U.S.C. 1262(g)(2), 15 U.S.C. 1193(h)(2). In 1989, the Commission adopted regulations to reflect the policies set forth by the 1981 amendments, making several changes in the agency's policies on employee participation in voluntary standards development activities. The 1989 amendments also combined parts 1031 (on employee membership and participation) and 1032 (on Commission involvement) into a revised part 1031, titled, Commission Participation and Commission Employee Involvement in Voluntary Standards Activities. 54 FR 6646 (Feb. 14, 1989).

In 2006, the Commission amended several provisions of part 1031. 71 FR 38754 (July 10, 2006). Among other things, the 2006 amendments provided that Commission employees only participate in voluntary standards efforts consistent with the Commission's priorities identified in the Commission's operating plan, performance budget, mid-year review, or other official Commission document. In addition, the Commission added a requirement that employees with ongoing participation in voluntary standards activities report regularly to the Voluntary Standards Coordinator, to help ensure ongoing oversight and coordination. Lastly, the 2006 amendments added a requirement that the CPSC provide notice and the opportunity for the public to comment on staff's positions on voluntary standards activities.

B. Recent Statutory Changes Involving Voluntary Standards

In the past, CPSC staff typically served on voluntary standards committees based on the Commission's priorities. Staff participated without any expectation that such voluntary standards would necessarily form the basis of a mandatory standard. The Consumer Product Safety Improvement Act of 2008 (''CPSIA''), however, gave rise to the expectation that, for certain children's products, voluntary standards would form the basis for mandatory standards development. For example, section 104(b) of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be ''substantially the same as'' applicable voluntary standards or more stringent than the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product.

Congress also has addressed participation by federal agencies in voluntary standards development. Public Law 104–113 directed federal agencies to ''use technical standards that are developed or adopted by voluntary consensus standards bodies'' and to ''participate with such bodies in the development of technical standards.'' Public Law 104–113, 12(d)(1) & (2), 110 Stat. 775, 783 (1996), 15 U.S.C. 272 note. Congress anticipated that federal agencies would ''work closely'' with voluntary standards organizations, that these organizations would ''include active government participation,'' and that agencies would ''work with these voluntary consensus bodies, whenever and wherever appropriate.'' H.R. Rep. 104–390 at 15, 25 (1995). *See also* 141 Cong. Rec. H14334 (daily ed. December 12, 1995) (Statement of Rep. Morella).

C. GAO Report

On May 16, 2012, the U.S. Government Accountability Office (''GAO'') issued a report titled, ''Consumer Product Safety Commission: A More Active Role in Voluntary Standards Development Should Be Considered'' (''GAO Report'') (available at: *http://www.gao.gov/assets/600/590990.pdf*). The GAO Report

recommended that the Commission review its policy for staff participation in voluntary standards development activities and determine the feasibility of agency staff assuming a more active, engaged role in developing voluntary standards. Specifically, the GAO Report recommended that CPSC staff be allowed to vote on balloted provisions of voluntary standards and to hold leadership positions at various levels of standards development organizations, including task groups, subcommittees, or committees. GAO concluded that changing the CPSC's regulations to allow staff to participate more actively in voluntary standards activities, especially when working with technical committees for which CPSC staff can provide expertise, and permitting CPSC staff to vote on voluntary standards, could result in stronger voluntary standards, without compromising the CPSC's independence.

D. Notice of Proposed Rulemaking

In response to the GAO Report recommendations, the Commission issued a proposed rule (''NPR'') to remove the prohibitions on CPSC staff participating as voting members and accepting leadership positions in voluntary standard development groups. 78 FR 57818 (Sept. 20, 2013). The NPR proposed that CPSC staff participation in such activities would receive prior approval by OEX. The preamble to the NPR stated that when approving staff's participation in such activities, OEX should consider the policy concerns set forth in 16 CFR 1031.9 (appearance of preferential treatment, loss of impartiality, compromise of the agency's independence, and a real or apparent conflict of interest) and balance these concerns against Commission priorities, available resources, the need for greater staff involvement, and the efficiency of the voluntary standards process. 78 FR at 57820. The NPR stated that OEX would evaluate each request for staff to participate as a voting member or to accept a leadership position on a case-by-case basis. Additionally, the preamble to the NPR stated that OEX would authorize staff to vote on actions for a specified voluntary standard but would not be approving each individual vote. *Id.*

E. Rationale for the Rule

The Commission is finalizing the proposed rule without any changes. As discussed in the preamble to the NPR, the Commission believes that permitting CPSC staff the option to vote on a voluntary standard and/or accept a leadership position in a voluntary standard development group may result in a more effective voluntary standards process and accelerate standards development and implementation, without compromising the CPSC's independence. Such participation could gain CPSC staff additional access to and familiarity with the latest technologies, and will provide an opportunity for staff to help establish standards that will advance CPSC's safety goals. In addition, ''full'' federal government participation in standards development increases the likelihood that the standards can meet both public and private sector needs. 141 Cong. Rec. H14334 (daily ed. December 12, 1995) (Statement of Rep. Morella).

Additionally, optional staff participation in voluntary standard development groups by voting and taking leadership roles is consistent with the guidance in OMB Circular A–119 Revised, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities'' (February 10, 1998). Among other things, OMB Circular A–119 encourages agency representatives serving as members of voluntary consensus standards bodies to ''participate actively and on an equal basis with other members,'' and to ''vote . . . at each stage of the standards development process unless prohibited from doing so by law of their agencies.''

When participating as a voting member of, or in a leadership position on, a voluntary standard development group, the Commission directs CPSC staff to indicate clearly that any views expressed in connection with such participation represent CPSC staff's position and may not necessarily represent the Commission's position. Making such a disclaimer is consistent with current staff practice regarding representations in oral and written presentations and staff documents intended for public release. In these contexts, CPSC staff's views cannot serve as a proxy for the Commission's or the agency's views on any particular issue, as stated in the final rule at § 1031.11(c). Similarly, CPSC staff serving in leadership positions on a voluntary standard development group will act in their capacity as CPSC staff members, and their views will not necessarily represent the views of the Commission. In particular, the Commission warns that CPSC staff participation in a voluntary standard development group, even in a leadership position, does not provide any assurance that the Commission will support the resulting voluntary standard.

Removing prohibitions on employees voting and serving in leadership positions should not result in the Commission compromising the policy concerns set forth in § 1031.9. Generally, before any substantive issue is balloted on a voluntary standards committee, the committee is given the opportunity to discuss the proposals in detail. Currently, Commission staff engages in these discussions, such that the technical opinions of staff are known before a proposed change in a voluntary standard is balloted. Accordingly, CPSC staff's ability to vote on such ballots should not fundamentally alter current procedures in a manner that impinges on the Commission's independence. Rather, staff's ability to vote on a voluntary standard may improve the credibility and efficiency of the standard. Additionally, not only can OEX consider policy concerns when deciding whether to authorize staff participation in voluntary standards activities as voting members or in leadership roles, but OEX's approval also can impose constraints or limitations tailored to specific circumstances, such as measures to avoid undue influence or any appearance of impropriety.

Finally, to serve in a leadership position on a voluntary standards development group, CPSC staff must agree to follow the procedures set forth by the voluntary standards development group for leadership positions. Staff's leadership role may involve helping the development group to run more smoothly and assisting the committee in achieving timely deliberations.

II. Response to Comments

CPSC received 14 comments regarding the NPR that address 29 separate issues. Comments submitted in response to the NPR are available at: *www.regulations.gov,* by searching under the docket number of the rulemaking, CPSC–2013–0034. We summarize the comments received on the NPR and CPSC's responses below. To make identification of the comments and our responses easier, we numbered the comments and responses, and placed the word ''Comment'' before each comment summary, and the word ''Response'' before the Commission's response.

A. Support for Greater Staff Participation in a Voting Capacity or in a Leadership Role in Voluntary Standards

Comment 1: A commenter noted that, ''involvement of CPSC personnel in voluntary standards activities ensures that the agency and other affected

stakeholders (standards developers, industry, consumers, etc.) can address safety needs in an open forum, thereby reducing the likelihood that mandatory rulemaking will be necessary. Such rulemaking is often time-consuming, can preclude more robust stakeholder input and participation, and may not be able to react and adapt to changing market dynamics on a rolling basis.'' Other commenters echoed the conclusion that staff engagement produces ''better, more protective and timelier voluntary standards'' and those members with voting privileges are often more engaged in the process.

Response 1: The Commission agrees that there are benefits to staff participation in voluntary standards organizations. Staff participation in a voluntary standards body facilitates more open, efficient interactions with stakeholders and such communication with stakeholders yields effective injury-prevention strategies for consumers. Sometimes, staff's participation in the voluntary standards process may be more efficient and timely in reducing safety hazards than mandatory rulemaking. For example, the ability to update standards quickly is an important benefit of voluntary standards. However, the ability to create mandatory rules is an important part of product safety. The Commission, not CPSC staff, generally determines when to follow a voluntary standard and when to initiate rulemaking, often based on staff's recommendations. Together, staff's participation in voluntary standards development and the Commission's rulemaking ability help fulfill the Commission's mission to prevent serious injury and death to consumers from unreasonable risks associated with consumer products. The Commission previously observed that an effective voluntary standards program, along with mandatory standards, can increase product safety better than either mandatory or voluntary standards alone (43 FR 19216 (May 4, 1978)).

Comment 2: A commenter expressed concern that staff's inability to ''officially'' represent CPSC in voluntary standards development activities might be perceived negatively by other standards development group participants who expect that individuals in the group represent the views of their organizations.

Response 2: CPSC staff currently provides input to voluntary standards development groups; this input represents the views and expertise of Commission staff, not the Commission. The fact that staff cannot represent the views of the Commission will not change if staff participates in voting. Leadership responsibilities in a voluntary standards organization are determined by each organization and generally require impartiality. A CPSC staff leader will be subject to all the rules and regulations of the voluntary standards, as any other member in the same role.

Comment 3: A commenter noted that staff from the U.S. Environmental Protection Agency (''EPA'') participates and votes in voluntary standards development groups and has held leadership positions.

Response 3: As GAO's report noted, CPSC's existing policy on voting and holding leadership positions in voluntary standards organizations is more restrictive than OMB's guidance on voluntary standard's participation in OMB Circular A–119 Revised, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities'' (February 10, 1998). Each agency independently decides on an appropriate policy for voluntary standards activities.

B. Concerns With Greater Staff Participation in a Voting Capacity or in a Leadership Role in Voluntary Standards

Comment 4: Some commenters stated that allowing staff to vote in voluntary standards development activities would ''compromise the CPSC's objectivity and have a 'chilling effect' on candid discussions needed to develop the most effective standards.'' The commenters do not see the benefit of allowing staff to vote when an ''abstention with comment'' serves to provide substantive staff input.

Response 4: Staff currently expresses its opinions of ballot items in voluntary standards development activities through an abstention with comment, participation in meetings, email communications, conference calls, and formal letters submitted to the standards development groups. At this time, the Commission is not aware of any instances in which expressions of opinion adversely affected discussions. Allowing staff to express staff's views through a vote may increase the speed and efficiency of staff communicating during standards development meetings. In addition to ballot votes, dozens of proposals can be made and voted on during any given standards development meeting. Allowing staff to cast a vote like other members can provide instant feedback about staff opinions.

Comment 5: A commenter expressed concern that CPSC staff's negative vote could effectively negate the legitimacy and effectiveness of an entire standard, even when a standard has the full support of an entire committee. The commenter expressed concern that allowing CPSC staff to vote could cause manufacturers to decline altogether from participating in voluntary standards development.

Response 5: The Commission disagrees. Staff regularly expresses its approval or disapproval of proposals in presentations and letters during standards development activities, usually verbally, but often in the form of a written ''abstention with comment.'' Even when staff provides negative feedback, voluntary standards development groups continue their work.

Comment 6: Several commenters suggested that any CPSC staff position on a subject could be seen as an official Commission position, implying that staff's usual disclaimer cannot be effective. One commenter stated that the Commission should vote on every position taken by a staffer and expressed concern that a CPSC staff member stating a view that was ''materially different from one or more Commissioners, could create a conflict with an ultimate Commission determination.''

Response 6: The Commission is comprised of five individual Commissioners. Accordingly, every Commissioner may not always agree with the recommendations or opinions of staff. The Commission's official position is determined by a majority vote of the five Commissioners. CPSC staff routinely expresses its opinions about proposals in voluntary standards activities with the disclaimer that staff cannot represent the Commission's opinions. The disclaimer that staff cannot ''represent the views of the Commission'' is generally understood within voluntary standards organizations and will be included as part of the comments attached to a staff vote if there is any indication that staff opinion could be misinterpreted as representing the views of the Commission.

Comment 7: A commenter noted that CPSC's current policy preventing staff from voting in and leading voluntary standards activities ensures that the CPSC ''maintain[s] its independence as an impartial participant . . .''

Response 7: The Commission's decision to permit the option for staff representatives to vote or hold leadership positions should not prevent the Commission from maintaining its independence. CPSC's regulation at 16 CFR 1031.13(e) states: ''Involvement by

Commission officials and employees in voluntary standards bodies or standards-development groups does not, of itself, connote Commission agreement with, or endorsement of, decisions reached, approved or published by such bodies or groups.'' The final rule requires OEX to approve staff participation, and to consider whether ''loss of impartiality'' would be an issue in each case.

Comment 8: A commenter asserted that having staff in leadership positions of voluntary standards development groups would have ''a chilling effect'' on participation because, ''it is difficult to believe that any manufacturer representative would ever risk the ire of CPSC (a potential enforcement action?) against its company by voicing disagreement with a CPSC committee or subcommittee chair or voting against a CPSC position.''

Response 8: According to CPSC staff, staff's experience participating in voluntary standards development groups does not support the commenter's claim. CPSC staff regularly engages in full and vigorous debates about staff's views in standards development meetings where a subcommittee disregards or votes against CPSC staff's position. Organizations, such as ASTM, have stated that leaders are subject to rules that maintain the development of consensus standards in accordance with rigorous democratic procedures that ensure open and balanced participation, due process, and consensus. Members may monitor, critique, and correct any actions of a subcommittee or task group chairman according to the rules and by-laws of the standards development organization. Additionally, although each organization may differ, leaders are nominated and appointed according to the standards development organization's rules and procedures. For example, UL employs UL staff to lead UL's standards technical panels. ASTM members elect a chairman who appoints subcommittee chairmen from the general membership, subject to the approval of ASTM's Executive Subcommittee (Section 6.3.1, ASTM, 2013).[1] Task group leaders are appointed during subcommittee meetings.

Under the final rule, CPSC staff could be nominated and appointed to leadership roles *only* after the approval of the standards development organization that makes the invitation. OEX will subsequently need to approve staff participation. The final rule gives standards development organizations the option to offer a leadership role to CPSC staff and for OEX to review and approve each offer on a case-by-case basis. Furthermore, execution of a leadership role is subject to the bylaws of the pertinent standards development organization, many of which require impartiality of people in leadership positions.

Comment 9: Commenters argued that having CPSC staff in a leadership role in a voluntary standards development group could create the practice or appearance of undue influence if staff is allowed, for example, to schedule meetings, set agendas, and decide the direction of the conversation on the voluntary standard.

Response 9: Standards development organizations have rules and bylaws that govern and protect the validity of their respective consensus-building procedures. Although the leader of a committee can have influence over the scheduling of meetings and discussions, the agenda and direction of the conversation are governed and selected by the committee members. Every proposal made by a member of the group must be voted on and approved by the members, and any irregularities in procedures are open to challenge by any member, as specified in the standards organization's rules of conduct or bylaws. Chairmen or other leaders cannot dictate the content or wording of a voluntary standard, nor can they move proposals forward without group consensus. Removing the prohibition will not alter or affect these rules and principles.

Comment 10: A commenter asserted that the Commission has not shown ''a reason why prohibiting staff from accepting leadership positions is no longer necessary.'' Another commenter termed the reasons for the proposed rule, ''a mystery.''

Response 10: As noted above, a GAO report recommended that the Commission review its policy for participating in voluntary standards development activities and determine the feasibility of agency staff assuming a more active, engaged role in developing voluntary standards. The GAO concluded that CPSC had interpreted its level of participation more strictly than OMB guidance specified for activities such as voting on standards and taking leadership positions. Other participants in voluntary standards development activities familiar with CPSC contributions agreed with OMB that ''earlier and more active participation could increase CPSC's efficiency and effectiveness in developing standards'' (p. 10, GAO–12–582). After reviewing the GAO report, the Commission agreed with CPSC staff, that in certain limited circumstances, if CPSC staff is allowed to vote or serve in leadership positions, CPSC staff's participation may advance efficient development of safety standards. Importantly, removing the prohibition against these activities from part 1031 does not require CPSC staff to vote or to serve as leaders; however, removing the prohibition does provide a framework for CPSC to consider, on a case-by-case basis, whether staff should undertake such activities.

C. Potential Legal Issues With Greater Staff Participation Identified by Commenters

Comment 11: Several commenters argued that allowing staff members to vote would ''usurp the regulatory process, effectively allowing the CPSC to develop a *de facto* 'mandatory standard' outside of the notice and comment rulemaking process in violation of the Administrative Procedures Act, as such vote would likely be given significant weight.'' The commenters further asserted that, if staff assumes a leadership role in a voluntary standards development group, such a role would equate to an ''end run'' around the normal rulemaking safeguards that are needed to give small businesses a voice in the creation of a mandatory rule.

Response 11: The Commission disagrees. Voluntary standards are not mandatory standards. Allowing staff to serve in leadership positions in a voluntary standards development group will not alter or circumvent any procedures for mandatory rulemaking. If the Commission engages in mandatory rulemaking, the Commission will continue to follow the appropriate notice and comment rulemaking procedures.

Comment 12: A commenter noted that the CPSIA requires the Commission to make some voluntary standards into mandatory rules and expresses concern that a ''blurring'' is occurring between the needed distinction between voluntary standards versus CPSC-mandated regulations. The commenter is concerned that this perceived ''blurring'' of the distinction between voluntary and mandatory standards is a ''slippery slope that could undermine the legitimacy, independence, and effectiveness of the entire voluntary standards framework.''

Response 12: Several provisions of the CPSIA mandated or provided for the Commission to adopt as mandatory

[1] *http://www.astm.org/COMMIT/Regs.pdf*—ASTM International, *Regulations Governing ASTM Technical Committees,* 100 Barr Harbor Drive, West Conshohocken, PA, October, 2013.

regulations, certain voluntary standards, such as those for toys, durable infant and toddler products, and all-terrain vehicles. In these circumstances, there is a closer link between voluntary standards and mandatory CPSC standards than in other situations. However, the Commission follows appropriate rulemaking procedures when issuing a mandatory rule and clearly distinguishes between the staff's activities with a voluntary standards development group and the Commission's promulgation of a mandatory rule. Allowing staff to hold leadership positions or vote will not conflict with the rulemaking process.

Most of CPSC staff's work with voluntary standards groups is outside of the unique circumstances of these provisions of the CPSIA and does not involve any rulemaking activity. Staff is engaged in the voluntary standards process for a range of other consumer products. Rather than ''undermining the legitimacy'' of the voluntary standards framework, CPSC staff, in addition to stakeholder engagement in the voluntary standards process, has added to the legitimacy and credibility of the voluntary standards process. Participation by all concerned stakeholders collectively to develop safety standards is the most effective way to mitigate the risk of injury through the sharing of information, such as testing and data.

Comment 13: A commenter suggested that the language of the NPR sounds like the Commission believes that voluntary standards development is ''some kind of precursor to mandatory rulemaking or a substitute for an Advanced Notice of Proposed Rulemaking (''ANPR'').''

Response 13: In the case of section 104 of the CPSIA, voluntary standards are the basis for the Commission's rulemaking for a durable infant or toddler product. Congress required the Commission to issue mandatory rules for certain durable infant and toddler products that are substantially the same as, or more stringent than, the voluntary standard for such products. Congress directed the Commission to issue such rules under section 553 of the Administrative Procedure Act (''APA''), rather than the Commission's rulemaking authority under sections 7 and 9 of the CPSA. In effect, Congress directed certain juvenile product voluntary standards to become precursors of mandatory rules, but still required the Commission to use notice and comment rulemaking to make such standards mandatory rules. Congress also made voluntary standards for both toys and ATVs mandatory CPSC rules.

Voluntary standards are important to CPSC, as demonstrated by the large number of voluntary standards committees staff participates in annually. However, staff involvement in a voluntary standard committee is not a precursor to a mandatory rule. When the Commission engages in rulemaking under the CPSA, the Commission must consider the efficacy of any existing voluntary standards to address the risk of injury or death identified, and whether products substantially comply with the voluntary standard.

Comment 14: A commenter stated that the proposed rule would have a ''chilling effect'' on participating in the development of standards because ''. . . . the plaintiffs' bar will likely attempt to argue in product liability cases that a negative CPSC vote suggests that a voluntary standard (that was properly adopted through, for example, the ANSI or ASTM process) is still 'unsafe.' ''

Response 14: If lawyers wanted to make an argument based on an individual CPSC staffer's opinion, lawyers could do that today, based on staff's communications with a voluntary standards development group. Staff regularly and openly expresses opinions about voluntary standards in documents easily obtained and during open meetings. Expressing the same opinion in a vote will not change this dynamic.

Comment 15: A commenter stated that one of the provisions of the *Regulations Governing ASTM Technical Committees* (Section 19.2.5) is that ''. . . no subcommittee or task group shall make any effort to bring about the standardization of any product or service for the purpose or with the effect of (a) preventing the manufacture or sale of any product or service not conforming to a specified standard. . . .'' The commenter argued that agency staff would violate this ASTM requirement if the proposed rule were approved.

Response 15: The Commission disagrees with the commenter. CPSC staff's voting or holding leadership positions will have no effect on ASTM's requirements or procedures used for standards development. All members, including CPSC staff participating in the ASTM subcommittees are required to follow the rules of standard development set out by ASTM.

Under the CPSA, the Commission must rely on a voluntary consumer product safety standard rather than promulgate a mandatory standard when compliance with the voluntary standard would eliminate or adequately reduce the risk of injury and it is likely there will be substantial compliance with the voluntary standard. Under section 104 of the CPSIA, the Commission is required to issue a mandatory regulation for certain durable infant or toddler products that is the same as, or more stringent than, the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. Contrary to the commenter's assertion, voluntary standards do not ''immediately become a mandatory standard.'' The Commission can only issue a final mandatory rule if the Commission follows the notice and comment rulemaking procedures under the APA or is otherwise instructed by Congress. Rulemaking can occur in parallel to the voluntary standards development process, but cannot be replaced by the voluntary standards development process.

Comment 16: One commenter recommended that, if staff is given the opportunity to vote on a ballot item, and staff casts a negative vote that is later deemed nonpersuasive by the subcommittee, then staff's recommendation or suggestion should not be included in any final mandatory standard that incorporates the standard by reference.

Response 16: This comment refers to the ASTM practice of allowing a subcommittee to find a negative vote nonpersuasive, thereby overriding the negative vote and allowing a ballot to pass, even though the ballot does not have the consensus of all voters. The commenter is confusing the roles of CPSC staff and the Commission. CPSC staff's opinions and suggestions are just that, they are the staff's opinions and suggestions, not the opinions and suggestions of the Commission. The creation of a mandatory standard, even one with origins in a voluntary standard, is separate from voluntary standards development and requires action by the Commission. Neither opinions of CPSC staff, nor the opinions of the standards organization members, can bind the Commission to any decision about a mandatory standard. CPSC rulemaking must be conducted following the appropriate statutory rulemaking procedure. Furthermore, the commenter's suggestion goes against separation of the voluntary and mandatory standards processes discussed previously.

Comment 17: Commenters suggested that staff leadership and voting in voluntary standards development activities might activate certain requirements of the APA. These requirements ''could hinder or cripple the process'' of developing a standard.

Response 17: CPSC staff voting and/or accepting a leadership position in a standards development organization does not implicate the APA. Procedural requirements of the APA do not apply to voluntary standard proceedings but only to rulemaking undertaken by the Commission through its statutory procedures.

Comment 18: A commenter suggested that staff leadership in standards development activities might trigger the need to follow the Federal Advisory Committee Act (''FACA'').

Response 18: FACA is not implicated by CPSC staff serving in a leadership position in a voluntary standards development group. FACA defines an ''advisory committee,'' in relevant part, as one that is ''established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government . . .'' 5 U.S.C. 3 App. 2. Voluntary standards organizations, committees, and subcommittees are not ''established or utilized'' by the Commission or CPSC staff. Voluntary standards committees exist to create and revise voluntary standards, irrespective of whether CPSC staff serves in a leadership function. Additionally, neither the Commission, nor staff, is establishing or utilizing a voluntary standards development group to advise the agency on any matter.

Comment 19: A commenter suggested that staff leadership roles might trigger certain requirements of the Sunshine Act (''SA''), such as calendar notices and the accommodation of additional public participation beyond members who regularly contribute to standards development activities. The commenter was concerned that SA obligations would suppress participation and raise the costs of holding meetings for standards development organizations.

Response 19: The SA, 5 U.S.C. 552b, does not apply to staff serving in leadership positions in a voluntary standards development group. As provided in the Commission's regulations implementing the SA, 16 CFR 1013.1, SA requirements only apply to Commissioners, not to staff. The CPSC does have a meetings policy for the agency that applies to CPSC staff, as well as Commissioners. 16 CFR part 1012. The meetings policy fosters transparency and openness. Under the meetings policy, certain meetings involving CPSC staff (such as meetings concerning the development of voluntary standards) must be open to the public and must be noticed in CPSC's public calendar. The Commission's voluntary standards regulations at 16 CFR part 1031 explicitly reference and incorporate the meetings policy requiring CPSC employees to comply with applicable provisions. 16 CFR 1031.11(f) and 1031.13(c). CPSC staff has followed this meetings policy since its 1981 implementation when participating in the voluntary standards development process, including routinely posting voluntary standards organization meeting notices on the CPSC's public calendar and creating meeting logs to record participation.

Comment 20: A commenter wrote that staff participation on technical committees ''could impede the ability of these committees to function effectively by precluding industry participants from discussing or disclosing privileged information.'' The commenter recommended allowing technical committee meetings to be closed to the public to facilitate ''the open, honest dialogue and self-critical analysis that are the cornerstones of voluntary standard development.''

Response 20: The final rule allows CPSC staff to vote on ballot items and to hold leadership positions. These revisions do not alter standards organizations' procedural rules or the CPSC's meetings policy (discussed in the previous response).

D. Other Procedural and Burden Considerations

Comment 21: A commenter recommended that CPSC staff engagement be consistent with the Office of Science and Technology Policy (''OSTP'') guidance,[2] namely:

1. Produce timely, effective standards and efficient conformity assessment schemes that are essential to addressing an identified need;

2. Achieve cost-efficient, timely, and effective solutions to legitimate regulatory procurement and policy objectives;

3. Promote standards and standardization schemes that promote and sustain innovation and foster competition;

4. Enhance U.S. growth and competitiveness and ensure non-discrimination, consistent with international obligations; and

5. Facilitate international trade and avoid the creation of unnecessary obstacles to trade.

The commenter also recommended that CPSC staff only accept leadership positions when the standard is a national priority and consistent with CPSC's current operating plan. Even then, the commenter recommended that leadership roles should be the exception, not the rule.

Response 21: The Commission believes that the final rule will contribute to the objectives outlined in the OSTP guidance. OEX will approve staff participation on a case-by-case basis, based on the considerations outlined in the rule. The Commission expects that standards organizations will only extend an invitation for staff to take leadership positions during exceptional circumstances because many willing standard organization members are often available for taking leadership roles in standards organizations.

Comment 22: Another commenter suggested that the Commission should be involved in the decision to approve staff participation because it is a policy decision, not just a budgetary concern.

Response 22: The Chairman, not the Commission, is responsible for allocating staff resources. 15 U.S.C. 2053(f)(1). The Executive Director, as chief operating officer, manages staff's work. 16 CFR 1000.18. Staff's work includes participation in voluntary standards activities, whether on a voting or non-voting basis and whether in a leadership or non-leadership capacity.

Comment 23: A commenter questioned the criteria OEX would apply to determine when it was advisable for staff to participate actively in a standards initiative. What rules for gaining approval would be set and what criteria would OEX apply in the decision?

Response 23: OEX will approve staff participation on a case-by-case basis, based on the considerations outlined in the rule, namely the policy concerns set forth in 16 CFR 1031.9:

- An appearance of preferential treatment,
- loss of impartiality,
- compromise of the agency's independence, and
- a real or apparent conflict of interest.

Policy concerns in 16 CFR 1031.9 should be balanced against Commission priorities, available resources, and the need for greater staff involvement, among other things. Nominations for leadership roles will be subject to the rules set by the standards development organization, and an OEX decision will be rendered in a timely manner.

Comment 24: Commenters strongly encouraged the Commission to ensure that the personnel assigned to participate in voluntary standards development groups have the technical

[2] Principles for Federal Engagement in Standards Activities to Address National Priorities (Jan. 17, 2012), available at *http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf* (last accessed March 25, 2014).

qualifications to address the entire subject of the standard, as opposed to a political appointee without relevant background training. Another commenter echoed this concern and also recommended that staff participation should involve regular attendance at meetings so that any votes cast by staff would be fully informed.

Response 24: Staff members approved by OEX to hold leadership positions will be qualified to fulfill the responsibilities of their positions. CPSC's regulation at 16 CFR 1031.12 prohibits certain Commission personnel who have final decision-making responsibilities, such as political appointees, from becoming members of a voluntary standards development group.

Comment 25: A commenter suggested that the procedures governing the chairman of a voluntary standards committee only allow that person to vote when there is a tie on a proposal. The commenter claimed that this would undermine one of the objectives of the rule.

Response 25: The chairman's role in a voluntary standard committee is defined by each organization's by-laws, policies, and procedures. Anyone from CPSC staff taking a leadership role in a standards organization is required to adhere to those bylaws and policies. If this role is defined in standards organization bylaws and policies as one of a facilitator, then, staff will work to facilitate open discussion and debate, in accordance with the defined role of a chairman, and will avoid casting a vote when in that role.

Comment 26: Some commenters expressed concern that the proposed rule could affect the ability of staff to monitor and informally participate in the greatest number of voluntary standards. Leadership roles demand significant resources and administrative responsibilities that may not be of significant interest to the Commission.

Response 26: The Commission understands and agrees that leadership roles can be demanding and that the Commission's resources are limited. Some leadership roles, such as leading a small task group, may take less time and fewer resources and be an appropriate use of staff's time. For a staff member already committed to participating in a task group, serving as chairman may not involve a significant amount of extra time and preparation. However, as noted previously, resource demands and availability will be factors considered by the OEX when deciding on a request for staff to hold a leadership position.

Comment 27: A commenter noted that the policy of limited staff participation in voluntary standards development activities was, in part, to reduce the financial burden on the government. The commenter did not see how lifting the prohibitions on staff participation in voluntary standards development activities would reduce the financial burdens on the government.

Response 27: The final rule allows staff participation in a leadership role on a voluntary standards development group with OEX approval after taking into consideration a variety of factors, which may include resource availability. The level of participation in the voluntary standards process and the necessary commitment of time and resources can vary from situation to situation, and will be taken into account by OEX in considering approval. Implementing or revising mandatory standards can be costly in terms of the time and resources required to achieve a product safety objective. Participation in the voluntary standards development process is often a cost-efficient means to achieve the Commission's product safety objectives when the result is an effective standard with industry compliance. Implementing or revising an effective voluntary standard is in the interest of the Commission, consumers, and the industry.

Comment 28: A commenter expressed concern that using staff in leadership roles could slow down the development of voluntary standards because those staffers would need to maintain their daily duties at the Commission.

Response 28: Before approving staff to serve in a leadership position, the OEX will consider many factors, including the employee's then current duties and activities. Leaders in voluntary standards development groups typically have other duties at their place of employment, and if a leader is unable to fulfill his/her duties, the standards organization has procedures for replacing the leader to get the work completed on a timely basis. These procedures will apply to staff in leadership roles as well. For standards organizations that use volunteers in leadership roles (rather than voluntary standards development groups led by paid employees like UL), having another committee member who is allowed to volunteer for leadership duties will be beneficial during times of increased activity.

Comment 29: Several commenters noted that if staff took leadership positions in voluntary standards activities and the government was shut down, then the standards development process would be slowed down.

Response 29: Government shut downs are not common; however, the inability of staff to participate in voluntary standards activities based on this situation are similar to other circumstances, such as health-related issues, which can prohibit any person from fulfilling their duties on a committee. In the event of a leadership lapse, voluntary standards organizations have standing procedures for replacing leaders who cannot complete their duties.

III. Description of the Final Rule

Following is a section-by-section description of the changes to part 1031. These changes are the same as those set out in the proposed rule.

Section 1031.10(b)—Existing § 1031.10(b), regarding definitions, lists the types of activities that may comprise ''employee involvement'' in voluntary standards development activities. Section 1031.10(b) of the final rule expands the list of activities to include: ''participating as a voting member of, or in a leadership position on, a voluntary standard development group, when authorized,'' to recognize that such activities are part of the term ''employee involvement.''

Section 1031.11(c)—Existing § 1031.11(c), regarding procedural safeguards, states that involvement in voluntary standards activities by Commission officials and employees is predicated on an understanding by the voluntary standards group that such involvement is on a non-voting basis. The final rule deletes this provision as inconsistent with the goal of allowing employees the option, with prior approval, to participate as voting members of a voluntary standards committee.

Section 1031.11(d)—Existing § 1031.11(d), regarding procedural safeguards, states: ''[i]n no case shall Commission employees or officials vote or otherwise formally indicate approval or disapproval of a voluntary standard during the course of a voluntary standard development process.'' The final rule renumbers this section to § 1031.11(c), and revises the content to remove the existing language, which is inconsistent with allowing Commission employees the option, with prior approval, to vote. The final rule provides that employees authorized to participate as voting members of a voluntary standard development group represent the position of CPSC staff. Such votes do not necessarily represent the opinions or views of the Commission, and would not be binding on the Commission.

Section 1031.11(e)—Existing § 1031.11(e), on procedural safeguards, states that Commission officials and employees cannot accept voluntary standards committee leadership positions, except that the Voluntary Standards Coordinator may accept leadership positions with the governing bodies of standards-making entities with the approval of the Executive Director. The final rule renumbers this provision to § 1031.11(d), and revises the language to state that Commission officials or employees may accept leadership positions in voluntary standards development groups or leadership positions with the governing bodies of standards-making entities, when authorized with prior approval by the Office of the Executive Director.

Section 1031.11(f)—The final rule renumbers existing § 1031.11(f) to § 1031.11(e).

Section 1031.12(b)—Existing § 1031.12(b), on membership criteria, states that all officials and employees not discussed in § 1031.12(a) [which lists Commissioners and employees who may not become members of voluntary standards groups because they either make or advise on final agency decisions] may be advisory, non-voting members of voluntary standards development and advisory groups with the prior approval of the Executive Director, including the Voluntary Standards Coordinator. Section 1031.12(b) of the final rule revises the language to provide that all other officials and employees not covered under § 1031.12(a) may participate as voting members or accept leadership positions in voluntary standard development groups, when authorized with the prior approval of the Office of the Executive Director. Section 1031.12(b) of the final rule removes the reference to the Voluntary Standards Coordinator because such person is not prohibited from becoming a member of a voluntary standards group in § 1031.12(a). Thus, the Voluntary Standards Coordinator would fall within the class of persons discussed in final § 1031.12(b) who may serve as a voting member and hold leadership positions, as authorized.

Section 1031.12(c)—Existing § 1031.12(c) references the Executive Director as the management official with the authority to approve staff serving as members of a voluntary standards organization or group. Section 1031.12(c) of the final rule removes the reference to the ''Executive Director'' and replaces it with ''Office of the Executive Director'' to reflect that prior approval for membership in voluntary standards activities must be approved by the Office of the Executive Director.

IV. Environmental Impact

Generally, the Commission's regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. *See* 16 CFR 1021.5(a). This final rule solely involves Commission procedure, and therefore, is not expected to have an adverse impact on the environment. The final rule generally falls within the categorical exclusion in 16 CFR 1021.5(c), eliminating the need for an environmental assessment or environmental impact statement.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') requires agencies conduct regulatory impact analyses to assess the potential economic impact on small entities, including small businesses, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Commission provided such a certification in the NPR because the rule would not impose any new requirements on businesses, including small businesses nor require any greater governmental participation in voluntary standards. The Commission did not receive any comments related to the certification, and the final rule does not differ from the proposed rule. Accordingly, the Commission finds that the final rule will not have a significant impact on a substantial number of small entities.

VI. Paperwork Reduction Act

The final rule does not require any stakeholder to create, maintain, or disclose information. Thus, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not implicated in this rulemaking.

VII. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). Because the final rule solely affects Commission procedure and does not require stakeholders to take any action, the final rule is effective 30 days after publication in the **Federal Register**.

List of Subjects in 16 CFR Part 1031

Business and industry, Consumer protection, Voluntary standards.

For the reasons stated in the preamble, the Commission amends 16 CFR part 1031 as follows:

PART 1031—COMMISSION PARTICIPATION AND COMMISSION EMPLOYEE INVOLVEMENT IN VOLUNTARY STANDARDS ACTIVITIES

■ 1. The authority citation for part 1031 is revised to read as follows:

Authority: 15 U.S.C. 2051–2083; 15 U.S.C. 1261–1276; 15 U.S.C. 1191–1204; Sec. 3, 104, 106, 223 Pub. L. 110–314, 122 Stat. 3016, 3017 (2008), Sec. 3, 4 Pub. L. 112–28 (2011).

■ 2. In § 1031.10 paragraph (b), revise the third sentence to read as follows:

§ 1031.10 Definitions.

* * * * *

(b) * * * Employee involvement may include regularly attending meetings of a standards development committee or group, taking an active part in discussions and technical debates, expressing opinions, expending other resources in support of a voluntary standard development activity, and participating as a voting member of, or in a leadership position on, a voluntary standard development group, when authorized. * * *

* * * * *

■ 3. In § 1031.11, remove paragraph (f) and revise paragraphs (c), (d), and (e) to read as follows:

§ 1031.11 Procedural safeguards.

* * * * *

(c) Commission officials or employees who are authorized to participate as a voting member of a voluntary standard development group represent the position of CPSC staff. Such votes or opinions do not bind the Commission in any way or necessarily represent the opinions or views of the Commission, but rather, solely represent the views of the CPSC staff.

(d) Commission employees and officials who are involved in the development of voluntary standards may accept leadership positions in voluntary standard development groups (*e.g.,* committee chairman or secretary) or leadership positions with the governing bodies of standard-making entities, when authorized with the prior approval of the Office of the Executive Director.

(e) Attendance of Commission personnel at voluntary standards meetings shall be noted in the public calendar, and meeting summaries shall be submitted to the Office of the Secretary, as required by the Commission's meetings policy, 16 CFR part 1012.

■ 4. In § 1031.12:

■ a. Revise paragraph (b).

■ b. In paragraph (c), remove the phrase: ''Executive Director,'' and add in its place ''Office of the Executive Director''.

The revision reads as follows:

§ 1031.12 Membership criteria.

* * * * *

(b) All other officials and employees not covered under § 1031.12(a) may participate as voting members or accept leadership positions in voluntary standard development groups, when authorized with the prior approval of the Office of the Executive Director.

* * * * *

Dated: January 27, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–01778 Filed 2–1–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 1b, 2, 157, and 380

[Docket No. RM15–26–000; Order No. 821]

Transferring Certain Dispute Resolution Service Matters to the Commission's Landowner Helpline

AGENCY: Federal Energy Regulatory Commission, Department of Energy (DOE).

ACTION: Final rule.

SUMMARY: The Commission is revising its regulations to reflect an internal reorganization. On June 14, 2013, the Dispute Resolution Service moved from the Commission's Office of Administrative Litigation (OAL) to the Commission's Office of Administrative Law Judges (OALJ), and the resulting new office was named the Office of Administrative Law Judges and Dispute Resolution (OALJDR). On January 11, 2015, the Commission designated a Landowner Helpline function in the OALJDR. The revised regulations substitute the Commission's recently established Landowner Helpline in place of the Commission's Dispute Resolution Service (DRS) as the contact for handling dispute-related calls, emails, and letters, pertaining to the construction and operation of jurisdictional infrastructure projects. This revision does not preclude disputants from utilizing other means to address disputes at the Commission. The transfer of responsibility for dispute-related calls, emails, and letters pertaining to infrastructure projects to the Landowner Helpline reflects an allocation of dedicated resources to serve the public interest.

DATES: This rule will become effective March 3, 2016.

FOR FURTHER INFORMATION CONTACT: Thomas Sharp, Office of the General Counsel, 888 First Street NE., Washington, DC 20426, 202–502–6461, *thomas.sharp@ferc.gov.*

SUPPLEMENTARY INFORMATION:

Order No. 821

Final Rule

(Issued January 21, 2016)

1. 1. By this instant Final Rule, the Commission is revising its regulations [1] to substitute the Commission's recently established Landowner Helpline in place of the Commission's Dispute Resolution Service (DRS) as the point of contact for dispute-related calls, emails, and letters, pertaining to the construction or operation of jurisdictional natural gas and hydroelectric projects. The Commission is implementing this Final Rule as a result of a recent internal reorganization, which designated a Landowner Helpline function in the Commission's Office of Administrative Law Judges and Dispute Resolution (OALJDR).

I. Background

2. The Commission's Enforcement Hotline has been in existence since June 1987. In April 1999, the Enforcement Hotline was codified under section 1b.21 of the Commission's regulations.[2] In addition to providing information to the public, and informal, non-binding staff opinions, any person may seek the Enforcement Hotline's assistance in the informal resolution of a dispute, provided that the dispute is not before the Commission in a docketed proceeding.[3] The Enforcement Hotline is staffed by personnel from the Division of Investigations in the Office of Enforcement.

3. On April 15, 2010, the Commission substituted the DRS, with its expertise in conflict resolution, for the Enforcement Hotline as the contact for landowners that have unresolved disputes with natural gas companies following use of the companies' environmental complaint resolution procedure.[4] The Commission also transferred the responsibility of dispute-related calls pertaining to the construction and operation of hydroelectric projects to DRS.[5]

4. The Commission's regulations require that natural gas companies seeking automatic authorization for replacement facilities or blanket certificate authorization for a project under the Natural Gas Act (NGA) must provide all affected landowners with a description of the company's environmental complaint resolution procedures, including company contact telephone numbers which landowners can use to identify and resolve environmental mitigation problems and concerns during construction of the project and restoration of the right-of-way.[6] Companies must also provide affected landowners with the current telephone number and email address of the DRS and instruct them that if they are not satisfied with the company's response to their complaints, they may contact the DRS.[7]

5. Going forward, the above-described DRS responsibilities will be handled by the new OALJDR Landowner Helpline.

II. Discussion

6. This Final Rule amends 18 CFR 157.203(d)(1)(iii)(D) to substitute the Commission's recently established Landowner Helpline for the DRS Helpline as the contact for members of the public that have unresolved disputes with pipeline companies following use of the pipeline companies' environmental complaint resolution procedure.[8] This Final Rule also removes and renumbers 18 CFR 1b.21 (g) and (h) to create 18 CFR 1b.22 (a) and (b), which substitutes the Commission's recently established Landowner Helpline for the DRS Helpline as the contact for any person affected by either the construction or operation of natural gas facilities under the NGA or by the construction or operation of a project under the Federal Power Act (FPA), who may wish to seek the informal resolution of a dispute. This final rule makes this same substitution in 18 CFR 2.55(c)(1)(ii)(C) and 18 CFR 380.15(c)(1)(ii)(C). These

[1] 18 CFR 1b.21(g-h), 2.55(c)(1)(ii)(C), 157.203(d)(1)(iii)(D), and 380.15(c)(1)(ii)(C) (2015).

[2] 18 CFR 1b.21 (2015).

[3] *Id.*

[4] *Instant Final Rule Transferring Certain Enforcement Hotline Matters to the Dispute Resolution Service,* 75 FR 21503, at 21504 (April 26, 2010); FERC Stat. & Regs. ¶ 31,308 (2010) (cross-referenced at 131 FERC ¶ 61,018 (2010)).

[5] *Id.* These include calls to OEP's Division of Hydropower Administration and Compliance (DHAC) regarding compliance with hydroelectric project licensing conditions which DHAC elects to refer to DRS.

[6] 18 CFR 157.203(d)(1)(iii) (2015).

[7] 18 CFR 157.203(d)(1)(iii)(D) (2015).

[8] Notwithstanding the name of the helpline, in accordance with section 1b.21(g), any person affected by a jurisdictional project—whether a landowner or not—may make use of the Landowner Helpline.

changes reflect the allocation of a dedicated Commission resource to serve the public interest.

III. Information Collection Statement

7. Office of Management and Budget (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.[9] However, this instant Final Rule does not contain or modify any information collection requirements.

IV. Environmental Analysis

8. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[10] Part 380 of the Commission's regulations lists exemptions to the requirement to draft an Environmental Assessment or Environmental Impact Statement, and this rulemaking qualifies under the exemption for procedural, ministerial or internal administrative actions.[11]

V. Regulatory Flexibility Act

9. The Regulatory Flexibility Act of 1980 (RFA) [12] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. This instant Final Rule concerns agency procedures. The Commission certifies that it will not have a significant economic impact upon participants in Commission proceedings. Therefore, an analysis under the RFA is thus not required.

VI. Document Availability

10. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

11. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

12. User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

13. These regulations are effective as an instant Final Rule without a period for public comment. Under 5 U.S.C. 533(b), notice and comment procedures are unnecessary where a rulemaking concerns only agency procedure or practice, or where the agency finds that notice and comment is unnecessary. This rule concerns only matters of agency procedure, and will not significantly affect regulated entities or the general public. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

14. These regulations are effective March 3, 2016.

List of Subjects

18 CFR Part 1b

Investigations.

18 CFR Part 2

Administrative practice and procedure, Electric utilities, Natural gas, Pipelines, Reporting and recordkeeping requirements.

18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

18 CFR Part 380

Environmental impact statements, Reporting and recordkeeping requirements.

By the Commission.

Issued: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission amends Parts 1b, 2, 157, and 380, Chapter I, Title 18, *Code of Federal Regulations,* as follows.

PART 1b—RULES RELATING TO INVESTIGATIONS

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

Authority: 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 792–828c, 2601–2645; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85 (1988); E.O. 12009, 3 CFR 1978 Comp., p. 142.

§ 1b.21 [Amended]

■ 2. Section 1b.21 is amended by removing paragraphs (g) and (h).

■ 3. Section 1b.22 is added to read as follows:

§ 1b.22 Landowner Helpline.

(a) Any person affected by either the construction or operation of a certificated or authorized natural gas project under the Natural Gas Act or by the construction or operation of a project under the Federal Power Act may seek the informal resolution of a dispute by contacting the Commission's Landowner Helpline. The Commission's Landowner Helpline may be reached by calling toll-free at 1–877–337–2237, or by email at *LandownerHelp@ferc.gov,* or writing to: Commission's Landowner Helpline, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

(b) Any person who contacts the Landowner Helpline is not precluded from filing a formal action with the Commission if discussions assisted by the Landowner Helpline staff are unsuccessful at resolving the matter. A caller may terminate the use of alternative dispute resolution procedures at any time.

PART 2—GENERAL POLICY AND INTERPRETATIONS

■ 4. The authority citation for Part 2 continues to read as follows:

Authority: 5 U.S.C. 601; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 792–828c, 2601–2645; 42 U.S.C. 4321–4370h, 7101–7352.

■ 5. Section 2.55(c)(1)(ii)(C) is revised to read as follows:

§ 2.55 Auxiliary installations and replacement facilities.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(C) A description of the Commission's Landowner Helpline, which an affected person may contact to seek an informal resolution of a dispute as explained in § 1b.22(a) of this chapter and the Landowner Helpline number.

* * * * *

[9] 5 CFR 1320.12 (2015).

[10] Order No. 486, *Regulations Implementing the National Environmental Policy Act of 1969,* 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986–1990 ¶ 30,783 (1987).

[11] 18 CFR 380.4(a)(1) (2015).

[12] 5 U.S.C. 601–612 (2012).

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

■ 6. The authority citation for Part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717z.

■ 7. Section 157.203(d)(1)(iii)(D) is revised to read as follows:

§ 157.203 Blanket certification.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(D) Instruct landowners that, if they are still not satisfied with the response, they may contact the Commission's Landowner Helpline at the current telephone number and email address, which is to be provided in the notification.

* * * * *

PART 380—REGULATIONS IMPLEMENTING THE NATIONAL ENVIRONMENTAL POLICY ACT

■ 8. The authority citation for Part 380 continues to read as follows:

Authority: 42 U.S.C. 4321–4370h, 7101–7352; E.O. 12009, 3 CFR 1978 Comp., p. 142.

■ 9. Section 380.15(c)(1)(ii)(C) is amended to read as follows:

§ 380.15 Siting and maintenance requirements.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(C) A description of the Commission's Landowner Helpline, which an affected person may contact to seek an informal resolution of a dispute as explained in § 1b.22(a) of this chapter and the Landowner Helpline number.

* * * * *

[FR Doc. 2016–01812 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 13–249; FCC 15–142]

Revitalization of the AM Radio Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) approved on January 19, 2016, for a period for three years, an information collection for FCC Form 338, AM Station Modulation Dependent Carrier Level (MDCL) Notification Form and 47 CFR 73.1560 contained in the Report and Order, FCC 15–142. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the requirements.

DATES: The amendment to 47 CFR 73.1560 in the final rule published at 81 FR 2751, January 19, 2016, is effective on March 3, 2016.

FOR FURTHER INFORMATION CONTACT: For additional information contact Cathy Williams, *Cathy.Williams@fcc.gov,* (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on January 19, 2016, OMB approved the information collection requirements for FCC Form 338, AM Station Modulation Dependent Carrier Level (MDCL) Notification Form and 47 CFR 73.1560, published at 81 FR2751 on January 19, 2016. The OMB Control Number is 3060–1194. The Commission publishes this document as an announcement of the effective date of the requirements. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–1194, in your correspondence. The Commission will also accept your comments via the Internet if you send them to *PRA@fcc.gov*.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on January 19, 2016, for the information collection requirements contained in the information collection 3060–1194.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1194. The foregoing document is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507. The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1194.

OMB Approval Date: January 19, 2016.

OMB Expiration Date: January 31, 2019.

Title: AM Station Modulation Dependent Carrier Level (MDCL) Notification Form; FCC Form 338.

Form Number: FCC Form 338.

Type of Review: New information collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 100 respondents and 100 responses.

Estimated Hours per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 100 hours.

Total Annual Costs: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 154(i), 303, 310 and 533 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality required with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On October 31, 2013, the Commission released the Notice of Proposed Rule Making, Revitalization of the AM Radio Service (NPRM), FCC 13–139, MB Docket No. 13–249. In the NPRM, the Commission recognized that in September 2011, the Media Bureau (Bureau) had released an MDCL Public Notice, in which it stated that it would permit AM stations, by rule waiver or experimental authorization, to use transmitter control techniques that vary either the carrier power level or both the carrier and sideband power levels as a function of the modulation level. This allows AM licensees to reduce power consumption while maintaining audio quality and their licensed station

coverage areas. These techniques are known as Modulation Dependent Carrier Level (MDCL) control technologies.

There are two basic types of MDCL control technologies. In one type, the carrier power is reduced at low modulation levels and increased at higher modulation levels. In the other type, there is full carrier power at low modulation levels and reduced carrier power and sideband powers at higher modulation levels. Use of any of these MDCL control technologies reduces the station's antenna input power to levels not permitted by 47 CFR 73.1560(a).

The MDCL Public Notice permitted AM station licensees wanting to use MDCL control technologies to seek either a permanent waiver of 47 CFR 73.1560(a) for those licensees already certain of the particular MDCL control technology to be used, or an experimental authorization pursuant to 47 CFR 73.1510 for those licensees wishing to determine which of the MDCL control technologies would result in maximum cost savings and minimum effects on the station's coverage area and audio quality. Since release of the MDCL Public Notice, 33 permanent waiver requests and 20 experimental requests authorizing use of MDCL control technologies have been granted by the Bureau.

AM station licensees using MDCL control technologies have reported significant savings on electrical power costs and few, if any, perceptible effects on station coverage area and audio quality. Accordingly, the NPRM tentatively concluded that use of MDCL control technologies reduces AM broadcasters' operating costs while maintaining a station's current level of service to the public, without interference to other stations. The Commission therefore, proposed wider implementation of MDCL control technologies by amending 47 CFR 73.1560(a), to provide that an AM station may commence operation using MDCL control technology without prior Commission authority, provided that the AM station licensee notifies the Commission of the station's MDCL control operation within 10 days after commencement of such operation using the Bureau's Consolidated Database System (CDBS). The NPRM solicited comments on the proposed rule change, as well as on the potential adverse effects of allowing AM stations to commence MDCL control technology operation without prior Commission authority. The NPRM also sought comment as to the potential adverse effects, if any, of MDCL control technology implementation on other AM stations.

AM broadcasters are allowed to implement MDCL technologies without prior authorization, by electronic notification within 10 days of commencing MDCL operations, the Commission created FCC Form 338, AM Station Modulation Dependent Carrier Level (MDCL) Notification. In addition to the standard general contact information, FCC Form 338 solicits minimal technical data, as well as the date that MDCL control operation commenced.

The following rule section is also covered by this information collection:

47 CFR 73.1560(a)(1) specifies the limits on antenna input power for AM stations. AM stations using MDCL control technologies are not required to adhere to these operating power parameters. AM stations may, without prior Commission authority, commence MDCL control technology use, provided that within ten days after commencing such operation, the licensee submits an electronic notification of commencement of MDCL operation using FCC Form 338. OMB preapproved the information collection requirements contained in FCC 13–139 on January 28, 2014. The final information collection requirements were adopted as proposed in FCC 15–142. OMB approved the final information collection requirements on January 19, 2016.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–01321 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 141021887–5172–02]

RIN 0648–XE418

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Pot Catcher/Processors in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher/processors using pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the A season apportionment of the 2016 Pacific cod total allowable catch allocated to catcher/processors using pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), January 29, 2016, through 1200 hours, A.l.t., September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season apportionment of the 2016 Pacific cod total allowable catch (TAC) allocated to catcher/processors using pot gear in the BSAI is 1,712 metric tons (mt) as established by the final 2015 and 2016 harvest specifications for groundfish in the BSAI (80 FR 11919, March 5, 2015) and inseason adjustment (81 FR 184, January 5, 2016).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the A season apportionment of the 2016 Pacific cod TAC allocated as a directed fishing allowance to catcher/processors using pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by pot catcher/processors in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from

responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by pot catcher/processors in the BSAI. NMFS was unable to publish a document providing time for public comment because the most recent, relevant data only became available as of January 27, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: January 28, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–01851 Filed 1–28–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 21
Tuesday, February 2, 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 ENERGY

10 CFR Part 900

RIN 1901–AB36

Coordination of Federal Authorizations for Electric Transmission Facilities

AGENCY: Office of Electricity Delivery and Energy Reliability, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Energy (DOE) proposes to amend its regulations for the timely coordination of Federal Authorizations for proposed interstate electric transmission facilities pursuant to section 216(h) of the Federal Power Act (FPA). The proposed amendments are intended to improve the pre-application procedures and result in more efficient processing of applications.

DATES: Public comment on this proposed rule will be accepted until April 4, 2016. DOE will hold a public workshop and will announce the date, time and location in a subsequent notice.

ADDRESSES: You may submit comments, identified by RIN 1901–AB36, by any of the following methods:

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

2. Send email to *oeregs@hq.doe.gov*. Include RIN 1901–AB36 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment.

3. Address postal mail to U.S. Department of Energy, Office of Electricity Delivery and Energy Reliability, Mailstop OE–20, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585.

Due to potential delays in the delivery of postal mail, we encourage respondents to submit comments electronically to ensure timely receipt.

This notice of proposed rulemaking and any comments that DOE receives will be made available on the DOE Web site at *http://energy.gov/oe/services/electricity-policy-coordination-and-implementation/transmission-planning/improving*. You may request a hardcopy of the workshop transcript or comments be sent to you via postal mail by contacting the DOE's Office of Electricity Delivery and Energy Reliability.

FOR FURTHER INFORMATION CONTACT: Julie A. Smith, Ph.D. with the U.S. Department of Energy, Office of Electricity Delivery and Energy Reliability, Mailstop OE–20, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585; or *oeregs@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: *Acronyms and Abbreviations.* A number of acronyms and abbreviations are used in this preamble. While this may not be an exhaustive list, to ease the reading of this preamble and for reference purposes, the following terms, acronyms, and abbreviations are defined as follows:

CEQ Council on Environmental Quality
CFR Code of Federal Regulations
DOE Department of Energy
EIS Environmental Impact Statement
E.O. Executive Order
EPAct Energy Policy Act of 2005
FERC Federal Energy Regulatory Commission
FPA Federal Power Act
FR Federal Register
IIP Integrated Interagency Pre-Application
MOU Memorandum of Understanding
NEPA National Environmental Policy Act
OMB Office of Management and Budget
PM Presidential Memorandum
PMA Federal Power Marketing Administration
RFI Request for Information
RRTT Rapid Response Team for Transmission
RTO Regional Transmission Operators

I. Background

The Energy Policy Act of 2005 (Pub. L. 109–58) (EPAct) established a national policy to enhance and, to the extent possible, increase the coordination and communication among Federal agencies with authority to site electric transmission facilities. The policies set forth by Congress in EPAct reinforced policies announced in E.O. 13212, Actions to Expedite Energy-Related Projects (66 FR 28357, May 22, 2001) by mandating each agency with the authority to issue Federal authorizations to ensure the timely and coordinated review and permitting of electric transmission facilities. Section 1221(a) of EPAct added a new section 216(h) to the Federal Power Act (16 U.S.C. 791–828c) (FPA), which sets forth provisions relevant to the siting of interstate electric transmission facilities. Section 216(h) of the FPA (16 U.S.C. 824p(h)), ''Coordination of Federal Authorizations for Transmission Facilities,'' provides for DOE to coordinate all Federal authorizations and related environmental reviews needed for siting interstate electric transmission projects, including National Environmental Policy Act of 1969 (NEPA) reviews.

Section 216(h) of the FPA provides for the coordination of Federal transmission siting determinations for project proponents seeking permits, special use authorizations, certifications, opinions, or other approvals required under Federal law to site an electric transmission facility. Section 216(h)(3) requires the Secretary, to the maximum extent practicable under Federal law, to coordinate the Federal authorization and review process with any Indian tribes, multi-state entities, and state agencies that have their own separate permitting and environmental reviews. Section 216(h)(4)(C) further requires that DOE establish an expeditious pre-application mechanism to allow project proponents to confer with Federal agencies involved, and for each such agency to communicate to the proponent any information needs relevant to a prospective application and key issues of concern to the

agencies and public. The DOE proposes to amend its existing regulations to implement the Integrated Interagency Pre-application (IIP) process described in section II.

On September 19, 2008, DOE published an interim final rule establishing procedures under which prospective applicants may request that DOE coordinate interstate electric transmission facilities and related environmental reviews pursuant to FPA section 216(h) (73 FR 54456). The interim final rule became effective on October 20, 2008, and the regulations can be found at 10 CFR 900.1 through 900.6. Also on September 19, 2008, DOE published a notice of proposed rulemaking (NOPR), which proposed amendments to the interim final rule (73 FR 54461) that was intended to amend the interim final rule. Comments were filed in response to the 2008 interim final rule and 2008 NOPR. DOE addressed the comments submitted in response to both the interim final rule and the 2008 NOPR in another NOPR issued on December 13, 2011 (76 FR 77432).[1]

On October 23, 2009, DOE and eight other Federal agencies with permitting or other Federal authorization responsibility for the siting of electric transmission facilities entered into a ''Memorandum of Understanding Regarding Coordination in Federal Agency Review of Electric Transmission Facilities on Federal Land'' (2009 MOU). The signatories to the 2009 MOU were DOE, the Departments of Defense, Agriculture (USDA), the Interior (DOI), and Commerce, the Federal Regulatory Energy Commission (FERC), the Environmental Protection Agency (USEPA), the Council on Environmental Quality (CEQ), and the Advisory Council on Historic Preservation.

The purpose of the 2009 MOU is to establish a framework to improve coordination among project proponents, Federal agencies, states, and tribes involved in the siting and permitting process for electric transmission facilities on Federal lands. The MOU is intended to improve uniformity, consistency, and transparency by describing each entity's role and responsibilities when project proponents wish to build electric transmission facilities. Additionally, the MOU designates a ''Lead Agency'' serving as the single point-of-contact for coordinating all Federal environmental reviews necessary to site electric transmission facilities on Federal lands. In most instances, the Departments of Agriculture or Interior will be the Lead Agency, since they have jurisdiction over most of the Federal lands and right-of-ways for proposed electric transmission facilities. Nothing in this proposed rule modifies this aspect of the MOU. The proposed 10 CFR 900.5 would maintain the agreements reached in the MOU in the context of identifying and selecting a potential NEPA lead for environmental reviews once applications for Federal authorizations are received by Federal agencies.

In October 2011, in an effort to improve the performance of Federal siting, permitting, and review processes for infrastructure development, the President created a Rapid Response Team for Transmission (RRTT), a collaborative effort involving nine executive departments and agencies that are signatories to the 2009 MOU. The RRTT is an interagency group working to improve the efficiency, effectiveness and predictability of transmission siting, permitting, and review processes, in part through increasing interagency coordination and transparency. Lessons learned through the RRTT have informed the Integrated Interagency Pre-application (IIP) process proposed in this proposed rule.

On March 22, 2012, the President issued Executive Order 13604, ''Improving Performance of Federal Permitting and Review of Infrastructure Projects'' that directed all Federal executive departments and agencies to take all authorized steps, consistent with available resources, to execute Federal permitting and review processes with maximum efficiency and effectiveness, ensuring the health, safety, and security of communities and the environment while supporting economic growth. The E.O. emphasized early and active consultation with tribal, state, and local governments to avoid conflicts or duplication of effort, resolve concerns, and allow for concurrent rather than sequential reviews. The E.O. also noted that these elements must be integrated into project planning processes so that projects are designed to avoid, minimize or mitigate, to the extent practicable, adverse impacts on public health, security, historic properties and cultural resources, and the environment.

On May 17, 2013, the President issued a memorandum on Modernizing Federal Infrastructure Review and Permitting Regulations, Policies, and Procedures to the heads of Executive Departments and Agencies, that discussed agency best practices identified as a result of E.O. 13604. These best practices include, but are not limited to: Early coordination among Federal agencies, as well as with tribal, state, and local governments; strategic outreach to stakeholders; project-planning processes and individual project designs that consider local and regional ecological planning goals; landscape- and watershed-level mitigation practices; sharing of scientific and environmental data in open-data formats to minimize redundancy, facilitate informed project planning, and identify data gaps early in the review and permitting process; and the application of best environmental and cultural practices as set forth in the governing statutes.

On June 7, 2013, the President issued a memorandum on Transforming our Nation's Electric Grid Through Improved Siting, Permitting, and Review to the heads of Executive Departments and Agencies. Building on the work of the RRTT, that memorandum strongly affirms that robust collaboration among Federal, tribal, state, and local governments must be a critical component of the Administration's effort to improve the Federal siting, permitting, and review processes for transmission projects because a single project may cross multiple governmental jurisdictions over hundreds of miles. Section 4(a) of the memorandum directs that Member Agencies of the Steering Committee created under E.O. 13604 to develop an integrated, interagency pre-application process for significant onshore electric transmission projects requiring Federal approval. The process must be designed to: Promote predictability in Federal siting, permitting, and review processes; encourage early engagement, coordination, and collaboration of Federal, tribal, state, and local governments, non-governmental organizations, and the public; increase the use of integrated project planning early in the siting, permitting, and review processes; facilitate early identification of issues that could diminish the likelihood that projects will ultimately be permitted; promote early planning for integrated and

[1] With the publication of this proposed rule, DOE withdraws a previously proposed rulemaking for the Coordination of Federal Authorizations for Electric Transmission Facilities in December 2011 (76 FR 77432; Dec. 13, 2011). In that action, DOE proposed requirements for permitting entities to inform DOE of requests for authorizations, established a process by which prospective Project Proponents may request DOE's coordination under section 216(h) for Federal authorizations for interstate electric transmission facilities, provided for the selection of a Federal lead agency for the purposes of compiling a single environmental review document and consolidated administrative record for Qualifying Projects, as well as provided for the establishment of intermediate and final deadlines for the review of Federal authorization decisions, as well as established a date certain after which all permit decisions and related environmental reviews under all applicable Federal laws shall be completed in one year or as soon thereafter as permissible by law.

strategic mitigation plans; expedite siting, permitting, and review processes through a mutual understanding of the needs of all affected Federal agencies and tribal, state, and local governments; and improve environmental and cultural resource outcomes.

On August 29, 2013, DOE published a Request for Information (RFI) seeking information on a new draft IIP Process for significant onshore electric transmission projects requiring Federal authorizations developed by the RRTT. The proposed IIP Process presented in the RFI consisted of a series of four (4) iterative meetings, with direct federal involvement throughout the entire development of a transmission line project—from the identification of two substation endpoints (study area), to the selection of study corridors within a study area, and through identification of route alternative(s) within those study corridors. In response to comments received from the public, Federal agencies, state agencies, environmental groups, and industry representatives,[2] DOE proposes a revised simplified IIP Process that consists of two (2) meetings that focus on projects in which study corridors and route alternatives are already under development. The IIP Process is discussed in section II of this proposed rule.

II. Discussion of Proposed Rule

A. General

10 CFR 900.1 states the purpose of the regulations, which is to provide a process for the timely coordination of Federal authorizations for proposed transmission facilities pursuant to section 216(h) of the FPA (16 U.S.C. 824p(h)), including the development of an early pre-application process in support of this coordination and the selection of a NEPA lead agency. These proposed regulations provide a framework for DOE to coordinate early cooperation and exchange of environmental information. These proposed regulations provide a framework for DOE to facilitate early cooperation and exchange of environmental information required to site qualified electric transmission facilities. These activities would occur prior to an applicant filing a request for authorization with Federal permitting agencies. The proposed regulations also provide an opportunity for non-Federal agencies (tribal, state, or local governments) to coordinate separate non-Federal permitting and environmental reviews with that of the Federal permitting agencies.

B. Applicability

Section 900.2 of the proposed rule explains when the provisions of part 900 would apply to the coordination of Federal authorizations. The provisions of part 900, which are consistent with DOE's existing regulations and the 2009 MOU, would apply to Qualifying Projects, and would also apply to Other Projects at the discretion of the Assistant Secretary of DOE's Office of Electricity Delivery and Energy Reliability (OE–1). Both types of projects must be for transmission facilities that are used for the transmission of electric energy in interstate commerce, but Qualifying Projects are generally 230 kV or above and cross jurisdictions administered by more than one Federal Entity or MOU Signatory Agency.

Further, there would be no coordination role for DOE for Federal authorizations for electric transmission facilities located within the Electric Reliability Council of Texas (ERCOT) interconnection because section 216(k) of the FPA states that section 216 of the FPA shall not apply within the ERCOT area (16 U.S.C. 824p(k)). Section 900.2 also provides that section 216(h) does not apply when an application has been submitted to FERC for issuance of a permit for construction or modification of a transmission facility, or a pre-filing procedure has been initiated, under section 216(b) of the FPA (16 U.S.C. 824p(b)) (transmission lines within a DOE-designated National Interest Electric Transmission Corridor). In those circumstances, DOE has delegated its section 216(h) coordination authority to FERC and, in Order No. 689,[3] FERC adopted regulations setting forth the procedures it will follow in such circumstances.

Section 900.2 also provides that this part does not apply to transmission lines that cross the U.S. international border, Federal submerged lands, national marine sanctuaries, marine national monuments, or facilities constructed by Federal Power Marketing Administrations (PMAs).[4] Section 216(h) does not affect any requirements of U.S. environmental laws, and in the above mentioned cases, does not waive any requirements to obtain necessary Federal authorizations for electric transmission facilities.

C. Definitions

Section 900.3 defines terms for this part.

D. Integrated Interagency Pre-Application (IIP) Process

Section 900.4 provides the procedures and information requirements of the proposed IIP Process. This section sets forth a proposed framework for implementing the proposed IIP Process, provisions for how DOE would fulfill its section 216(h) Lead Coordinating Agency role as defined in § 900.2 of this part, provisions describing expected outcomes of each IIP Initial Meeting and IIP Close-Out Meeting, and provisions describing the nature and purpose of products generated during the IIP Process (*e.g.,* Final IIP Environmental Report).

For proponents of Qualifying Projects, participation in the IIP Process is voluntary. A Project Proponent initiates the IIP Process by submitting an Initiation Request as described in proposed § 900.4. A Project Proponent may elect to request initiation of the IIP Process for a Qualifying Project or Other Project as defined in § 900.2. The timing of the Initiation Request is determined by the Project Proponent.

When a Project Proponent elects to utilize the IIP Process, DOE will require the active participation of the Project Proponent to ensure effective coordination covered in this part. Active participation includes providing project-related and environmental information required as part of the Initiation Request to DOE. DOE must determine that adequate information has been provided by the Project Proponent consistent with § 900.4 before DOE will initiate its coordination function under this part.

Information requested as part of the Initiation Request in this proposed rule retains many of the existing requirements contained in § 900.5 ''Request for coordination' of the existing section 216(h) regulation (January 2011), and expands on some of those elements based on RRTT agency experience and information received in response to the August 2013 RFI (78 FR 53436). DOE will provide electronic access to a checklist, as well as other helpful information and publicly-available resources in a central electronic repository, as currently

[2] Comments received in response to the 2013 RFI may be accessed at: *http://energy.gov/oe/downloads/comments-request-information-improving-performance-Federal-permitting-and-review.*

[3] Department of Energy Delegation Order No. 00–004–00A, sec. 1.22, issued May 16. 2006.

[4] DOE does not consider applications to the PMAs for transmission interconnections to be Federal authorization requests within the meaning of 216(h).

provided for in § 900.6(b) of the existing regulations at 10 CFR part 900.[5]

DOE will notify and request participation by all Federal Entities in the IIP Process that have a potential authorization or consultation for a Qualifying Project after DOE has reviewed and determined that an Initiation Request meets the informational requirements of § 900.4(a) through (d). All Federal Entities notified by DOE as having a potential authorization or consultation required for the siting of a Qualifying Project will be expected to participate in the Initial Meeting and the Final Meeting, unless the notified agency clarifies in writing to DOE within seven (7) calendar days of notification that they do not have any involvement or have minimal involvement, along with the supporting rationale used by the notified agency for their non- or minimal involvement. [6]

DOE will schedule IIP meetings no less than thirty (30) calendar days from each other and only after Federal Entities are given notice of the need for their participation in the IIP Process. The notification described applies to both initiation and close-out of the IIP Process, in response to the Project Proponent's request for such meetings.

The list of Federal Entities notified by DOE following its review of the Initiation Request as having a potential authorization or consultation required for the siting of a Qualified Project may be revised as necessary during the IIP Process based on information provided by the Project Proponent, the Federal Entity, and otherwise publicly-available information. DOE will oversee the IIP Process and coordinate the involvement of the Federal Entities as described below in § 900.4 even though DOE is not responsible for issuing a Federal Authorization. DOE will provide Federal Entities and Non-Federal Entities access to all information received from the Project Proponent as a part of an Initiation Request determined by DOE to meet the information requirements of this part in § 900.4, which will be coordinated through the use of the Office of Management and Budget's (OMB's) MAX electronic system (*https://max.omb.gov/maxportal*) throughout an IIP Process for a Qualifying Project.

In-person attendance at IIP Process meetings by each Federal Entity will depend on the availability of resources or the authority to recover costs from Project Proponents. Currently, certain Federal Entities may recover costs only after an application has been submitted, and some Federal entities lack cost recovery authority altogether. Even in instances where cost recovery may be available, each Federal agency will make its own determination regarding its participation and use of resources. Each Federal agency will provide its rationale to DOE in writing when or if a determination is made that it may not be expeditious to use of staff time and funds to attend all or some meetings. To the extent allowed by law Federal Entities may seek cost recovery from the Project Proponents during the IIP Process. DOE will provide an opportunity for Federal and Non-Federal Entities to participate in IIP meetings by using teleconferencing and webinars.

Coordinating the preparation of the Final IIP Resources Report document prepared by DOE and related administrative file will facilitate more efficient preparation of a single environmental review document that all agencies can strive to utilize to inform their relevant decision making. The Final IIP Resources Report is designed in terms of format and substance to be similar to an ''early corporate environmental assessment'' or typical applicant-generated environmental study in accordance with: (1) Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR parts 1500 through 1508); (2) CEQ guidance related to early consultation or engagement of Federal agencies with prospective applicants; and (3) NEPA's Forty Most Asked Questions related to the ability of agencies to authorize preparation of environmental assessments by applicants (46 FR 18026; March 23, 1981, as amended). [7] Such actions continue to be encouraged by CEQ as ''they call for private, Federal and non-Federal entities to build environmental considerations into their own planning processes in a way that facilitates the application of NEPA and avoids delay.'' [8]

The Final IIP Resources Report will be included by DOE, along with all other support information, datasets, maps, figures, etc. collected as part of the IIP Process in an IIP Process Administrative File that would be provided to the NEPA Lead Agency to inform their environmental reviews once an application is filed. This information can, and should, also be used by other agencies on related decision making. DOE will maintain the IIP Process Administrative File for the duration of the IIP Process and until no later than thirty (30) calendar days after the IIP Close out Meeting has been convened.

E. Selection of NEPA Lead Agency

Section 900.5 provides a mechanism for the identification and selection of a NEPA Lead Agency responsible for meeting Federal environmental review requirements [9] for permitting interstate transmission lines across multiple Federal jurisdictions once applications are filed with permitting agencies. This section incorporates the terms and mechanisms provided for identification and determination of NEPA Lead Agency for transmission facilities proposed for siting on majority Federal lands as set forth in the 2009 MOU and in accordance with CEQ's NEPA regulations.

F. IIP Process Administrative File

Section 900.6 defines the contents of a consolidated IIP Process Administrative File intended to document IIP Process-related products and information. This new section replaces the existing § 900.6. This section also describes the intent and process by which this file will be maintained by DOE as Lead 216(h) Agency in coordination with the Federal Entities for the duration of the IIP Process.

III. Regulatory Review

A. Executive Orders 12866 and 13563

This regulatory action has been determined to be a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

DOE has also reviewed this regulation pursuant to Executive Order 13563,

[5] Electronic tools currently exist that may serve as a resource for the information required as a part of the IIP Process. For example, the Regulatory and Permitting Information Desktop (RAPID) Toolkit, an online tool that streamlines the challenge of siting and permitting transmission lines in the West. The RAPID Toolkit offers a single location for agencies, developers, and industry stakeholders to work together on electric energy transmission regulatory processes by using a wiki environment to collaborate on regulatory processes, permit guidance, regulations, contacts, and other relevant information. The RAPID Toolkit can be accessed at *http://en.openei.org/wiki/RAPID*.

[6] Provided, however, that a Federal Entity whose permitting authority for the construction or modification of electric transmission facilities is limited to those facilities for which an application is filed under section 216(b) of the Federal Power Act may participate at its sole discretion.

[7] CEQ, NEPA's Forty Most Asked Questions (46 FR 18026; March 23, 1981, as amended), Question 8 discusses ''early corporate environmental assessments''

[8] *Id.*

[9] Each participating Federal Entity is responsible for meeting its own agency-specific requirements.

issued on January 18, 2011 (76 FR 3281, Jan. 21, 2011). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE concludes that this proposed rule is consistent with these principles. Specifically, this proposed rule sets forth voluntary procedures for DOE coordination of Federal Authorizations for the siting of interstate electric transmission facilities. As described in section III.C., therefore, the costs of the rule will impact Federal agencies. Among the benefits expected from this proposed rule, actions taken to coordinate information and agency communication before applications for Federal Authorizations are submitted to Federal agencies for review and consideration would help reduce application review and decision-making timelines. Because use of the proposed IIP Process is voluntary, DOE further expects that the Project Proponent requesting assistance has made the calculation that the request was in the best interests of the Project Proponent. The request would also help transmission developers determine the likelihood that they would successfully obtain permits, which is necessary to make their proposed project successful in the competitive, regional transmission planning processes.

B. National Environmental Policy Act

DOE has determined that promulgation of these regulations fall into a class of actions that does not individually or cumulatively have a significant impact on the human environment as set forth under DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq*). Specifically, this rulemaking is covered under the Categorical Exclusion found in the DOE's National Environmental Policy Act regulations at paragraph A6 of Appendix A to Subpart D, 10 CFR part 1021, which applies to Rulemakings that are strictly procedural. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.)* requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of General Counsel's Web site: *http://www.gc.doe.gov.*

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. This proposed rule sets forth simplified or revised procedures for DOE coordination of Federal Authorizations for the siting of interstate electric transmission facilities. As a result, the rule directly impacts Federal agencies and not small entities. In those cases where a Project Proponent requests DOE assistance for a project that is not a Qualifying Project, DOE expects that the provisions of this proposed rule, if adopted, would not affect the substantive interests of such Project Proponents, including any Project Proponents that are small entities. DOE expects actions taken under the proposed provisions to coordinate information and agency communication before applications for Federal Authorizations are submitted to Federal agencies for review and consideration would help reduce application review and decision-making timelines. Because use of the IIP Process set forth in the proposed rule is voluntary, DOE further expects that the Project Proponent requesting assistance has made the calculation that the request was in the best interests of the Project Proponent. The request would also help facilitate transmission developers with determining the likelihood that they would successfully obtain permits, which is necessary to make their proposed project successful in the competitive, regional transmission planning processes. On the basis of the foregoing, DOE certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

D. Paperwork Reduction Act

The proposed rule contains information collection requirements subject to review and approval by OMB pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.* This requirement has been submitted to OMB for approval. Public reporting burden for requesting information during the pre-application process is estimated to average 30 minutes per response. Public reporting burden for requesting DOE assistance in the Federal authorization process is estimated to average one hour per response. Both of these burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

DOE invites public comment on: (1) Whether the proposed information collection requirements are necessary for the performance of DOE's functions, including whether the information will have practical utility; (2) the accuracy of DOE's estimates of the burden of the proposed information collection requirements; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection requirements on respondents. Comments should be addressed to the DOE Desk Officer, Office of Information and Regulatory Affairs, OMB, 725 17th Street NW.,

Washington, DC 20503. Persons submitting comments to OMB also are requested to send a copy to the contact person at the address given in the **ADDRESSES** section of this notice of proposed rulemaking. Interested persons may obtain a copy of the DOE's Paperwork Reduction Act Submission to OMB from the contact person named in this notice of proposed rulemaking.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) generally requires Federal agencies to examine closely the impacts of regulatory actions on tribal, state, and local governments. Subsection 101(5) of title I of that law defines a Federal intergovernmental mandate to include any regulation that would impose upon tribal, state, or local governments an enforceable duty, except a condition of Federal assistance or a duty arising from participating in a voluntary Federal program. Title II of that law requires each Federal agency to assess the effects of Federal regulatory actions on tribal, state, and local governments, in the aggregate, or to the private sector, other than to the extent such actions merely incorporate requirements specifically set forth in a statute. Section 202 of that title requires a Federal agency to perform a detailed assessment of the anticipated costs and benefits of any rule that includes a Federal mandate which may result in costs to tribal, state, or local governments, or to the private sector, of $100 million or more in any one year (adjusted annually for inflation). 2 U.S.C. 1532(a) and (b). Section 204 of that title requires each agency that proposes a rule containing a significant Federal intergovernmental mandate to develop an effective process for obtaining meaningful and timely input from elected officers of tribal, state, and local governments. 2 U.S.C. 1534.

This proposed rule would revise procedures for an Integrated Interagency Pre-application process by which transmission developers, Federal, state, local agencies and tribes may coordinate early either in person or via teleconference/web conference and share information through the existing Office of Management and Budget MAX Web site collaborative tool. DOE has determined that the proposed rule would not result in the expenditure by tribal, state, and local governments in the aggregate, or by the private sector, of $100 million or more in any one year. Accordingly, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

F. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well being. The proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

G. Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt state law and would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

H. Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

I. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on

energy supply, distribution, and use. This regulatory action, which is intended to improve the pre-application procedures for certain transmission projects and therefore result in the more efficient processing of applications, would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved the publication of this proposed rule.

List of Subjects in 10 CFR Part 900

Electric power, Electric utilities, Energy, Reporting and record keeping requirements.

Issued in Washington, DC, on January 20, 2016.

Patricia A. Hoffman,

Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

For the reasons stated in the preamble, DOE proposes to revise part 900 of chapter II of title 10, Code of Federal Regulations as set forth below:

PART 900—COORDINATION OF FEDERAL AUTHORIZATIONS FOR ELECTRIC TRANSMISSION FACILITIES

Sec.

Authority: 16 U.S.C. 824p(h).

§ 900.1 Purpose.

This part provides a process for the timely coordination of information needed for Federal authorizations for proposed electric transmission facilities pursuant to section 216(h) of the Federal Power Act (FPA) (16 U.S.C. 824p(h)). This part seeks to ensure electric transmission projects are consistent with the nation's environmental laws, including laws that protect endangered and threatened species, critical habitats and historic properties. This part provides a framework called the Integrated Interagency Pre-Application (IIP) process by which DOE cooperates with applicable Federal and non-Federal entities for the purpose of early coordination of information for permitting and environmental reviews required under Federal law to site qualified electric transmission facilities prior to submission of required Federal request(s). The IIP process provides for timely and focused pre-application meetings with key Federal and non-Federal entities, as well as for early identification of potential siting constraints or opportunities, and seeks to promote thorough and consistent stakeholder outreach by a project proponent during transmission line planning efforts. The IIP process occurs before any application or request for authorization is submitted to Federal entities. This part improves the siting process by facilitating the early submission, compilation, and documentation of information needed for subsequent coordinated, transparent environmental review of a Qualifying Project or approved Other Project by Federal entities under the National Environmental Policy Act (NEPA) following the submission of an application or request for authorization. This part also provides an opportunity for non-Federal entities to coordinate their non-Federal permitting and environmental reviews with that of the Federal entities.

§ 900.2 Applicability.

(a) The regulations under this part apply to Qualifying Projects. At the discretion of the Assistant Secretary (OE–1) the provisions of part 900 may also apply to Other Projects.

(b) *Other Projects.* (1) Persons seeking DOE assistance in the Federal Authorization process for Other Projects must file a request for coordination with the OE–1. The request must contain:

(i) The legal name of the requester; its principal place of business; whether the requester is an individual, partnership, corporation, or other entity; citations to the state laws under which the requester is organized or authorized; and the name, title, and mailing address of the person or persons to whom communications concerning the request for coordination are to be addressed;

(ii) A concise general description of the proposed Other Project sufficient to explain its scope and purpose;

(iii) A list of all potential Federal entities; and

(iv) A list of anticipated non-Federal entities, including any agency serial or docket numbers for pending applications.

(2) Within thirty (30) calendar days of receiving this request, the OE–1, in consultation with the affected Federal Entities with jurisdiction, will determine if the Other Project should be treated as a Qualifying Project under this part and will notify the Project Proponent of one of the following:

(i) If accepted for processing under this rule, the project will be treated as a Qualifying Project and the Project Proponent must submit an Initiation Request as set forth under § 900.5; or

(ii) If not accepted for processing under this rule, the Project Proponent must follow the standard procedures for Federal Entities that will have jurisdiction over the project.

(c) This part does not apply to Federal Authorizations for electric transmission facilities wholly located within the Electric Reliability Council of Texas interconnection.

(d) This part does not apply to electric transmission facilities in a DOE-designated National Interest Electric Transmission Corridor where a Project Proponent seeks a construction or modification permit from the Federal Energy Regulatory Commission (FERC) under section 216(b) of the Federal Power Act (16 U.S.C. 824p(b)).

(e) This part does not affect any requirements of Federal law. Participation or non-participation in the IIP process does not waive any requirements to obtain necessary Federal authorizations for electric transmission facilities. This part shall not alter or diminish any responsibilities of the Federal entities to consult under applicable law.

(f) This part does not supplant but rather complements the Federal entities' pre-application procedures for a Federal authorization. Participation in the IIP Process does not guarantee issuance of any required Federal authorization for a proposed Qualifying Project or selection of the project proponent's proposed study corridors and proposed routes as a range of reasonable alternatives or the preferred alternative for NEPA purposes.

(g) DOE, in exercising its responsibilities under this part, will communicate regularly with the FERC, electric reliability organizations and electric transmission organizations approved by FERC, other Federal entities, and Project Proponents. DOE will use information technologies to provide opportunities for Federal entities to participate remotely.

(h) DOE, in exercising its responsibilities under this part, will to the maximum extent practicable and consistent with Federal law, coordinate the IIP Process with any non-Federal entities. DOE will use information technologies to provide opportunities for non-Federal entities to participate remotely.

§ 900.3 Definitions.

As used in this part:

Affected landowner means an owner of real property interests who is usually referenced in the most recent county or

city tax records, and whose real property:

(1) Is located within either 0.25 miles of a proposed centerline of a Qualifying Project or at a minimum distance specified by state law, whichever is greater; or

(2) Contains a residence within 3000 feet of a proposed construction work area for a Qualifying Project.

DOE means the United States Department of Energy.

Early identification of project issues refers to an early and open stakeholder participation process carried out by a project proponent to identify potential environmental issues Federal and non-Federal entities' may consider for further study, issues of concern to the affected public and stakeholders, and potential project alternatives.

Federal authorization means any authorization required under Federal law to site an electric transmission facility, including permits, rights-of-way, special use authorizations, certifications, opinions, or other approvals. This term includes those authorizations that may involve determinations under Federal law by either Federal or non-Federal entities.

Federal entity means any Federal agency with jurisdictional interests that may have an effect on a proposed Qualifying Project, that is responsible for issuing a Federal authorization for the proposed Qualifying Project or attendant facilities, has relevant expertise with respect to environmental and other issues pertinent to or that are potentially affected by the proposed Qualifying Project or its attendant facilities, or provides funding for the proposed Qualifying Project or its attendant facilities. Federal entities include those with either permitting or non-permitting authority; for example, those entities with which consultation or review must be completed before a project may commence, such as the Department of Defense for an examination of military test, training or operational impacts.

FPA means the Federal Power Act (16 U.S.C. 791 through 828c).

IIP Process Administrative File means the information assembled and maintained by DOE as the Lead 216(h) Agency and the NEPA Lead Agency for all Federal authorization decisions. The IIP Process Administrative File will include, without limitation, the IIP Initiation Request, which includes a summary of Qualifying Project, Affected Environmental Resources and Impacts summary, associated maps, geospatial information, and data (provided in electronic format), and a summary of Early Identification of Project Issues, IIP meeting summaries, and other documents, including but not limited to maps, publicly-available data, and other supporting documentation submitted by the project proponent as part of the IIP Process, and that inform the Federal entities.

IIP Resource Report means the resource summary information provided by the Project Proponent as a part of the IIP process that meets the content requirements pursuant to § 900.4. The IIP Resource Report contains the environmental information used by a Project Proponent to plan a Qualifying Project.

Indian tribe has the same meaning as provided for in 25 U.S.C. 450b(e).

Lead 216(h) Agency means the Department of Energy, which section 216(h) of the FPA (16 U.S.C. 824p(h)) makes responsible for timely coordination of Federal authorization requests for proposed electric transmission facilities.

MOU signatory agency means a signatory of the interagency MOU executed on October 23, 2009, entitled, ''Memorandum of Understanding among the United States (U.S.) Department of Agriculture (USDA), the Department of Commerce, Department of Defense (DoD), Department of Energy (DOE), Environmental Protection Agency (EPA), the Council on Environmental Quality (CEQ), the Federal Energy Regulatory Commission (FERC), the Advisory Council on Historic Preservation (ACHP), and Department of the Interior (DOI), regarding Coordination in Federal Agency Review of Electric Transmission Facilities on Federal Lands.''

MOU principals means the heads of each of the MOU signatory agencies.

NEPA means the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*)

NEPA Lead Agency means the Federal agency or agencies preparing or having primary responsibility for preparing an environmental impact statement or environmental assessment as defined in 40 CFR 1508.16 and in accordance with 40 CFR 1501.5(c).

Non-Federal entity means an Indian tribe, multistate governmental entity, or state and local government agency with relevant expertise and/or jurisdiction within the project area, that is responsible for conducting permitting and environmental reviews of the proposed Qualifying Project or its attendant facilities, that has special expertise with respect to environmental and other issues pertinent to or that are potentially affected by the proposed Qualifying Project or its attendant facilities, or provides funding for the proposed Qualifying Project or its attendant facilities. Non-Federal entities may include those with either permitting or non-permitting authority, *e.g.,* entities such as State Historic Preservation Offices, with whom consultation must be completed in accordance with section 106 of the National Historic Preservation Act, 54 U.S.C. 306108, before a project can commence.

OE–1 means the Assistant Secretary for DOE's Office of Electricity Delivery and Energy Reliability.

Other Projects mean electric transmission facilities that are not Qualifying Projects. Other Projects include facilities for the transmission of electric energy in interstate commerce for the sale of electric energy at wholesale, but do not need to meet the 230 kV or above qualification, or be otherwise identified as regionally or nationally significant with attendant facilities, in which all or part of a proposed transmission line crosses jurisdictions administered by more than one Federal entity.

Project area means the geographic area considered when the project proponent develops study corridors and then potential routes for environmental review and potential project siting as a part of the project proponent's planning process for a Qualifying Project. It is an area located between the two end points of the project (*e.g.,* substations), including their immediate surroundings within at least one-mile of that area, and over any proposed intermediate substations. The size of the project area should be sufficient to allow for the evaluation of various potential alternative routes with differing environmental, engineering, and regulatory constraints. Note that the project area does not necessarily coincide with ''permit area,'' ''area of potential effect,'' ''action area,'' or other defined terms of art that are specific to types of regulatory review.

Project Proponent means a person or entity who initiates the IIP Process in anticipation of seeking Federal authorizations for a Qualifying Project or Other Project.

Qualifying Project means—

(1) A non-marine high voltage electric transmission line (230 kV or above) and its attendant facilities or other regionally or nationally significant non-marine electric transmission line and its attendant facilities, in which:

(i) All or part of the proposed electric transmission line is used for the transmission of electric energy in interstate commerce for sale at wholesale; and

(ii) All or part of the proposed electric transmission line crosses jurisdictions administered by more than one Federal entity or crosses jurisdictions administered by a Federal entity and is considered for Federal financial assistance from a Federal entity.

(2) Qualifying Projects do not include those for which a project proponent seeks a construction or modification permit from the FERC for electric transmission facilities in a DOE-designated National Interest Electric Transmission Corridor under section 216(b) of the FPA (16 U.S.C.824p(b)).

Regional mitigation approach means an approach that applies the mitigation hierarchy (first seeking to avoid, then minimize impacts, then, when necessary, compensate for residual impacts) when developing mitigation measures for impacts to resources from Qualifying Projects at scales relevant to the resource, however narrow or broad, necessary to sustain, or otherwise achieve established goals for those resources. The approach identifies the needs and baseline conditions of targeted resources, potential impacts from the Qualifying Projects, cumulative impacts of past and likely projected disturbance to those resources, and future disturbance trends. The approach then uses such information to identify priorities for avoidance, minimization, and compensatory mitigation measures across that relevant area to provide the maximum benefit to the impacted resources.

Regional mitigation strategies or plans mean documents developed through or external to, the NEPA process that apply a regional mitigation approach to identify appropriate mitigation measures in advance of potential impacts to resources from Qualifying Projects.

Route means a linear area within which a Qualifying Project could be sited. It should be wide enough to allow minor adjustments in the alignment of the Qualifying Project so as to avoid sensitive features or accommodate potential engineering constraints but narrow enough to allow detailed study.

Stakeholder means any non-Federal entity, any non-governmental organization, affected landowner, or other person potentially affected by a proposed Qualifying Project.

Stakeholder outreach plan means a concise description and plan for how a project proponent coordinates stakeholder interface, communications, and involvement so as to provide information to and receive feedback from stakeholders as defined in this part as part of the development of a Qualifying Project and during the IIP Process. It directly informs and supports the development of the summary of early identification of project issues required as part of the initiation request pursuant to § 900.5. The purpose of the stakeholder outreach plan is to ensure that a Project Proponent actively engages and receives feedback from stakeholders when the Project Proponent is evaluating potential study corridors or potential routes before and during the IIP Process.

Study corridor means a contiguous area (but not to exceed one-mile) in width within the project area where alternative routes may be considered for further study.

§ 900.4 Integrated interagency pre-application (IIP) process.

(a) The IIP Process is intended for a Project Proponent who has identified potential study corridors and/or potential routes within an established project area and the proposed locations of any intermediate substations for a Qualifying Project. The IIP Process is also intended to accommodate proposed Qualifying Projects that have been selected in a regional electric transmission plan for purposes of cost allocation or a similar process where an electric transmission plan has been identified and the permitting and siting phase must commence. While the IIP Process is optional, the early coordination provided by DOE between Federal entities, non-Federal entities, and the Project Proponent ensures that the Project Proponent fully understands application and permitting requirements, including data potentially necessary to satisfy application requirements for all permitting entities. The two-meeting structure also allows for early interaction between the Project Proponents, Federal entities, and non-Federal entities in order to enhance early understanding by those having an authorization or consultation related to the Qualifying Project with a clear description of a Qualifying Project, the Project Proponent's siting process, and the environmental and community setting being considered by the Project Proponent for siting the transmission line, including early identification of project issues.

(b) A Project Proponent electing to utilize the IIP Process must submit an initiation request to DOE to start the IIP Process. The timing of the submission of the initiation request for IIP Process is determined by the Project Proponent. The initiation request must include, based on best available information, a Summary of Qualifying Project, Affected Environmental Resources and Impacts Summary, associated maps, geospatial information, and studies (provided in electronic format), a summary of early identification of project issues, and must adhere to the page limits established by this part.

(c) *Summary of the Qualifying Project.* The Summary of the Qualifying Project is limited to a maximum length of ten (10) pages, single-spaced and must include:

(1) A statement that the Project Proponent requests to use the IIP Process;

(2) Primary contact information for the Project Proponent, including a primary email address;

(3) The legal information for the Project Proponent: legal name; principal place of business; whether the requester is an individual, partnership, corporation, or other entity; the state laws under which the requester is organized or authorized; and if the Project Proponent resides or has its principal office outside the United States, documentation related to designation by irrevocable power of attorney of an agent residing within the United States;

(4) A description of the Project Proponent's financial and technical capability to construct, operate, maintain, and decommission the Qualifying Project;

(5) A statement of the Project Proponent's interests and objectives;

(6) To the extent available, regional electric transmission planning documents, including status of regional reliability studies, regional congestion or other related studies where applicable, and interconnection requests;

(7) A brief description of the evaluation criteria and methods that are being used by the Project Proponent to identify and develop the potential study corridors or potential routes for the proposed Qualifying Project;

(8) A brief description of the proposed Qualifying Project, including endpoints, voltage, ownership, justification for the line, intermediate substations if applicable, and, to the extent known, any information about constraints or flexibility with respect to the Qualifying Project;

(9) Project Proponent's proposed schedule, including timeframe for filing necessary Federal and State applications, construction start date, and planned in-service date if the Qualifying Project receives needed Federal authorizations and approvals by non-Federal entities; and

(10) A list of potentially affected Federal and non-Federal entities.

(d) *Affected Environmental Resources and Impacts Summary.* The Affected

Environmental Resources and Impacts Summary is limited to a maximum length of twenty (20), single-spaced pages, not including associated maps, and must include concise descriptions, based on existing, relevant, and reasonably-available information, of the known existing environment, and major site conditions in project area, including:

(1) An overview of topographical and resource features that are relevant to the siting of electric transmission lines present;

(2) Summary of known land uses, including Federal and state public lands of various types (*e.g.,* parks and monuments), associated land ownership, and any land use restrictions;

(3) Summary of known or potential adverse effects to cultural and historic resources;

(4) Summary of known or potential conflicts with or adverse impacts on military activities;

(5) Summary of known or potential impacts on the U.S. aviation system, including FAA restricted airspace;

(6) Summary of known or potential impacts on the U.S. marine transportation system, including impacts on waterways under jurisdiction of the U.S. Coast Guard;

(7) Summary of known information about Federal- and State-protected avian, aquatic, and terrestrial species, and Critical Habitat or otherwise protected habitat, that may be present, as well as other biological resources information that is necessary for an environmental review;

(8) Summary of the aquatic habitats (to include estuarine environments, and water bodies, including wetlands, as well as any known river crossings and potential constraints caused by impacts to navigable waters of the United States considered for the Qualifying Project);

(9) Summary of known information about the presence of low-income communities and minority populations that could be affected by the Qualifying Project;

(10) Identification of existing or proposed Qualifying Project facilities or operations in the project area;

(11) Summary of the proposed use of previously-disturbed lands, existing, agency-designated corridors, including but not limited to corridors designated under section 503 of the Federal Land Policy and Management Act and section 368 of the Energy Policy Act of 2005,transportation rights-of-way, and the feasibility for co-location of the Qualifying Project with existing facilities or location in existing corridors and transportation rights-of-way; and

(12) Summary of potential avoidance, minimization, and conservation measures, such as compensatory mitigation (onsite and offsite), developed through the use of regional mitigation approach or, where available, regional mitigation strategies or plans, and considered by the Project Proponent to reduce the potential impacts of the proposed Qualifying Project to resources requiring mitigation.

(e) *Maps, geospatial information, and studies.* Maps, geospatial information, and studies in support of the information provided in the summary descriptions for the known existing environmental, cultural, and historic resources in the project area under paragraph (d) of this section must be included, and do not contribute to the overall page length of the IIP Initiation Request. Project proponents must provide maps as electronic data files that may be readily accessed by Federal entities and non-Federal entities, including:

(1) A map of the project area showing the locations of potential study corridors or potential routes;

(2) Detailed maps that accurately show information supporting summaries of the known existing environmental resources within the potential study corridors or potential routes;

(3) Electronic access to existing data or studies that are relevant to the summary information provided as part of paragraphs (c) and (d) of this section; and

(4) Citations identifying sources, data, and analyses used to develop the IIP Process Initiation Request materials.

(f) *Summary of Early Identification of Project Issues.* The Summary of Early Identification of Project Issues must not exceed ten (10), single-spaced pages in length and is intended to provide a summary of stakeholder outreach or interactions conducted for the Qualifying Project prior to submission of the initiation request and inform the development of issues and project alternatives for study in an environmental review document. The Summary of Early Identification of Project Issues will:

(1) Discuss the specific tools and actions used by the project proponent to facilitate stakeholder communications and public information, including an existing, current project proponent Web site for the proposed Qualifying Project, where available, and a readily-accessible, easily-identifiable, single point of contact for the project proponent;

(2) Identify how and when meetings on the location of potential study corridors or potential routes have been and would be publicized prior to the submission of applications for Federal authorization, as well as where and when those meetings were held and how many more meetings may be planned during the IIP Process;

(3) Identify known stakeholders and how stakeholders are identified;

(4) Briefly explain how the project proponent responds to requests for information from stakeholders, as well as records stakeholder requests, information received, and project proponent responses to stakeholders;

(5) Provide the type of location (for example, libraries, community reading rooms, or city halls) in each county potentially affected by the proposed Qualifying Project, and specify those where the Project Proponent has provided publicly-available copies of documents and materials related to the proposed Qualifying Project;

(6) Describe the evaluation criteria being used by the Project Proponent to identify and develop the potential study corridors or potential routes and that are presented by the Project Proponent to stakeholders during its project planning outreach efforts prior to submission of applications for Federal authorizations or non-Federal permits or authorizations;

(7) Provide information collected as result of the Project Proponent's stakeholder outreach efforts; and

(8) Include a summary of issues identified, differing project alternative corridors or routes, and revisions to routes developed as a result of issues identified by stakeholders during the project proponent's stakeholder outreach efforts the Qualifying Project.

(g) Within fifteen (15) calendar days of receiving the initiation request, DOE shall notify by electronic mail all Federal entities and non-Federal entities with an authorization potentially necessary to site the Qualifying Project that:

(1) Based on its initial review of information submitted by the Project Proponent in response to requirements in paragraphs (c) through (f) of this section, DOE has identified the contacted Federal entities or non-Federal entities as having an authorization or consultation responsibility related to the Qualifying Project; and

(2) Federal and non-Federal entities notified by DOE should participate in the IIP Process for the Qualifying Project with DOE's rationale for that determination provided; and

(3) Federal and non-Federal entities notified by DOE will provide DOE with a name and information for a point of contact, and any initial questions or concerns about their level of participation in the IIP Process based on DOE's justification within seven (7) calendar days of receiving DOE's notification.

(h) Within thirty (30) calendar days of receiving the initiation request, DOE shall notify the Project Proponent that:

(1) The initiation request meets the requirements in paragraphs (c) through (f) of this section, including whether the project constitutes a Qualifying Project; or

(2) The initiation request does not meet the requirements in paragraphs (c) through (f) of this section and provide the reasons for that finding and a description of how the Project Proponent may, if applicable, address any deficiencies through supplementation of the information contained in the initiation request and DOE will consider its determination.

(i) DOE shall provide Federal and non-Federal entities with access to an electronic copy of the initiation request and associated maps, geospatial data, and studies that meet the requirements in paragraphs (c) through (f) of this section, at the same time that DOE provides notice to the Project Proponent.

(j) *IIP initial meeting.* DOE, in consultation with the identified Federal entities, shall convene the IIP initial meeting with the Project Proponent and all Federal entities and non-Federal entities notified by DOE as having an authorization or consultation related to the Qualifying Project as soon as practicable and no later than forty-five (45) calendar days after notifying the Project Proponent and Federal and non-Federal entities that the initiation request meets the requirements in paragraphs (c) through (f) of this section. The initial meeting shall be convened in the area or region where the proposed Qualifying Project is located. Federal and non-Federal entities shall have at least thirty (30) calendar days to review the information provided by the Project Proponent as part of the initiation request prior to the meeting. Federal entities identified by DOE as having a Federal authorization related to the Qualifying Project are expected to participate in the initial meeting. DOE also shall invite non-Federal entities identified by DOE as having an authorization or consultation related to the Qualifying Project to participate in the initial meeting. During the initial meeting:

(1) DOE shall discuss the IIP process with the Project Proponent and any cost recovery requirements, where applicable.

(2) The Project Proponent shall describe the proposed Qualifying Project and the contents of its initiation request.

(3) The Federal entities shall, to the extent possible and based on agency expertise and experience, review the information provided by the Project Proponent, and publicly-available information, preliminarily identify the following and other reasonable criteria for adding, deleting, or modifying preliminary routes from further consideration within the identified study corridors:

(i) Potential environmental visual, historic, cultural, economic, social, or health effects or harm based on potential project or proposed siting, and anticipated constraints;

(ii) Potential cultural resources and historic properties of concern;

(iii) Areas under special protection by Federal statute or other Federal entity or non-entity decision that could potentially increase the time needed for project evaluation and potentially foreclose approval of siting a transmission line route through such areas, and may include but are not limited to properties or sites which may be of traditional or cultural importance to Indian tribe(s), National Scenic and Historic Trails, National Landscape Conservation system units managed by BLM, National Wildlife Refuges, units of the National Park System, national marine sanctuaries, or marine national monuments;

(iv) Opportunities to site routes through designated corridors, previously disturbed lands, and lands with existing infrastructure as a means of potentially reducing impacts and known conflicts as well as the time needed for affected Federal land managers to evaluate an application for a Federal authorization if the route is sited through such areas (*e.g.,* co-location with existing infrastructure or location on previously disturbed lands or in energy corridors designated by the DOI or USDA under section 503 of the Federal Land Policy and Management Act or section 368 of the Energy Policy Act of 2005, an existing right-of-way, or a utility corridor identified in a land management plan);

(v) Potential constraints caused by impacts on military test, training, and operational missions, including impacts on installations, ranges, and airspace;

(vi) Potential constraints caused by impacts on the United States' aviation system;

(vii) Potential constraints caused by impacts to navigable waters of the United States;

(viii) Potential avoidance, minimization, and conservation measures, such as compensatory mitigation (onsite and offsite), developed through the use of a regional mitigation approach or, where available, regional mitigation strategies or plans to reduce the potential impact of the proposed Qualifying Project to resources requiring mitigation; and

(ix) Based on available information provided by the project proponent, biological (including threatened, endangered, or otherwise protected avian, aquatic, and terrestrial species and aquatic habitats), visual, cultural, historic, and other surveys and studies that may be required for preliminary proposed routes.

(4) Information and feedback provided in paragraphs (j)(1) through (3) of this section to the Project Proponent does not constitute a commitment by Federal entities to approve or deny any Federal authorization request. Moreover, no agency would or could determine that the Project Proponent's proposed preliminary routes presented or discussed during the IIP Process would constitute a range of reasonable alternatives for NEPA purposes. The IIP Process does not limit agency discretion regarding NEPA review. Participating non-Federal entities are encouraged to identify risks and benefits of siting the proposed Qualifying Project within the preliminary proposed routes.

(5) The DOE shall record key issues, information gaps, and data needs identified by Federal and non-Federal entities during the initial meeting, and shall convey a summary of the meeting discussions, key issues, and information gaps and requests to the project proponent, all Federal entities, and any non-Federal entities that participated in the IIP Process in a draft initial meeting summary within fifteen (15) calendar days after the meeting. Participating Federal entities and non-Federal entities, and the Project Proponent will then have fifteen (15) calendar days following its receipt of the IIP Process meeting summary to review the IIP Process meeting summary and provide corrections to DOE for resolution in a final initial meeting summary, as appropriate. Thirty (30) calendar days following the close of the 15-day review period, DOE will incorporate the final initial meeting summary into the IIP Process administrative file for the Qualifying Project, and at the same time, provide all Federal and non-Federal entities and the Project Proponent an

electronic copy of a final IIP initial meeting summary.

(k) *IIP close-out meeting request.* A Project Proponent electing to utilize the IIP Process pursuant to this section must submit a close-out meeting request to DOE to complete the IIP Process. The timing of the submission of the close-out meeting request for the IIP Process is determined by the Project Proponent but must be submitted no less than forty-five (45) calendar days following the initial meeting. The close-out meeting request shall include:

(1) A statement that the Project Proponent is requesting the close-out meeting for the IIP Process;

(2) A summary table of changes made to the Qualifying Project during the IIP Process, including potential environmental and community benefits from improved siting or design;

(3) Maps of updates to potential proposed routes within study corridors, including the line, substations and other infrastructure, which include at least as much detail as required for the initial meeting described above and as modified in response to early stakeholder input and outreach and agency feedback documented as a part of the IIP initial meeting summary;

(4) An updated summary of all project-specific biological (including threatened, endangered or otherwise protected avian, aquatic, and terrestrial species, and aquatic habitats), visual, cultural, historic or other surveys sponsored by the Project Proponent;

(5) If known, a schedule for completing upcoming field resource surveys;

(6) An updated summary of all known or potential adverse impacts to natural resources;

(7) An updated summary of any known or potential adverse effects to cultural and historic resources;

(8) A conceptual plan for potential implementation and monitoring of mitigation measures, including avoidance, minimization, and conservation measures, such as compensatory mitigation (offsite and onsite), developed through the use of a regional mitigation approach or, where available, regional mitigation strategies or plans to reduce the potential impact of the proposed Qualifying Project to resources requiring mitigation;

(9) An estimated time of filing its requests for Federal authorizations for the proposed Qualifying Project; and

(10) An estimated time of filing its requests for all other authorizations and consultations with non-Federal entities.

(l) *Close-out meeting.* The IIP process close-out meeting shall result in a description by Federal entities of the remaining issues of concern, identified information gaps or data needs, and potential issues or conflicts that could impact the time it will take affected Federal entities to process applications for Federal authorizations for the proposed Qualifying Project. The non-Federal entities shall also be encouraged to provide a description of remaining issues of concern, information needs, and potential issues or conflicts. The IIP Process close-out meeting will also result in the identification of a potential NEPA lead agency pursuant to § 900.6.

(1) Within fifteen (15) calendar days of receiving the close-out meeting request, DOE shall notify by electronic mail the appropriate POCs of all Federal entities and non-Federal entities with a known or potential authorization necessary to site the Qualifying Project.

(2) Within thirty (30) calendar days of receiving a close-out meeting request, DOE shall determine whether the close-out meeting request meets the requirements in paragraph (k) of this section and inform the Project Proponent of its acceptance, and provide Federal entities and non-Federal entities with close-out meeting request materials, including map, geospatial data, and surveys in electronic format, preferably via the OMB MAX collaboration Web site at *https://max.omb.gov/maxportal/.*

(3) Within (sixty) 60 calendar days of making a determination that the close-out meeting request meets the requirements of this section, DOE shall convene the close-out meeting in the same region or location at the initial meeting with the project proponent and all Federal entities. All non-Federal entities participating in the IIP Process shall also be invited to attend. During the close-out meeting:

(i) The Project Proponent's updates to the siting process to date shall be discussed, including stakeholder outreach activities, resultant stakeholder input, and Project Proponent response to stakeholder input;

(ii) Based on information provided by the Project Proponent to date, the Federal entities shall discuss key issues of concern and potential mitigation measures identified for the proposed Qualifying Project;

(iii) Led by DOE, all Federal entities shall discuss statutory and regulatory standards that must be met to make decisions for Federal authorizations required for the proposed Qualifying Project;

(iv) Led by DOE, all Federal entities shall describe the estimated time to make decisions for required Federal authorizations and the anticipated cost (*e.g.,* processing and monitoring fees and land use fees);

(v) Led by DOE, all affected Federal entities shall describe their expectations for a complete application for a Federal authorization for the proposed Qualifying Project;

(vi) DOE shall prepare and include a final IIP Resources Report in the IIP Process Administrative File, which provides an accurate description of the proposed Qualifying Project, including stakeholder outreach activities and feedback, summary information on environmental resources, and potential impacts (with electronic access to associated maps, geospatial data and/or survey data), potential issues, and identification of constraints by Federal entities and non-Federal entities for the proposed Qualifying Project;

(vii) When it is included in the IIP Process Administrative File, DOE shall recommend that participating Federal entities use the final IIP Resources Report to inform the NEPA process for the proposed Qualifying Project, for example, during scoping for an EIS and identifying potential routes, explaining why certain alternatives were eliminated from further consideration, and preliminarily identifying impacts, potential avoidance, minimization, and conservation measures, such as compensatory mitigation (onsite and offsite), developed through the use of a regional mitigation approach or, where available, regional mitigation strategies or plans and considered by the project proponent to reduce the potential impacts of the proposed Qualifying Project to resources requiring mitigation; and

(viii) All participating Federal and non-Federal entities shall identify a preliminary schedule for authorizations for the proposed Qualifying Project contingent upon timely filing of applications and related materials by the Project Proponent.

§ 900.5 Selection of the NEPA lead agency.

DOE, in consultation with the Federal entities, shall coordinate the selection of a potential NEPA Lead Agency responsible for preparing an environmental review document under NEPA for proposed Qualifying Projects. Determination and responsibilities of the NEPA Lead Agency for preparing the EIS shall be in compliance with applicable law, including the National Environmental Policy Act of 1969 and CEQ implementing regulations at 40 CFR part 1500, and each agency's respective NEPA implementing regulations and procedures. However:

(a) For proposed Qualifying Projects that cross lands administered by both

DOI and USDA, DOI and USDA shall consult and jointly determine within thirty (30) calendar days of receiving the initiation request information from DOE to determine which Department has a greater land management interest in the proposed Qualifying Project and which Department should therefore assume the role of NEPA Lead Agency.

(b) DOI and USDA shall notify DOE of their determination regarding the NEPA Lead Agency in writing within ten (10) calendar days of making the determination.

(c) Unless DOE notifies DOI and USDA in writing of its objection to that determination within ten (10) calendar days of the DOI/USDA notification, the determination shall be deemed accepted and final. In deciding whether to object to the determination, DOE shall consider the CEQ regulations pertaining to selection of the lead agency, including 40 CFR 1501.5(c).

(d) When the NEPA Lead Agency is not established pursuant to paragraphs (a) through (c) of this section, the Federal entities that will likely constitute the cooperating agencies for an environmental review document under NEPA shall consult and jointly recommend a NEPA Lead Agency within 45 calendar days of receiving an IIP Process close-out meeting request to the Council on Environmental Quality for a fine determination. No determination of a Federal entity as the NEPA Lead Agency under this part shall be made absent that Federal entity's consent.

§ 900.6 IIP Process administrative file.

(a) When communicating with the Project Proponent during the IIP Process, Federal entities are expected to include DOE involved in the IIP Process for the Project Proponent's proposed Qualifying Project.

(b) DOE shall maintain all information, including documents and communications, it disseminates or receives from the Project Proponent, Federal entities, and non-Federal entities during the IIP Process for future use in reviewing any applications for required Federal authorizations for the proposed Qualifying Project. Before disseminating information specific to a Federal entity's or non-Federal entity's review, DOE must receive approval from that agency in accordance with that Federal entity's Freedom of Information Act requirements.

(c) DOE shall document the list of issues identified during the IIP process for a proposed Qualifying Project and updates to information provided as part of the close-out meeting discussion in a final IIP Resources Report, if any, for the IIP Process Administrative File.

(d) Each Federal entity is encouraged to maintain the documents and communications developed in the IIP Process subject to each Federal entity's administrative record policies and, as appropriate and applicable, those documents and communications could become part of that Federal entity's administrative record for granting or denying a Federal authorization for each Qualifying Project.

[FR Doc. 2016–01641 Filed 2–1–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–7490; Directorate Identifier 2015–NE–40–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Turbomeca S.A. Astazou XIV B and H turboshaft engines. This proposed AD was prompted by a report of a crack on the 3rd stage turbine wheel. This proposed AD would require a one-time inspection of the front surface of the 3rd stage turbine for a groove. We are proposing this AD to prevent cracks in the 3rd stage turbine wheel, failure of the engine, in-flight shutdown, and loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by April 4, 2016.

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

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

For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; fax: 33 (0)5 59 74 45 15. You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

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–2015–7490; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–7490; Directorate Identifier 2015–NE–40–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2015–0223, dated November 16, 2015 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

During the overhaul of an ASTAZOU XIV engine, a crack was detected on the front face

of the third stage turbine wheel between two balancing lugs. The cause of the crack is probably linked to a geometric singularity, likely caused by the transformation operation aimed at introducing expansion slots between the blades during embodiment of Turbomeca mod AB 173. Although there is only one known case of this type of crack, and although it was detected, the possibility exists that additional parts have the same geometric singularity.

This condition, if not detected and corrected, may lead to failure of a turbine blade and its associated piece of rim, possibly resulting in an uncommanded in-flight shut-down and/or release of high energy debris.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–7490.

Related Service Information Under 1 CFR Part 51

Turbomeca S.A. has issued Service Bulletin (SB) No. 283 72 0811, Version A, dated August 25, 2015. The SB describes procedures for inspection of the 3rd stage turbine wheel. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of France, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this NPRM because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This NPRM would require inspecting the front surface of the 3rd stage turbine for a groove.

Costs of Compliance

We estimate that this proposed AD affects 9 engines installed on helicopters of U.S. registry. We also estimate that it would take about 5 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $3,825.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Turbomeca S.A.: Docket No. FAA–2015–7490; Directorate Identifier 2015–NE–40–AD.

(a) Comments Due Date

We must receive comments by April 4, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Astazou XIV B and XIV H turboshaft engines with 3rd stage turbine wheel, part number (P/N) 0 265 25 700 0 or P/N 0 265 25 706 0, installed, if the engine incorporates Turbomeca modification AB–173 or AB–208.

(d) Reason

This AD was prompted by a report of a crack on the 3rd stage turbine wheel. We are issuing this AD to prevent cracks in the 3rd stage turbine wheel, failure of the engine, in-flight shutdown, and loss of control of the helicopter.

(e) Actions and Compliance

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

(1) At the next piece part exposure of the 3rd stage turbine wheel or within 1,000 engine hours after the effective date of this AD whichever comes first, perform a one-time inspection for a groove on the front surface of the 3rd stage turbine wheel. Use Accomplishment Instructions, paragraph 4.4.2, of Turbomeca S.A. Service Bulletin (SB) No. 283 72 0811, Version A, dated August 25, 2015 to perform the inspection.

(2) If the 3rd stage turbine wheel passes inspection required by paragraph (e)(1) of this AD, no further action is required.

(3) If the 3rd stage turbine wheel fails inspection required by paragraph (e)(1) of this AD, remove the part and replace with a part eligible for installation.

(f) Installation Prohibition

After the effective date of this AD, do not install any 3rd stage turbine wheel, P/N 0 265 25 700 0 or P/N 0 265 25 706 0, unless it was inspected per the Accomplishment Instructions, paragraph 4.4.2, of Turbomeca S.A. SB No. 283 72 0811, Version A, dated August 25, 2015.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(h) Related Information

(1) For more information about this AD, contact Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–

7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0223, dated November 16, 2015, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–7490.

(3) Turbomeca S.A. SB No. 283 72 0811, Version A, dated August 25, 2015, can be obtained from Turbomeca S.A., using the contact information in paragraph (h)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact Turbomeca S.A., 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; fax: 33 (0)5 59 74 45 15.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on January 27, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–01770 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 401

[CMS–5061–P]

RIN 0938–AS66

Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement new statutory requirements that would expand how qualified entities may use and disclose data under the qualified entity program to the extent consistent with applicable program requirements and other applicable laws, including information, privacy, security and disclosure laws. In doing so, this proposed rule would explain how qualified entities may create non-public analyses and provide or sell such analyses to authorized users, as well as how qualified entities may provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users. This proposed rule would also implement certain privacy and security requirements, and impose assessments on qualified entities if the qualified entity or the authorized user violates the terms of a data use agreement (DUA) required by the qualified entity program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 29, 2016.

ADDRESSES: In commenting, please refer to file code CMS–5061–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5061–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5061–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Allison Oelschlaeger, (202) 690–8257. Kari Gaare, (410) 786–8612.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted. The law included a provision, Section 105, Expanding the Availability of Medicare Data, which takes effect on July 1, 2016. This section expands how qualified entities will be allowed to use and disclose data under the qualified entity program, including data subject to section 1874(e) of the Social Security Act (the Act), to the extent consistent with other applicable laws, including information, privacy, security and disclosure laws.

The Qualified Entity program was established by Section 10332 of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). The implementing regulations, which became effective January 6, 2012, are found in subpart G of 42 CFR part 401 (76 FR 76542). Under those provisions, CMS provides standardized extracts of Medicare Part A and B claims data and Part D drug event data

(hereinafter collectively referred to as Medicare claims data) covering one or more geographic regions to qualified entities at a fee equal to the cost of producing the data. Under the original statutory provisions, such Medicare claims data must be combined with other non-Medicare claims data and may only be used to evaluate the performance of providers and suppliers. The measures, methodologies and results that comprise such evaluations are subject to review and correction by the subject providers and suppliers, after which the results are to be disseminated in public reports.

Those wishing to become qualified entities are required to apply to the program. Currently, thirteen organizations have applied and received approval to be a qualified entity. Of these organizations, two have completed public reporting while the other eleven are in various stages of preparing for public reporting. While we have been pleased with the participation in the program so far, we expect that the changes required by MACRA will increase interest in the program.

Under section 105 of MACRA, effective July 1, 2016, qualified entities will be allowed to use the combined data and information derived from the evaluations described in 1874(e)(4)(D) of the Act to conduct non-public analyses and provide or sell these analyses to authorized users for non-public use in accordance with the program requirements and other applicable laws. In highlighting the need to comply with other applicable laws, we particularly note that any qualified entity that is a covered entity or business associate as defined in the Health Insurance Portability and Accountability Act of 1996 (''HIPAA'') regulations at 45 CFR 160.103 will need to ensure compliance with any applicable HIPAA requirements, including the bar on the sale of Protected Health Information.

In addition, qualified entities will be permitted to provide or sell the combined data, or provide the Medicare claims data alone at no cost, again, in accordance with the program requirements and other applicable laws, to providers, suppliers, hospital associations, and medical societies. Qualified entities that elect to provide or sell analyses and/or data under these new provisions will be subject to an assessment if they or the authorized users to whom they disclose beneficiary identifiable data in the form of analyses or raw data act in a manner that violates the terms of a program-required Qualified EntityData Use Agreement (QE DUA). Furthermore, qualified entities that make analyses or data available under these new provisions will be subject to new annual reporting requirements to aid CMS in monitoring compliance with the program requirements. These new annual reporting requirements will only apply to qualified entities that choose to provide or sell non-public analyses and/or provide or sell combined data, or provide Medicare claims data alone at no cost.

We believe these changes to the qualified entity program will be important in driving higher quality, lower cost care in Medicare and the health system in general. We also believe that these changes will drive renewed interest in the qualified entity program, leading to more transparency regarding provider and supplier performance and innovative uses of data that will result in improvements to the healthcare delivery system while still ensuring appropriate privacy and security protections for beneficiary-identifiable data.

II. Provisions of the Proposed Regulations

To implement the new statutory provisions of section 105 of MACRA, we propose to amend and make conforming changes to Part 401 Subpart G, ''Availability of Medicare Data for Performance Measurement.'' Throughout the preamble, we identify options and alternatives to the provisions we propose. We strongly encourage comments on our proposed approach, as well as any alternatives.

A. Non-Public Analyses

Section 105(a)(1) of MACRA expands how qualified entities will be allowed to use and disclose the combined data and any information derived from the evaluations described in section 1874(e)(4)(D) of the Act. The section provides for such data's use and/or disclosure in additional non-public analyses that may be given or, in certain circumstances, sold to authorized users in accordance with program requirements and other applicable laws, including information, privacy, security, and disclosure laws. An authorized user is defined at § 401.703(j) and the definition is discussed below in section II.C. The new proposals regarding the disclosure and/or sale of combined data or the disclosure of Medicare data at no cost are discussed below in section II.B.

To implement the non-public analyses provisions, we propose to add a new § 401.716. Under § 401.716, paragraph (a) would provide for the qualified entity's use of the combined data or information derived from the evaluations described in section 1874(e)(4)(D) of the Act to create non-public analyses. Paragraph (b) would provide for the provision or sale of these analyses to authorized users in accordance with the program requirements discussed later in this section, as well as other applicable laws.

1. Additional Analyses

We propose at § 401.703(q) to define combined data as a set of CMS claims data provided under subpart G combined with a subset of claims data from at least one of the other claims data sources described in § 401.707(d). § 401.707(d) requires qualified entities to submit to CMS information on the claims data it possesses from other sources, that is, any other provider-identifiable or supplier-identifiable data for which the qualified entity has full data usage rights. In defining the term in this manner, we are not proposing to establish a minimum amount of data that must be included in the combined data set from other sources, but, as we noted in our December 7, 2011 final rule (76 FR 76542), we believe that the requirement to use combined data is likely to lead to increased validity and reliability of the performance findings through the use of larger and more diverse samples. As such, we expect qualified entities will choose to use sufficient claims data from other sources to ensure such validity and reliability. That said, we recognize that there may be instances in which other sources of claims data (for example, Medicaid or private payer data) may be of limited value. For instance, depending on the other claims data a given qualified entity may hold, Medicare data may provide the best opportunity to conduct analyses on chronically ill or other resource-intensive populations that may not be commonly represented in other sources of claims data. Thus, while the statute requires the use of combined data for the analyses, it does not specify the minimum amount of data from other sources to qualify as combined data, and, as we believe it would be difficult to establish a threshold given the variability in the analyses that the qualified entities may conduct, we propose not to adopt any minimum standard for the amount of other sources of claims data that must be included in a combined data set. We are requesting comments on this proposal as well as suggestions for other possible alternatives or options.

2. Limitations on the Qualified Entities With Respect to the Sale and Provision of Non-Public Analyses

MACRA imposes a number of limitations on qualified entities with

respect to the sale and provision of non-public analyses. It mandates that a qualified entity may not provide or sell non-public analyses to a health insurance issuer unless the issuer is providing the qualified entity with claims data under section 1874(e)(4)(B)(iii) of the Act. In doing so, the statute does not specify the minimum amount of data that the issuer must be providing to the qualified entity. We considered not imposing a threshold on the amount of data being provided by the issuer, but decided that specifying a threshold would encourage issuers to submit data to the qualified entity to be included in the public performance reports, increasing the reports' reliability and sample size. As a result, we propose at § 401.716(b)(1) to limit qualified entities to only providing or selling non-public analyses to issuers after they provide the qualified entity with claims data that represents a majority of the issuers' covered lives in the geographic region and during the time frame of the non-public analyses requested by the issuer. For example, if an issuer requested non-public analyses using the combined data for the first 6 months of 2015 in Minnesota, it would need to provide the qualified entity with data that represents over 50 percent of the issuer's covered lives during those 6 months in Minnesota. We believe this threshold will ensure that issuers submit a large portion of their data to the qualified entity without requiring them to share data for their entire population in order to be eligible to receive non-public analyses. We seek comment on whether the threshold of a majority of the issuer's covered lives in the desired geographic area during the time frame covered by the non-public analyses requested by the issuer is too high or low, as well as other alternatives to specify the amount of data the issuer must provide to a qualified entity to be eligible to receive or purchase non-public analyses.

Section 105(a)(3) of MACRA imposes additional requirements on the dissemination of non-public analyses or data that contain information that individually identify a patient. Because we define the term ''patient'' later in this section and in a manner that does not relate to de-identification of individually identifiable information, we will use the word beneficiary in relation to de-identification rather than patient. In light of these MACRA provisions, as well as our belief that protecting the privacy and security of beneficiaries' information is of the utmost importance and our belief that identifiable information on individual beneficiaries would generally not be needed by authorized users, we propose to impose limits on the content of the non-public analyses. In doing so, we recognize that when non-public analyses are provided or sold to a provider or supplier, individually identifying information such as name, age, gender, or date of birth may be essential for the provider or supplier to proactively use the information gleaned from the analyses. For example, a provider may not know who a patient is based on the unique identifier assigned by the payer and as a result would not be able to use the analyses to improve care or better coordinate care with other providers for that patient. In addition, there is a high likelihood that providers may have patients with the same or similar names, so age or date of birth may be necessary to identify the patient in the analyses. We therefore propose at § 401.716(b)(2) to limit the provision or sale of non-public analyses that individually identify a beneficiary to providers or suppliers with whom the subject individual(s) have established a patient relationship.

While the term ''patient'' is commonly used in the provision of healthcare, reasonable minds may differ on the periodicity with which an individual must have contact with a provider or supplier to maintain a ''patient'' relationship. Depending on individual practice or applicable laws, a person may still be considered a patient of a provider or supplier even though a number of years have passed since they were seen or provided services by the provider or supplier. However, when the individual has not visited a provider or supplier in a number of years, analyses that contain individually identifiable information about that patient may not be very useful, as any care coordination or quality improvement efforts would, presumably, require continued contact with that patient. Therefore, for the purposes of this program, we propose to define patient as an individual who has visited the provider or supplier for a face-to-face or telehealth appointment at least once in the past 12 months. This definition is similar to that used in the Medicare Shared Savings Program which assigns beneficiaries to Accountable Care Organizations based on services delivered in the past 12 months. We also believe this definition will ensure that providers and suppliers are able to receive information about patients they are actively treating. We seek comments on this proposal, particularly any beneficiary concerns if we were to implement this proposal, and any reasonable alternatives to this proposal that might address those concerns.

Except when patient-identifiable non-public analyses are shared with the patient's provider or supplier as described above, we propose at § 401.716(b)(3) to require that all non-public analyses must be beneficiary de-identified using the de-identification standards in the HIPAA Privacy Rule at 45 CFR 164.514(b). De-identification under this standard requires the removal of specified data elements or reliance on a statistical analysis that concludes that the information is unlikely to be able to be used alone or in combination with other available information to identify/re-identify the patient subjects of the data. The statistical de-identification approach may be more difficult because an entity may not have access to an expert capable of performing the analysis in accordance with HIPAA Rules, but we believe that the protections afforded by HIPAA-like standards of de-identification are appropriate, as HIPAA has, in many ways, established a reasoned and appropriate privacy and security floor for the health care industry. That said, the framework for de-identification that is laid out in the HIPAA Privacy Rule represents a widely accepted industry standard for de-identification, so we think its concepts are appropriate for adoption into this program. Additional information on the HIPAA de-identification standards can be found on the HHS Office for Civil Rights Web site at *http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html*.

We seek comment on this proposal and whether another set of de-identification standards would be more appropriate to ensure that non-public analyses do not contain information that individually identifies a beneficiary, except as provided for above where the individual is a patient of the provider or supplier who is receiving the analyses, and how qualified entities that are HIPAA-covered entities could comply with such alternate qualified entity program standards while still meeting any applicable HIPAA obligations.

In addition, section 105(a)(6) of MACRA preserves providers' and suppliers' opportunity to review analyses (now including non-public analyses) that individually identify the provider or supplier. As such, we propose at § 401.716(b)(4) to bar qualified entities' disclosure of non-public analyses that individually identify a provider or supplier unless: (a) The analysis only individually

identifies the singular recipient of the analysis or (b) each provider or supplier who is individually identified in a non-public analysis that identifies multiple providers/suppliers has been afforded an opportunity to review the aspects of the analysis about them, and, if applicable, request error correction. We describe the proposed appeal and error correction process in more detail in section II.A.4 below.

3. Limitations on the Authorized User

While CMS has been granted statutory authority to impose requirements and limitations on the qualified entity, it has limited authority to oversee authorized users. As such, this proposed regulatory scheme is generally structured to require the qualified entity to ensure authorized users' compliance with the concepts laid out in MACRA through contractual means. In keeping with this, we propose at § 401.716(b)(2) and § 401.716(c) to require the qualified entity's use of legally binding agreements with any authorized users to whom it provides or sells the non-public analyses.

Types of Legally Binding Agreements

For non-public analyses that include patient identifiable data, we propose at § 401.716(b)(2) to require the qualified entity to enter into a QE DUA with any authorized users as a pre-condition to providing or selling such non-public analyses. As we are also proposing to require use of the QE DUA in the context of the provision or sale of combined data, or the provision of Medicare data at no cost, we discuss the QE DUA in the data disclosure discussion in section II.B below. For non-public analyses that include beneficiary de-identified data, we propose at § 401.716(c) to require the qualified entity to enter into a contractually binding non-public analyses agreement with any authorized users as a pre-condition to providing or selling such non-public analyses. A discussion of the proposed requirements for the non-public analyses agreements follows in this section.

We believe that the use of the non-public analyses agreement when authorized users receive non-public analyses containing de-identified data and the QE DUA when authorized users receive non-public analyses that contain patient identifiable information are the best mechanisms for ensuring that both qualified entities and authorized users are aware of and compliant with the data use and disclosure limitations established by MACRA. We seek comment on whether the non-public analyses agreement and the QE DUA are the best mechanisms to ensure compliance with these restrictions given the authorities established by MACRA.

Requirements in the Non-Public Analyses Agreement

The statute generally allows qualified entities to provide or sell their non-public analyses to authorized users for non-public use, but it bars use or disclosure of such analyses for marketing (see section 105(a)(3)(c) of MACRA). Such analyses therefore may include, but would not be limited to analyses intended to assist providers' and suppliers' development of, and participation in, quality and patient care improvement activities, including development of new models of care. But, while many types of non-public analyses could lead to improvements in the health care delivery system, certain types of analyses could cause harm to patients or lead to additional fraud and/or abuse concerns for the delivery system. Therefore, despite the breadth of the statutory authority, we believe it is important to establish additional limits on the non-public analyses, given the expansive types of non-public analyses that could be conducted by the qualified entities if no limits are placed on such analyses, and the potential deleterious consequences of some such analyses.

With this in mind, we propose at § 401.716(c)(1) that the non-public analyses agreement require that non-public analyses conducted using combined data or the information derived from the evaluations described in section 1874(e)(4)(D) of the Act may not be used or disclosed for the following purposes: marketing, harming or seeking to harm patients and other individuals both within and outside the healthcare system regardless of whether their data are included in the analyses (for example, an employer using the analyses to attempt to identify and fire employees with high healthcare costs), or effectuating or seeking opportunities to effectuate fraud and/or abuse in the healthcare system (for example, a provider using the analyses to identify ways to submit fraudulent claims that might not be caught by auditing software).

Rather than developing a new definition for marketing under this program, we propose at § 401.703(s) to generally define marketing using the definition at 45 CFR 164.501 in the HIPAA Privacy Rule. Under this definition, marketing means making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. In doing so, we note that the HIPAA Privacy Rule also includes a general restriction on use of an individual's Protected Health Information (PHI) for marketing. Given the similarities between the use and disclosure of PHI under HIPAA and the data sharing limitations under this program, we believe the definition of marketing in HIPAA should also generally be used for this program, but, given the categorical statutory bar on marketing in this program, we are not proposing a consent exception to the bar like that seen in the HIPAA Privacy Rule. We also believe that use of this HIPAA definition as modified will simplify compliance with the qualified entity program requirements, especially decisions regarding what is and is not considered marketing. We seek comment on the proposal to use this definition as modified from HIPAA for the purposes of this program.

The proposed restrictions on using analyses and/or derivative data, meaning data gleaned from the analyses, that would or could be used to exploit patients or other individuals or to effectuate fraud and/or abuse in the healthcare system are intended to ensure that the analyses are unlikely to result in physical or financial harm to patients or other individuals within or outside the health care delivery system. We seek comments on these proposals as well as whether there are other restrictions that should be imposed to limit potential physical or financial harm to patients or other individuals within or outside the healthcare system.

Section 105(a)(1)(B)(i) of MACRA requires that any non-public analyses provided or sold to an employer may only be used by the employer for the purposes of providing health insurance to employees and retirees of the employer. We believe this limit should also apply to ''dependents'' of either category whenever the employer offers coverage for family members who are neither employees nor retirees. As such, we further propose that if the qualified entity is providing or selling non-public analyses to an employer that this requirement be included in the non-public analyses agreement. We seek comment on whether the resulting non-public analyses agreement between the qualified entity and the employer is the best mechanism to ensure compliance with this restriction given the authorities established by MACRA.

The statute also contains limitations on the re-disclosure of non-public analyses provided or sold to authorized users at section 105(a)(5) of MACRA. Under that provision, re-disclosure is limited to authorized users who are a provider or supplier. Furthermore, these

providers and suppliers are to limit any re-disclosures to instances in which the recipient would use the non-public analyses for provider/supplier ''performance improvement.'' As many if not most providers and suppliers that receive non-public analyses from the qualified entity will be HIPAA-covered entities, we propose to limit performance improvement re-disclosures to those that would support quality assessment and improvement, and care coordination activities by or on behalf of the eligible downstream provider or supplier. For example, providers may need to share the non-public analyses or derivative data with someone working on their behalf to carry out such quality assessment and improvement or care coordination activities. That is, if they are a HIPAA-covered entity, they may wish to share the non-public analyses or derivative data with their business associate. Such a scenario could arise when a consultant is hired to assist the provider/supplier in interpreting the non-public analyses, or in determining what changes in the delivery of care are needed to assess or improve the quality of care, or to better coordinate care. Another example is if the provider or supplier wants to share the non-public analyses with other treating providers/suppliers for quality assessment and improvement or care coordination purposes.

In addition, especially under circumstances in which patient identifiable data is included in the non-public analysis, we recognize that there are instances in which a provider or supplier may be required to produce information to a regulatory authority as required by a statute or regulation. For example, a HIPAA-covered entity may be required to produce PHI to the Secretary for purposes of an investigation of a potential HIPAA violation. Therefore, for purposes of this qualified entity program, we propose to adopt the HIPAA definition of ''required by law'' at 45 CFR 164.103 so as to allow for such mandatory disclosures. As defined at 45 CFR 164.103, ''required by law'' means any mandate in law that compels an entity to make a use or disclosure of PHI that is enforceable in a court of law (including disclosures compelled by court order, statute, or regulation). An example would be a court order to turn over medical records as part of litigation. Another common example would be disclosures required by the regulations governing the submission of a claim for payment for Medicare fee-for-service covered services.

As a result, we propose at § 401.716(c)(3)(i) to require qualified entities to include in the non-public analysis agreement a requirement to limit re-disclosure of non-public analyses or derivative data to instances in which the authorized user is a provider or supplier, and the re-disclosure is as a covered entity would be permitted under 45 CFR 164.506(c)(4)(i) or 164.502(e)(1). Accordingly, a qualified entity may only re-disclose individually identifiable health information to a covered entity for the purposes of the covered entity's quality assessment and improvement or for the purposes of care coordination activities, where that entity has a patient relationship with the individual who is the subject of the information, or to a business associate of such a covered entity under a written contract as defined at 45 CFR 164.502(e)(1). Furthermore, as section 105(a)(5)(A) of MACRA states that the analyses generally may not be re-disclosed or released to the public, we generally propose at § 401.716(c)(3)(ii) to require qualified entities to use non-public analyses agreements to explicitly bar authorized users from any other re-disclosure of the non-public analyses or any derivative data except to the extent a disclosure qualifies as a ''required by law'' disclosure. We seek comment on our proposal to require qualified entities to contractually limit re-disclosures of beneficiary de-identified non-public analyses or any derivative data other than as described above.

As discussed above, the non-public analyses agreement can only be used in the disclosure of analyses that include beneficiary de-identified data. However, even though the analyses subject to a non-public analyses agreement are beneficiary de-identified, we believe that additional restrictions on the authorized user are necessary to ensure appropriate privacy and security protections for our beneficiaries. We therefore propose at § 401.716(c)(5) to require qualified entities to impose a legally enforceable bar on the authorized user's use or disclosure of any non-public analyses (or data or analyses derived from such non-public analyses) to re-identify or attempt to re-identify any individual whose data is included in the analyses or any derivative data. We believe this additional level of privacy and security protection is necessary to protect beneficiaries. We seek comment on this proposal.

Finally, we propose at § 401.716(d)(6) to require qualified entities to use their non-public analyses agreements to bind their non-public analyses recipients to reporting any violation of the terms of that non-public analyses agreement to the qualified entity. As explained below in Section D, qualified entities will be expected to report on these violations as part of their annual reporting to CMS. Even though the analyses covered by the non-public analyses agreement will be de-identified, due to the risk of re-identification of beneficiary information, we still believe that this requirement is essential to our ability to monitor and ensure the privacy and security of beneficiary information. We seek comment on these proposals.

4. Confidential Opportunity To Review, Appeal, and Correct Analyses

As noted briefly above, section 105(a)(6) of MACRA directs us to ensure that qualified entities provide providers and suppliers who are individually identified in a non-public analysis with an opportunity to review and request corrections before the qualified entity provides or sells the non-public analyses to an authorized user. But, as noted above, we have proposed one exception to this general rule in cases where the analysis only individually identifies the (singular) provider or supplier who is being provided or sold the analysis. In all other cases, we propose that the qualified entity must follow the confidential review, appeal, and error correction requirements in section 1874(e)(4)(C)(ii) of the Act.

Specifically, we propose at § 401.717(f) that a qualified entity generally must comply with the same error corrections process and timelines as are required for public performance reporting before disclosing non-public analyses. This process includes confidentially sharing the measures, measure methodologies and measure results that comprise such evaluations with providers and suppliers at least 60 calendar days before providing or selling the analyses to one or more authorized users. During these 60 calendar days, the provider or supplier may make a request for the Medicare claims data and beneficiary names that may be needed to confirm statements about the care that they delivered to their patients. If the provider or supplier requests such data, the qualified entity must release the Medicare claims and beneficiary names relevant to what is said about the requesting provider/supplier in the draft non-public analyses. We believe that for many providers and suppliers, a beneficiary's name will be of more practical use in determining the accuracy of analyses than the underlying claims used in the analyses. The sharing of such data must be done via a secure mechanism that is suitable for transmitting or providing access to individually identifiable

health information. The qualified entity also must ensure that the provider or supplier has been notified of the date on which the analyses will be shared with the authorized user. If any requests for error correction are not resolved by the date on which the analyses are to be shared, the qualified entity may release the analyses, but must inform the authorized user that the analyses are still under appeal, and the reason for the appeal.

We believe that the process we established for review and error correction for public performance reporting finds the right balance between allowing providers and suppliers the opportunity to review the non-public analyses while also ensuring that the information is disseminated in a timely manner. However, we have had limited public reporting thus far to confirm this. Furthermore, using the same process for review and error correction for non-public analyses and the public reports creates continuity and a balance between the needs and interests of providers and suppliers and those of the qualified entities, authorized users and the public. We also believe that using the same timeframes and requirements will simplify the review process for providers and suppliers. We seek comment on our proposal generally to require qualified entities to comply with the same error corrections process and timelines as are required for public performance reporting when sharing analyses that individually identify a provider or supplier.

Although we do not believe that we have statutory authority to require it given that section 1874(e) of the Act only covers the disclosure of Medicare claims data, to the extent permitted by applicable law, we strongly encourage qualified entities to also share the claims data from other sources with providers and suppliers if they ask for the underlying data used for the analyses.

B. Dissemination of Data and the Use of QE DUAs for Data Dissemination and Patient-Identifiable Non-Public Analyses

Subject to other applicable law, section 105(a)(2) of MACRA expands the permissible uses and disclosures of data by a qualified entity to include providing or selling combined data for non-public use to certain authorized users, including providers of services, suppliers, medical societies, and hospital associations. Subject to the same limits, it also permits a qualified entity to provide Medicare claims data for non-public use to these authorized users; however, a qualified entity may not charge a fee for providing such Medicare claims data. But, in order to provide or sell combined data or Medicare data, section 501(a)(4) of MACRA instructs the qualified entity to enter into a DUA with their intended data recipient(s).

1. General Requirements for Data Dissemination

To implement these provisions in MACRA, we propose at § 401.718(a) to provide that, subject to other applicable laws (including applicable information, privacy, security and disclosure laws) and certain defined program requirements, including that the data be used only for non-public purposes, a qualified entity may provide or sell combined data or provide Medicare claims data at no cost to certain authorized users, including providers of services, suppliers, medical societies, and hospital associations. Where a qualified entity is a HIPAA-covered entity or is acting as a business associate, compliance with other applicable laws will include the need to ensure that it fulfills the requirements under the HIPAA Privacy Rule, including the bar on the sale of PHI.

We note that we propose definitions for authorized user, medical societies, and hospital associations in section II.C below, and have already proposed a definition for combined data in section II.A above.

2. Limitations on the Qualified Entity Regarding Data Disclosure

The statute places a number of limitations on the sale or provision of combined data and the provision of Medicare claims data by qualified entities, including generally barring the disclosure of beneficiary identifiable data obtained through the qualified entity program. Therefore, in keeping with our other proposals at § 401.716(b)(3), we propose at § 401.718(b)(1) to generally require that any combined data or Medicare claims data that is provided to an authorized user by a qualified entity under subpart G be beneficiary de-identified in accordance with the de-identification standards in the HIPAA Privacy Rule at 45 CFR 164.514(b). As noted above, we believe that the HIPAA Privacy Rule de-identification standard represents a widely accepted industry standard for de-identification, so we think its concepts are appropriate for adoption under the qualified entity program.

We do recognize, however, that providers or suppliers with current treatment relationships with the patient subjects of such data may desire and benefit from receiving data that contains individually identifiable information about those patients. Therefore, we also propose an exception at § 401.718(b)(2) that would allow a qualified entity to provide or sell patient identifiable combined data/and or provide patient identifiable Medicare claims data at no cost to an individual or entity that is a provider or supplier if the provider or supplier has a patient relationship with every patient about whom individually identifiable information is provided and the disclosure is consistent with applicable law.

MACRA also requires qualified entities to bind the recipients of their data to a DUA that will govern the use and, where applicable, re-disclosure of any data received through this program prior to the provision or sale of such data to an authorized user. Therefore, we further propose at § 401.718(c), to require that a qualified entity impose certain contractually binding use/re-disclosure requirements as a condition of providing and/or selling combined data and/or providing Medicare claims data to an authorized user. The following section provides the proposed requirements for such DUAs between qualified entities and authorized users.

3. Data Use Agreement

Section 501(a)(4) of MACRA requires execution of a DUA as a precondition to a qualified entity's provision or sale of data to an authorized user. The DUA must address the use and, if applicable, re-disclosure of the data, and the applicable privacy and security requirements that must be established and maintained by or for the authorized user. The statute also imposes a number of other limitations on the authorized user. But, while CMS has authority to impose requirements on the qualified entity, we must rely upon the qualified entity to impose legally enforceable obligations on the authorized users.

Therefore, in § 401.713(a), we propose certain clarifying changes that will recognize that there are now two distinct DUAs in the qualified entity program—the CMS DUA, which is the agreement between CMS and a qualified entity, and what we will refer to as the QE DUA, which will be the legally binding agreement between a qualified entity and an authorized user. We are not proposing any changes to the requirements for the CMS DUA, but rather are clarifying that there are now two DUAs—the CMS DUA and the QE DUA.

Furthermore, in § 401.713(d), we propose a number of provisions that address the privacy and security of the combined data and/or the Medicare

claims data and/or non-public analyses that contain patient identifiable data. These provisions require the qualified entity to condition the disclosure of data on the imposition of contractually binding limits on the permissible uses and re-disclosures that can be made of the combined data and/or the Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data. Such contractually binding provisions would be included in the QE DUA.

First, we propose to require that the QE DUA contain certain limitations on the authorized user's use of the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data. In § 401.713(d)(1), we propose that the QE DUA limit authorized users use of the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data to the purposes described in the first or second paragraph of the definition of ''health care operations'' under 45 CFR 164.501, or that which qualifies as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4). If finalized, this means that authorized users would only be permitted to use the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data provided by the qualified entity for quality assessment and improvement activities, care coordination activities, including the review of provider or supplier performance, and/or for fraud, waste, and abuse detection and compliance purposes. We believe these uses need to be permitted to support quality improvement and care coordination activities, as well as efforts to ensure fraud, waste, and abuse detection and compliance, and that these uses should encompass the full range of activities for which the authorized users will legitimately need the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data. We also propose to require that all other uses and disclosures of combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data be forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

The statute also prohibits the authorized user from using the combined data and/or Medicare claims data for marketing purposes. We therefore propose at § 401.713(d)(2) to require qualified entities to use the QE DUA to contractually prohibit the authorized users from using the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data for marketing purposes. As noted above, we propose to define ''marketing'' as it is defined in the HIPAA Privacy Rule, but, given the statutory bar, we do not propose to adopt an exception to the bar for ''consent''-based marketing. As noted above, HIPAA provides well-recognized standards for the appropriate use and disclosure of certain individually identifiable health information, and we believe that the HIPAA definition for ''marketing'' is appropriate for the qualified entity program as well. For additional information and guidance on the HIPAA Privacy Rule, including guidance on what constitutes marketing, please visit the HHS Office for Civil Rights Web site at *http://www.hhs.gov/ocr/privacy/.*

Furthermore, we propose to require qualified entities' use of the QE DUA to address minimum privacy and security standards. CMS is committed to protecting the privacy and security of beneficiary-identifiable data when it is disseminated, including when it is in the hands of authorized users. This is especially important as there are no guarantees that authorized users will be subject to the HIPAA Privacy and Security Rules. Therefore, we propose at § 401.713(d)(3) to require qualified entities to contractually bind authorized users using the QE DUA to protect patient identifiable combined data and/or Medicare data, any patient identifiable derivative data, and/or non-public analyses that contain patient identifiable data, with at least the privacy and security protections that would be required of covered entities and their business associates under HIPAA Privacy and Security Rules. Additional guidance on the Security rule can be found on the Office for Civil Rights Web site at *http://www.hhs.gov/ocr/privacy/hipaa/.* Such protections would apply when using, disclosing, or maintaining patient identifiable data, regardless of whether the authorized user is a HIPAA Covered Entity or business associate. In addition, we propose to require that the QE DUA contain provisions that require that the authorized user maintain written privacy and security policies and procedures that ensure compliance with these HIPAA-based privacy and security standards and the other standards required under this subpart for the duration of the QE DUA, or for so long as they hold combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data that was subject to the QE DUA, should return/destruction of the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data not be feasible as of the expiration of the QE DUA.

Furthermore, we propose to require QE DUA provisions detailing such policies and procedures must survive termination of the QE DUA, whether for cause or not. We believe that requiring compliance with these HIPAA Privacy and Security Rule concepts outside of the HIPAA context will provide the needed protection for the combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data provided or sold to authorized users under the qualified entity program.

We also propose at § 401.713(d)(7) to require that the qualified entity use the QE DUA to contractually bind an authorized user as a condition of receiving combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data under the qualified entity program to notify the qualified entity of any violations of the QE DUA. Violations might include reportable breaches of data, such as those defined in the HIPAA Breach Rule, or other violations of QE DUA provisions. The QE DUA also will require the authorized user to fully cooperate in the qualified entity's effort to mitigate any harm that may result from such violations, as well as any assistance the qualified entity may request to fulfill the qualified entity's obligations under this subpart.

We request comment on whether the proposed privacy and security requirements are appropriate and adequate, or whether there are more appropriate standards or additional protections that are advisable.

MACRA section 105(a)(5) directs that any combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data provided or sold under this program to authorized users is to be non-public, and it requires the imposition of re-disclosure limitations on authorized users. Under those provisions, qualified entities may only permit providers and suppliers to re-disclose combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data for the

purposes of performance improvement and care coordination. We propose to require qualified entities to include provisions in their QE DUA that contractually limit the re-disclosure and/or linking of combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data provided or sold under this program.

We therefore propose at § 401.713(d)(4) to require that the qualified entity include a provision in its QE DUAs that prohibits the authorized user from re-disclosing or making public any combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data subject to QE DUA except as provided under the QE DUA. Furthermore, we propose at § 401.713(d)(5) to require that the qualified entity use the QE DUA to limit provider's and supplier's re-disclosures to a covered entity pursuant to 45 CFR 164.506(c)(4)(i) or 164.502(e)(1). Therefore, a provider or supplier would only be permitted to re-disclose combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data, subject to the QE DUA, to a covered entity for activities focused on quality assessment and improvement, including the review of provider or supplier performance or a business associate of the provider or supplier. We also propose to require re-disclosure when required by law. We propose these limitations in an effort to ensure that the combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data will be protected in the hands of the downstream entity despite these regulations not reaching such individuals/entities directly. We believe that limiting downstream re-disclosures to entities that are subject to the HIPAA Privacy and Security rules will ensure that the combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data and/or any derivative data is appropriately maintained, used, and disclosed. We seek comment on whether the proposed re-disclosure requirements should be more restrictive or should be broadened to allow for additional re-disclosure.

We also propose to require qualified entities to impose a contractual bar using their QE DUA on the downstream recipients' linking of the re-disclosed combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data to any other identifiable source of information. The only exception to this general policy would be if a provider or supplier were to receive identifiable information limited to their/its own patients. We request comment on whether an authorized user should be permitted to link combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data with other data sources, and whether the proposed provisions are adequate to protect the privacy and security of the combined data, Medicare claims data, and/or non-public analyses that contain patient identifiable data and/or any derivative data given to downstream users.

C. Authorized Users

1. Definition of Authorized User

As discussed above, section 105(a)(1) of MACRA permits qualified entities to provide or sell non-public analyses to authorized users. In addition, section 105(a)(2) of MACRA permits qualified entities to provide or sell combined data, or to provide Medicare data at no cost, only to certain authorized users. These include providers, suppliers, medical societies, and hospital associations.

Section 105(a)(9)(A) of MACRA defines authorized users as:

- A provider of services.
- A supplier.
- An employer (as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974).
- A health insurance issuer (as defined in section 2791 of the Public Health Service Act).
- A medical society or hospital association.
- Any entity not yet described in clauses (i) through (v) that is approved by the Secretary (other than an employer or health insurance issuer not described in clauses (iii) and (iv), respectively, as determined by the Secretary).

We propose a definition for authorized user at § 401.703(k) that is consistent with these statutory provisions. Specifically, we define an authorized user as: (1) A provider; (2) a supplier; (3) an employer; (4) a health insurance issuer; (5) a medical society; (6) a hospital association; (7) a health care professional association; or (8) a state agency.

We also propose definitions for entities that are authorized users, but are not yet defined within this subpart. Therefore, we propose definitions for employer, health insurance issuer, medical society, hospital association, a healthcare professional association, and a state agency.

2. Definition of Employer

We have proposed a definition for employer at § 401.703(k) that is consistent with existing statutory provisions. Specifically, we propose to define an employer as having the same meaning as the term ''employer'' defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974. Under that provision, an employer means any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity.

3. Definition of Health Insurance Issuer

We have also proposed a definition for health insurance issuer at § 401.703(l) that is consistent with existing statutory provisions. Specifically, we propose to define a health insurance issuer as having the same meaning as the term ''health insurance issuer'' defined in section 2791(b)(2) of the Public Health Service Act. Under that provision, health insurance issuer means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

4. Definition of ''Medical Society''

We propose to define ''medical society'' at § 401.703(m) as a nonprofit organization or association that provides unified representation for a large number of physicians at the national or state level and whose membership is comprised of a majority of physicians.

We conducted extensive research to develop this definition, including reviewing mission statements of national and state healthcare professional associations and medical societies, as well as state laws. While we were unable to identify a commonly recognized definition of ''medical society,'' our research did reveal a number of common themes that shaped our proposed definition of medical society.

We propose to define medical society as comprised of a majority of physicians, based on state law definitions around the practice of medicine. Although medical societies may also include non-physician members, due to the strong emphasis on physicians as practitioners of medicine, we propose that a medical society's

membership must be comprised of a majority of physicians. Medical societies often serve as the consensus voice of their members in matters related to their profession, the patient-physician relationship, and other issues pertaining to the practice of medicine. Therefore, we propose that medical societies be at the national or state level as we believe these larger groups will have the capacity to act on the data and analyses available through this program, and to do so in accordance with the statute and the implementing regulations.

While we recognize that there are many local medical societies (for example, regional and county) performing similar functions to their national and state counterparts, we propose to maintain the definition of a medical society at the national or state level to reduce redundancy in the dissemination of data. State societies often serve as federations of local medical societies, and therefore, any use of the data by state societies could benefit their constituent local organizations.

We also propose that these organizations be nonprofit as many of the existing medical societies are nonprofit organizations. In addition, because medical societies will be eligible to receive non-public analyses and data, we believe it is important that these entities be nonprofit to ensure that data provided under this program are used to support quality improvement and assessment activities with their members rather than for profit driven purposes.

5. Definition of ''Hospital Association''

We propose to define a ''hospital association'' at § 401.703(n) as a nonprofit organization or association that provides unified representation for a large number of hospitals or health systems at a national or state level and whose membership is comprised of a majority of hospitals and health systems.

For purposes of this definition, we propose to give hospitals the same meaning as SSA § 1861(e), 42 U.S.C. 1395x(e). We propose to include health systems in this definition as our review of national and state hospital associations member lists revealed that these larger organizations (that are generally comprised of healthcare facilities, such as surgical centers and long terms care facilities, as well as hospitals) were members. Due to their membership status in existing hospital associations, we find it appropriate to propose their inclusion into this definition. Hospital associations often serve as the consensus voice of their members in matters related to their facilities, quality and affordability of services, and other issues regarding the provision of health care. Therefore, we propose that hospital associations at the national or state level be included in this definition as we believe that these larger groups will have the capacity to act on the data, and to do so in accordance with the statute and implementing regulations.

While we recognize that there are many local hospital associations (for example, regional and county) performing similar functions to their national and state counterparts, we proposed to maintain the definition at the national or state level to reduce redundancy. State-level hospital associations are often affiliated with those local associations, and therefore, any use of the data by state hospital associations could benefit those affiliated associations.

We also propose that these organizations be nonprofit as many of the existing hospital associations are nonprofit organizations. In addition, because hospital associations will be eligible to receive non-public analyses and data, we believe it is important that these entities be nonprofit to ensure that data provided under this program are used to support quality improvement and assessment activities with their members rather than for profit driven purposes.

6. Definition of ''Healthcare Provider and/or Supplier Association''

We recognize that within the field of health care, there are many other suppliers and providers beyond physicians, hospitals, and health systems. These entities also form organizations for the betterment of their professions and to improve the quality of patient care. We believe these types of entities would also benefit from the opportunity to purchase or receive non-public analyses and data from qualified entities.

While the term ''healthcare professional association'' is not specifically included in the definition of authorized user, the Secretary, in the exercise of her discretion pursuant to 105(a)(9)(A)(vi) of MACRA, proposes to include these organizations as authorized users. Therefore, we propose to define ''healthcare provider and/or supplier association'' at § 401.703(o) as a nonprofit organization or association that represents suppliers and providers at the national or state level and whose membership is comprised of a majority of suppliers or providers. Similar to the themes that emerge for medical societies and hospital associations, we believe these organizations and associations often serve as the consensus voice of their members in matters related to their respective professions, and that representation at the national or state level is most appropriate as we believe that these larger groups will have the capacity to act on the data and analyses available through this program, and to do so in accordance with the statute and the implementing regulations.

7. Definition of ''State Agency''

While state agencies were not specifically included in the definition of authorized user at section 105(a)(9) of MACRA, we believe that state agencies would benefit from the ability to purchase or receive non-public analyses from qualified entities. States are important partners with CMS in transforming the health care delivery system, and these analyses would have the potential to help states improve the quality of care and reduce costs. Therefore, the Secretary, in the exercise of her discretion pursuant to 105(a)(9)(A)(vi) of MACRA, proposes to include state agencies within the definition of authorized user and to define it at § 401.703(p) as any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

Because there is currently no federal definition of a state agency, we looked to state laws for definitions. While states differ in the definition of state agency, we propose to exclude the judiciary and legislative branches from our proposed definition of state agency under this subpart. We believe that entities within the executive branch of a state government, for example state Medicaid agencies or state public health departments, will have the greatest interest in and need to receive these analyses. We solicit comment on whether we should expand the definition to include other branches of state government or should further limit the definition of state agency to only certain agencies, such as those working to regulate the health and/or insurance industry.

We invite comments on the proposed definitions for authorized user, medical society, hospital association, healthcare professional association, and state agency.

D. Annual Report Requirements

1. Reporting Requirements for Analyses

Section 105(a)(8) of MACRA expands the information that a qualified entity must report annually to the Secretary if

a qualified entity provides or sells non-public analyses. Specifically, it requires the qualified entity to provide a summary of the analyses provided or sold, including information on the number of such analyses, the number of purchasers of such analyses, and the total amount of fees received for such analyses. It also requires the qualified entity to provide a description of the topics and purposes of such analyses. Furthermore, the Secretary may impose other reporting requirements, as appropriate.

In § 401.719(b)(3), we propose the annual reporting requirements that a qualified entity must perform if it provides or sells non-public analyses under this subpart. Consistent with the statutory requirements, we propose to require that the qualified entity provide a summary of the non-public analyses provided or sold under this subpart, including specific information about the number of analyses, the number of purchasers of such analyses, the types of authorized users that purchased analyses, the total amount of fees received for such analyses. We also propose to require the qualified entity to provide a description of the topics and purposes of such analyses. In addition, we propose to require a qualified entity to provide information on QE DUA and non-public analyses agreement violations.

2. Reporting Requirements for Data

Section 105(a)(8) of MACRA also requires a qualified entity to submit a report annually if it provides or sells data. It specifically requires information on the entities who received data under section 105(a)(2) of MACRA, the uses of the data, and the total amount of fees received for providing, selling, or sharing the data. In addition, the Secretary may require additional information as determined appropriate.

Therefore, in § 401.719(b)(4), we also propose to require qualified entities that provide or sell data under this subpart to provide the following information as part of its annual report: Information on the entities who received data, the uses of the data, the total amount of fees received for providing, selling, or sharing the data, and any QE DUA violations.

We do not propose to require any additional information at this time; however, we seek comment on whether any additional information should be collected in the future.

E. Assessment for a Breach

1. Violation of a DUA

Section 105(a)(7) of MACRA requires the Secretary to impose an assessment on a qualified entity in the case of a ''breach'' of a CMS DUA between the Secretary and a qualified entity or a breach of a QE DUA between a qualified entity and an authorized user. Because the term ''breach'' is defined in HIPAA, and this definition is not consistent with the use of the term for this program, we propose instead to adopt the term ''violation'' when referring to a ''breach'' of a DUA for purposes of this program. We anticipate this will reduce the potential for confusion. Therefore in § 401.703(t), we propose to define the term ''violation'' to mean a failure to comply with a requirement in a CMS DUA or QE DUA. We request comments on the proposed definition of violation.

We also propose at § 401.719(d)(5) to impose an assessment on any qualified entity that violates a CMS DUA or fails to ensure that their authorized users do not violate a QE DUA.

MACRA provides guidance only on the assessment amount and what triggers an assessment, but it does not dictate the procedures for imposing such assessments. We therefore propose to adopt certain relevant provisions of section 1128A of the Social Security Act (the Act) (Civil Money Penalties) and part 402 (Civil Money Penalties, Assessments, and Exclusions) to specify the process and procedures for calculating the assessment, notifying a qualified entity of a violation, collecting the assessment, and providing qualified entities an appeals process.

2. Amount of Assessment

Section 105(a)(7)(B) of MACRA specifies that when a violation occurs, the assessment is to be calculated based on the number of affected individuals who are entitled to, or enrolled in, benefits under part A of title XVIII of the Act, or enrolled in part B of such title. Affected individuals are those whose information, either identifiable or de-identified, was provided to a qualified entity or an authorized user under a DUA. Assessments can be up to $100 per affected individual, but, given the broad discretion in establishing some lesser amount, we looked to part 402 as a model for proposing aggravating and mitigating circumstances that would be considered when calculating the assessment amount per impacted individual. However, violations under section 105(a)(7)(B) of MACRA are considered point-in-time violations, not continuing violations.

Number of Individuals

We propose at § 401.719(d)(5)(i) that CMS will calculate the amount of the assessment of up to $100 per individual entitled to, or enrolled in part A of title XVIII of the Act and/or enrolled in part B of such title whose data was implicated in the violation.

We generally propose to determine the number of potentially affected individuals by looking at the number of beneficiaries whose Medicare claims information was provided either by CMS to the qualified entity or by the qualified entity to the authorized user in the form of individually identifiable or de-identified data sets that were potentially affected by the violation.

We recognize that, depending on the number and types of datasets requested, a single beneficiary may appear multiple times within a dataset or non-public analysis. We propose that a single beneficiary, regardless of the number of times their information appears in a singular non-public report or dataset, would only count towards the calculation of an assessment for a violation once. We propose to use the unique beneficiary identification number in the Chronic Conditions Warehouse (CCW) to establish the number of beneficiaries that were included in a given dataset that was transferred to the qualified entity, and subsequently re-disclosed in accordance with this subpart. For qualified entities that provide or sell subsets of the dataset that CMS provided to them, combined information, or non-public analyses, we propose to require that the qualified entity provide the Secretary with an accurate number of beneficiaries whose data was sold or provided to the authorized user and, thereby, potentially affected by the violation. In those instances in which the qualified entity is unable to establish a reliable number of potentially affected beneficiaries, we propose to impose the assessment based on the total number of beneficiaries that were included in the data set(s) that was/were transferred to the qualified entity under that DUA.

Assessment Amount per Impacted Individual

MACRA allows an assessment in the amount of up to $100 per potentially affected individual. We therefore propose to draw on factors established in 42 CFR part 402 to specify the factors and circumstances that will be considered in determining the assessment amount per potentially affected individual.

We propose at § 401.719(d)(5)(i)(A) that the following basic factors be considered in establishing the assessment amount per potentially affected individual: (1) The nature and extent of the violation; (2) the nature and extent of the harm or potential harm resulting from the violation; and (3) the degree of culpability and history of prior violations.

In addition, in considering these basic factors and determining the amount of the assessment per potentially affected individual, we propose to take into account certain aggravating and mitigating circumstances.

We propose at § 401.719(d)(5)(i)(B)(1) that CMS consider certain aggravating circumstances in determining the amount per potentially affected individual, including the following: Whether there were several types of violations, occurring over a lengthy period of time; whether there were many violations or the nature and circumstances indicate a pattern of violations; and whether the nature of the violation had the potential or actually resulted in harm to beneficiaries.

In addition, we propose at § 401.719(d)(5)(i)(B)(2) that CMS take into account certain mitigating circumstances in determining the amount per potentially affected individual, including the following: Whether all of the violations subject to the imposition of an assessment were few in number, of the same type, and occurring within a short period of time, and/or whether the violation was the result of an unintentional and unrecognized error and the qualified entity took corrective steps immediately after discovering the error.

We request comment on the proposed method for calculating the number of individuals. In addition, we request comments on whether the proposed factors for determining the amount of the assessment per potentially affected individual are sufficient, or whether additional factors should be considered. We also request comment on the proposed basic, aggravating, and mitigating factors.

3. Notice of Determination

We looked to the relevant provisions in 42 CFR part 402 and Section 1128A of the Act to frame proposals regarding the specific elements that would be included in the notice of determination. To that end, we propose at § 401.719(d)(5)(ii) that the Secretary would provide notice of a determination to a qualified entity by certified mail with return receipt requested. The notice of determination would include information on (1) the assessment amount, (2) the statutory and regulatory bases for the assessment, (3) a description of the violations upon which the assessment was proposed, (4) information concerning response to the notice, and (5) the means by which the qualified entity must pay the assessment if they do not intend to request a hearing in accordance with procedures established at Section 1128A of the Act and implemented in 42 CFR part 1005.

We believe this information will provide a qualified entity with sufficient information to understand why an assessment was imposed and how the amount of the assessment was calculated. We seek comment regarding these proposals, including whether any additional information should be provided in the notice of determination.

4. Failure To Request a Hearing

We also looked to the relevant provisions in 42 CFR part 402 and section 1128A of the Act to inform our proposals regarding what happens when a hearing is not requested.

We propose at § 401.719(d)(5)(iii) that an assessment will become final if a qualified entity does not request a hearing within 60 days of receipt of the notice of the proposed determination. At this point, CMS would impose the proposed assessment. CMS would notify the qualified entity, by certified mail with return receipt, of the assessment and the means by which the qualified entity may pay the assessment. Under these proposals a qualified entity would not have the right to appeal an assessment unless it has requested a hearing within 60 days of receipt of the notice of the proposed determination.

5. When an Assessment Is Collectible

We again looked to the relevant provisions in 42 CFR part 402 and section 1128A of the Act to inform our proposed policies regarding when an assessment becomes collectible.

We propose at § 401.719(d)(5)(iv) that an assessment becomes collectible after the earliest of the following situations: (1) On the 61st day after the qualified entity receives CMS's notice of proposed determination under § 401.719(d)(5)(ii), if the entity does not request a hearing; (2) immediately after the qualified entity abandons or waives its appeal right at any administrative level; (3) 30 days after the qualified entity receives the Administrative Law Judge's (ALJ) decision imposing an assessment under § 1005.20(d), if the qualified entity has not requested a review before the Department Appeal Board (DAB); or (4) 60 days after the qualified entity receives the DAB's decision imposing an assessment if the qualified entity has not requested a stay of the decision under § 1005.22(b).

6. Collection of an Assessment

We also looked to the relevant provisions in 42 CFR part 402 and section 1128A of the Act in framing our proposals regarding the collection of an Assessment.

We propose at § 401.719(d)(5)(v) that CMS be responsible for collecting any assessment once a determination is made final by HHS. In addition, we propose that the General Counsel may compromise an assessment imposed under this part, after consulting with CMS or Office of Inspector General (OIG), and the Federal government may recover the assessment in a civil action brought in the United States district court for the district where the claim was presented or where the qualified entity resides. We also propose that the United States may deduct the amount of an assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing the qualified entity. Finally, we propose that matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect an assessment.

We seek comments on these proposals.

F. Termination of Qualified Entity Agreement

We propose at § 401.721(a)(7) that CMS may unilaterally terminate the qualified entity's agreement and trigger the data destruction requirements in the CMS DUA if CMS determines that a qualified entity or its contractor fails to monitor authorized users' compliance with the terms of their QE DUAs or non-public analysis use agreements. We believe this proposed provision is consistent with the intent of MACRA to ensure the protection of data and analyses provided by qualified entities to authorized users under this subpart. We request comments on this proposed provision.

G. Additional Data

Section 105(c) of MACRA expands, at the discretion of the Secretary, the data that the Secretary may make available to qualified entities, including standardized extracts of claims data under titles XIX (Medicaid) and XXI (the Children's Health Insurance Program, CHIP) for one or more specified geographic areas and time periods as may be requested by the

qualified entity. Currently, CMS is only required to provide qualified entities with standardized extracts of claims data from Medicare Parts A, B, and D. While CMS has data for Medicare and Medicaid/CHIP, the timeliness and quality of data differs significantly between the programs.

Medicare is a national program that is administered by CMS and, as a result, the claims data are available on a relatively timely basis, and guidelines about claims submission and data cleaning are consistent across the entire program. Medicaid and CHIP, however, are state-run programs where the states submit data to CMS. Each state's Medicaid agency collects enrollment and claims data for persons enrolled in Medicaid and CHIP. These data are collected in the state's Medicaid Management Information System (MMIS). Each state's MMIS is tailored to the needs of that state's Medicaid program. In partnership with the states, the federal government does manage aspects of the Medicaid program, and works with the various Medicaid State Agencies to monitor health care delivery and payment on a national level. To aid in that work the data in the MMIS are converted into a national standard and submitted to CMS via the Medicaid and CHIP Statistical Information System (MSIS). But the MSIS data (enrollment and claims data) are only reported to CMS on a quarterly basis, and the MSIS data can be challenging to use due to the data representing a mixture of time periods.

Given the difficulties in using the MSIS data, the timeliness issues with our Medicaid data, and the variation of time periods reflected in our data, we believe that qualified entities would be better off seeking Medicaid and/or CHIP data through the State Medicaid Agencies. As a result, we propose not to expand the data available to qualified entities from CMS.

H. Qualified Clinical Data Registries

Section 105(b) of MACRA allows qualified clinical data registries to request access to Medicare data for the purposes of linking the data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses, and research to support quality improvement or patient safety. The CMS research data disclosure policies already allow qualified clinical data registries to request Medicare data for these purposes, as well as other types of research. More information on accessing CMS data for research can be found on the Research Data Assistance Center (ResDAC) Web site at *www.resdac.org.* Given these existing processes and procedures, we propose not to adopt any new policies or procedures regarding qualified clinical data registries' access to Medicare claims data for quality improvement or patient safety research.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this proposed rule that contain information collection requirements (ICRs).

Proposed § 401.718(c) and § 401.716(b)(2)(ii) require a qualified entity to enter into a QE DUA with an authorized user prior to providing or selling data or selling a non-public analyses that contains individually identifiable beneficiary information. Proposed § 401.713(d) requires specific provisions in the QE DUA. Proposed § 401.716(c) requires a qualified entity to enter into a non-public analyses agreement with the authorized user as a pre-condition to providing or selling de-identified analyses. We estimate that it will take each qualified entity a total of 40 hours to develop the QE DUA and non-public analyses agreement. Of the 40 hours, we estimate it will take a professional/technical services employee with an hourly labor cost of $75.08 a total of 20 hours to develop both the QE DUA and non-public analyses agreement and estimate that it will require a total of 20 hours of legal review at an hourly labor cost of $77.16 for both the QE DUA and non-public analyses agreement. We also estimate that it will take each qualified entity 2 hours to process and maintain each QE DUA or non-public analyses agreement with an authorized user by a professional/technical service employee with an hourly labor cost of $75.08. While there may be two different staff positions that perform these duties (one that is responsible for processing the QE DUAs and/or non-public analyses agreement and one that is responsible for maintaining the QE DUA and/or non-public analyses agreement), we believe that both positions would fall under the professional/technical services employee labor category with an hourly labor cost of $75.08. This would mean that to develop each QE DUA and non-public analysis agreement, the burden cost per qualified entity would be $3,045 with a total estimated burden for all 15 qualified entities of $45,675. This does not include the two hours to process and maintain each QE DUA.

As discussed in the regulatory impact analysis below, we estimate that each qualified entity would need to process and maintain 70 QE DUAs or non-public analyses agreements as some authorized users may receive both datasets and a non-public analyses and would only need to execute one QE DUA. We estimate that it will take each qualified entity 2 hours to process and maintain each QE DUA or non-public analyses agreement. This would mean the burden cost per qualified entity to process and maintain 70 QE DUAs or non-public analyses agreements would be $10,511 with a total estimated burden for all 15 qualified entities of $157,668. While we anticipate that the requirement to create a QE DUA and/or non-public analyses agreement will only be incurred once by a qualified entity, we believe that the requirement to process and maintain the QE DUAs and/or non-public analyses will be an ongoing cost. We request comment on the number of hours that will be needed to create and process the QE DUA and non-public analyses agreement.

If finalized, these regulations would also require a qualified entity to submit additional information as part of its annual report to CMS. A qualified entity is currently required to submit an annual report to CMS under § 401.719(b). Proposed § 401.719(b)(3) and (4) provide for additional reporting requirements if a qualified entity chooses to provide or sell analyses and/or data to authorized users. The burden associated with this requirement is the time and effort necessary to gather, process, and submit the required information to CMS. There are currently 13 qualified entities; however we estimate that number will increase to 20 if these proposals are finalized. Some qualified entities may not want to bear the risk of the potential assessments and

have been able to accomplish their program goals under other CMS data sharing programs, therefore some qualified entities may not elect to provide or sell analyses and/or data to authorized users. As a result, we estimate that 15 qualified entities will choose to provide or sell analyses and/or data to authorized users, and therefore, would be required to comply with these additional reporting requirements within the first three years of the program. We further estimate that it would take each qualified entity 50 hours to gather, process, and submit the required information. We estimate that it will take each qualified entity 34 hours to gather the required information, 15 hours to process the information, and 1 hour to submit the information to CMS. We believe a professional or technical services employee of the qualified entity with an hourly labor cost of $75.08 will fulfill these additional annual report requirements. We estimate that 15 qualified entities will need to comply with this requirement and that the total estimated burden associated with this requirement is $56,310. We request comment on the type of employee and the number of hours that will be needed to fulfill these additional annual reporting requirements.

As a reminder, the final rule for the qualified entity program, published December 7, 2011, included information about the burden associated with the provisions in that rule. Specifically, Sections 401.705–401.709 provide the application and reapplication requirements for qualified entities. The burden associated with these requirements is currently approved under OMB control number 0938–1144 with an expiration date of May 31, 2018. This package accounts for 35 responses. Section 401.713(a) states that as part of the application review and approval process, a qualified entity would be required to execute a DUA with CMS, that among other things, reaffirms the statutory bar on the use of Medicare data for purposes other than those referenced above. The burden associated with executing this DUA is currently approved under OMB control number 0938–0734 with an expiration date of December 31, 2017. This package accounts for 9,240 responses (this package covers all CMS DUAs, not only DUAs under the qualified entity program). We currently have 13 qualified entities and estimate it will increase to 20 so we have not surpassed the previously approved numbers.

We based the hourly labor costs on those reported by the Bureau of Labor Statistics (BLS) at *http://data.bls.gov/pdq/querytool.jsp?survey=ce* for this labor category. We used the annual rate for 2014 and added 100 percent for overhead and fringe benefit costs.

TABLE 1—COLLECTION OF INFORMATION

Regulation section(s)	OMB control No.	Number of respondents	Number of responses per respondent	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($) *	Total labor cost of reporting ($)	Total cost ($)
§ 401.718, § 401.716, and § 401.713 (DUA and non-public analyses agreement Development).	0938—New	15	1	20	300	75.08	22,524	22,524
§ 401.718 and § 401.716 (Legal Review)	0938—New	15	1	20	300	77.16	23,148	23,148
§ 401.718 and § 401.716 (Processing and Maintenance).	0938—New	15	70	2	2,100	75.08	157,668	157,668
§ 401.719(b)	0938—New	15	1	50	750	75.08	56,310	56,310
Total		15	73		3,450			259,650

* The values listed are based on 100 percent overhead and fringe benefit calculations.
Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 1.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by April 4, 2016.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, 96), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). For the reasons discussed below, we estimate that the total impact of this proposed rule would be less than $58 million and therefore, it would not reach the threshold for economically significant effects and is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals and most other providers are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). However, since the total estimated impact of this rule is less than $100 million, and the total estimated impact would be spread over 82,500 providers and suppliers (who are the subject of reports), no one entity would face significant impact. Of the 82,500 providers, we estimate that 78,605

would be physician offices that have average annual receipts of $11 million and 4,125 would be hospitals that have average annual receipts of $38.5 million. As discussed below, the estimated cost per provider is $8,426 (see table 5 below) and the estimated cost per hospital is $6,523 (see table 5 below). For both types of entities, these costs would be a very small percentage of overall receipts. Thus, we are not preparing an analysis of options for regulatory relief of small businesses because we have determined that this rule would not have a significant economic impact on a substantial number of small entities.

For section 105(a) of MACRA, we estimate that two types of entities may be affected by the additional program opportunities: Qualified entities that choose to provide or sell non-public analyses or data to authorized users; and providers and suppliers who are identified in the non-public analyses create by qualified entities and provided or sold to authorized users.

We anticipate that most providers and suppliers that may be identified in qualified entities' non-public analyses would be hospitals and physicians. Many hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than $38.5 million in any 1 year) (for details see the Small Business Administration's Web site at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf* (refer to the 620000 series). For purposes of the RFA, physicians are considered small businesses if they generate revenues of $11 million or less based on Small Business Administration size standards. Approximately 95 percent of physicians are considered to be small entities.

The analysis and discussion provided in this section and elsewhere in this proposed rule complies with the RFA requirements. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis for the remaining provisions and addresses comments received on these issues.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule has impact on significant operations of a substantial number of small rural hospitals because we anticipate that most qualified entities would focus their performance evaluation efforts on metropolitan areas where the majority of health services are provided. As a result, this rule would not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This proposed rule will not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of $144 million or more. Specifically, as explained below we anticipate the total impact of this rule on all parties to be approximately $58 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined this proposed rule in accordance with Executive Order 13132 and have determined that this regulation would not have any substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

B. Anticipated Effects

1. Impact on Qualified Entities

Because section 105(a) of MACRA allows qualified entities to use the data in new ways to provide or sell non-public analyses or data to authorized users, there is little quantitative information to inform our estimates on the number of analyses and datasets that the qualified entity costs may provide or sell or on the costs associated with the creation of the non-public analyses or datasets. Therefore, we look to the estimates from the original qualified entity rules to estimate the number of hours that it may take to create non-public analyses and to process provider appeals and revisions. We also looked to the Centers for Medicare and Medicaid's cost of providing data to qualified entities since qualified entities' data fees are equal to the government's cost to make the data available.

There are currently 13 qualified entities and these qualified entities all are in different stages of the qualified entity program. For example, some qualified entities have released public reports and some qualified entities are still completing the security requirements in order to receive CMS data. Given the requirements in the different phases and the current status of the qualified entities, we estimate that 11 qualified entities will be able to provide or sell analyses and/or data to authorized users within the first year of the program, and therefore, would be incurring extra costs. As discussed above, we believe the total number of qualified entities will ultimately grow to 20 in subsequent years, with 15 entities providing or selling analyses and/or data to authorized users. In estimating qualified entity impacts, we used hourly labor costs in several labor categories reported by the Bureau of Labor Statistics (BLS) at *http://data.bls.gov/pdq/querytool.jsp?survey=ce.* We used the annual rates for 2014 and added 100 percent for overhead and fringe benefit costs. These rates are displayed in Table 2.

TABLE 2—LABOR RATES FOR QUALIFIED ENTITY IMPACT ESTIMATES

	2014 hourly wage rate (BLS)	OH and fringe (100%)	Total hourly costs
Professional and technical services	$37.54	$37.54	$75.08
Legal review	38.58	38.58	77.16
Custom computer programming	43.05	43.05	86.10
Data processing and hosting	34.02	34.02	68.04

TABLE 2—LABOR RATES FOR QUALIFIED ENTITY IMPACT ESTIMATES—Continued

	2014 hourly wage rate (BLS)	OH and fringe (100%)	Total hourly costs
Other information services	39.72	39.72	79.44

We estimate that within the first year that 11 qualified entities will provide or sell on average 55 non-public analyses or provide or sell 35 datasets. We do not believe the number of datasets and non-public analyses per qualified entity will change in future years of the program. We seek comment on the number of non-public analyses or datasets that a qualified entity will create and provide or sell within the first year and future years.

In the original proposed rule for the qualified entity program (76 FR 33566), we estimated that each qualified entities' activities to analyze the Medicare claims data, calculate performance measures and produce public provider performance reports would require 5,500 hours of effort per qualified entity. We anticipate under this proposed rule that implements section 105(a) of MACRA that qualified entities will base the non-public analyses on their public performance reports. Therefore, the creation of the non-public analyses will require much less effort and only require a fraction of the time it takes to produce the public reports. We estimate that a qualified entity's activities for each non-public analysis to analyze the Medicare claims data, calculate performance measures, and produce the report would require 320 hours, between five and six percent of the time to produce the public reports. We anticipate that half of this time will be spent on data analysis, measure calculation, and report creation and the other half on data processing. We request comment on the level of effort to create the non-public analyses.

We anticipate that within the first year of the program a qualified entity will, on average, provide one-year datasets containing all data types for a cohort of 750,000 to 1.75 million beneficiaries to 35 authorized users. We estimate that it will require 226 hours to create each dataset that will be provided to an authorized user. We looked to the Centers for Medicare and Medicaid Centers' data costs and time to estimate a qualified entity's costs and time to create datasets. While the majority of the time will be devoted to computer processing, we anticipate about 100 hours will be spent on computer programming, particularly if the qualified entity is de-identiying the data. We seek comment of the level of effort required to create each dataset and the number of authorized users that will obtain or purchases data from a qualified entity.

We further estimate that, on average, each qualified entity would expend 7,500 hours of effort processing providers' and suppliers' appeals of their performance reports and producing revised reports, including legal review of the appeals and revised reports. These estimates assume that, as discussed below in the section on provider and supplier impacts, on average 25 percent of providers and suppliers would appeal their results from a qualified entity. Responding to these appeals in an appropriate manner would require a significant investment of time on the part of qualified entities. This equates to an average of four hours per appeal for each qualified entity. These estimates are similar to those in the Qualified Entities final rule. We assume that the complexity of appeals would vary greatly, and as such, the time required to address them would also vary greatly. Many appeals may be able to be dealt with in an hour or less while some appeals may require multiple meetings between the qualified entity and the affected provider or supplier. On average, however, we believe that this is a reasonable estimate of the burden of the appeals process on qualified entities. We discuss the burden of the appeals process on providers and suppliers below.

We estimate that each qualified entity would spend 40 hours creating a non-public analyses agreement template and a QE DUA. We also estimate that it would take a qualified entity 2 hours to process a QE DUA or non-public analyses agreement.

Finally, we estimate that each qualified entity would spend 50 hours on the additional annual reporting requirements.

Qualified entities would be required to notify CMS of inappropriate disclosures or use of beneficiary identifiable data pursuant to the requirements in the CMS DUA. We believe that the report generated in response to an inappropriate disclosure or use of beneficiary identifiable data would be generated as a matter of course by the qualified entities and therefore, would not require significant additional effort. Based on the assumptions we have described, we estimate the total impact on qualified entities for the first year of the program to be a cost of $27,925,198.

TABLE 3—IMPACT ON QUALIFIED ENTITIES FOR THE FIRST YEAR OF THE PROGRAM

Impact on qualified entities									
Activity	Hours				Labor hourly cost	Cost per authorized user	Number of authorized users	Number of qualified entities	Total cost impact
	Professional and technical	Legal	Computer programming	Data processing and hosting					
Dissemination of Data:									
Data processing & hosting	.....	.....	.....	126	$68.04	$8,573	35	11	$3,300,620
Computer programming	.....	.....	100	.....	86.10	8,610	35	11	3,314,850
Total: Dissemination of Data	.....	.....	.....	.....	.....	.....	.....	.....	6,615,470
Non-Public Analyses:									
Data analysis/measure calculation/report preparation	.....	.....	160	.....	86.10	13,776	55	11	8,334,480

TABLE 3—IMPACT ON QUALIFIED ENTITIES FOR THE FIRST YEAR OF THE PROGRAM—Continued

Impact on qualified entities									
Activity	Hours				Labor hourly cost	Cost per authorized user	Number of authorized users	Number of qualified entities	Total cost impact
	Professional and technical	Legal	Computer programming	Data processing and hosting					
Data Processing and hosting				160	68.04	10,886	55	11	6,586,272
Total Non-public Analyses									14,920,752
Qualified entity processing of provider appeals and report revision	5,500				75.08	412,940		11	4,542,340
Qualified entity legal analysis of provider appeals and report revisions		2,000			77.16	154,320		11	1,697,520
Total qualified entity processing of provider appeals and report revision									6,239,860
QE DUA and Non-public analyses:									
Development of the QE DUA and non-public analyses agreement	20				75.08	1,502		11	16,518
Legal review of the QE DUA and non-public analyses agreement		20			77.16	1,543		11	16,975
Processing QE DUA and non-public analyses agreement	2				75.08	150	70	11	115,623
Total QE DUA and non-public analyses agreements									149,116
Additional Annual Report Requirements	50				75.08	3,754		11	41,294
Total qualified entity Impacts									27,966,492

2. Impact on Health Care Providers and Suppliers

We note that numerous health care payers, community quality collaboratives, States, and other organizations are producing performance measures for health care providers and suppliers using data from other sources, and that providers and suppliers are already receiving performance reports from these sources. We anticipate that the review of non-public analyses would merely be added to those existing efforts to improve the statistical validity of the measure findings. However, we invite comments on the impact of this new voluntary program.

Table 4 reflects the hourly labor rates used in our estimate of the impacts of the first year of section 105(a) of MACRA on health care providers and suppliers.

TABLE 4—LABOR RATES FOR PROVIDER AND SUPPLIER IMPACT ESTIMATES

	2014 hourly wage rate (BLS)	Overhead and fringe benefits (100%)	Total hourly costs
Physicians' offices	$38.27	$38.27	$76.54
Hospitals	29.65	29.65	59.30

We anticipate that the impacts on providers and suppliers consist of costs to review the performance reports generated by qualified entities and, if they choose, appeal the performance calculations. We believe, on average, each qualified entity would produce non-public analyses that in total include information on 7,500 health providers and suppliers. This is based on estimates in the qualified entity final rule, but also include an increase of 50 percent because we believe that more providers and suppliers will be included in the non-public analyses. We anticipate that the largest proportion of providers and suppliers would be physicians because they comprise the largest group of providers and suppliers, and are a primary focus of many recent performance evaluation efforts. We also believe that many providers and suppliers will be the recipients of the non-public analyses in order to support their own performance improvement activities, and therefore, there would be no requirement for a correction or appeals process. As discussed above, there is no requirement for a corrections or appeals process where the analysis only individually identifies the (singular) provider or supplier who is being provided or sold the analysis.

Based on our review of information from existing programs, we assume that 95 percent of the recipients of performance reports (that is, an average of 7,125 per qualified entity) would be physicians, and 5 percent (that is, an average of 375 per qualified entity) would be hospitals and other suppliers. Providers and suppliers receive these reports with no obligation to review them, but we assume that most would do so to verify that their calculated performance measures reflect their actual patients and health events. Because these non-public analyses will be based on the same underlying data as the public performance reports, we estimate that it would take less time for providers or suppliers to review theses analyses and generate an appeal. We estimate that, on average, each provider or supplier would devote three hours to reviewing these analyses. We also estimate that 25 percent of the providers and suppliers would decide to appeal their performance calculations, and that preparing the appeal would involve an average of seven hours of effort on the part of a provider or supplier. As with our assumptions regarding the level of effort required by qualified entities in operating the appeals process, we believe that this average covers a range of provider efforts from providers who would need just one or two hours to clarify any questions or concerns regarding their performance reports to providers who would devote significant time and resources to the appeals process.

Using the hourly costs displayed in Table 4, the impacts on providers and suppliers are calculated below in Table 5. Based on the assumptions we have described, we estimate the total impact on providers for the first year of the program to be a cost of $29,690,386.

As stated above in Table 3, we estimate the total impact on qualified entities to be a cost of $27,966,492. Therefore, the total impact on qualified entities and on providers and suppliers for the first year of the program is estimated to be $57,656,878.

TABLE 5—IMPACT ON PROVIDERS AND SUPPLIERS FOR THE FIRST YEAR OF THE PROGRAM

Impact on Providers and Suppliers							
Activity	Hours per provider		Labor hourly cost	Cost per provider	Number of providers per qualified entity	Number of qualified entities	Total cost impact
	Physician offices	Hospitals					
Physician office review of performance reports	3	.....	76.54	$230	7,125	11	$18,026,250
Hospital review of performance reports	.....	3	59.30	178	375	11	734,250
Physician office preparing and submitting appeal requests to qualified entities	7	.....	76.54	536	1,781	11	10,500,776
Hospital preparing and submitting appeal requests to qualified entities	.....	7	59.30	415	94	11	429,110
Total Impact on Providers and Suppliers	.....	.....	.....	.....	.....	.....	29,690,386

C. Alternatives Considered

The statutory provisions added by section 105(a) of MACRA are detailed and prescriptive about the permissible uses of the data under the Qualified Entity Program. We believe there are limited approaches that would ensure statutory compliance. We considered proposing less prescriptive requirements on the provisions that would need to be included in the agreements between qualified entities and authorized users that received or purchased analyses or data. For example, we could have required less strenuous data privacy and security protections such as not setting a minimum standard for protection of beneficiary identifiable data or non-public analyses. In addition, we could have reduced additional restrictions on re-disclosure or permitted data or analyses to be re-disclosed to additional downstream users. While these approaches might reduce costs for qualified entities, we did not adopt such an approach because of the importance of protecting beneficiary data. We believe if we do not require qualified entities to provide sufficient evidence of data privacy and security protection capabilities, there would be increased risks related to the protection of beneficiary identifiable data.

D. Conclusion

As explained above, we estimate the total impact for the first year of the program on qualified entities and providers to be a cost of $57,656,878. While we anticipate the number of qualified entities to increase slightly, we do not anticipate significant growth in the qualified entity program given the qualified entity program requirements, as well as other existing programs that allow entities to obtain Medicare data. Based on these estimates, we conclude this proposed rule does not reach the threshold for economically significant effects and thus is not considered a major rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 401 as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302,

1395hh, and 1395w–5) and section 105 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10).

■ 2. Section 401.703 is amended by adding paragraphs (j) through (u) to read as follows:

§ 401.703 Definitions.

* * * * *

(j) *Authorized user* is a third party (meaning not the qualified entity or its contractors) to whom/which the qualified entity provides or sells data as permitted under this subpart. Authorized users are limited to the following entities:

(1) A provider.

(2) A supplier.

(3) A medical society.

(4) A hospital association.

(5) An employer.

(6) A health insurance issuer.

(7) A healthcare provider and/or supplier association.

(8) A state agency.

(k) *Employer* has the same meaning as the term ''employer'' as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974.

(l) *Health insurance issuer* has the same meaning as the term ''health insurance issuer'' as defined in section 2791 of the Public Health Service Act.

(m) *Medical society* means a nonprofit organization or association that provides unified representation and advocacy for physicians at the national or state level and whose membership is comprised of a majority of physicians.

(n) *Hospital association* means a nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national or state level and whose membership is comprised of a majority of hospitals and health systems.

(o) *Healthcare Provider and/or Supplier Association* means a nonprofit organization or association that provides unified representation and advocacy for providers and suppliers at the national or state level and whose membership is comprised of a majority of suppliers or providers.

(p) *State Agency* means any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

(q) *Combined data* means a set of CMS claims data provided under subpart G combined with claims data, or a subset of claims data from at least one of the other claims data sources described in § 401.707(d).

(r) *Patient* means an individual who has visited the provider or supplier for a face-to-face or telehealth appointment at least once in the past 12 months.

(s) *Marketing* means the same as the term ''marketing'' at 45 CFR 164.501 without the exception to the bar for ''consent'' based marketing.

(t) *Violation* means a failure to comply with a requirement of a CMS DUA or QE DUA.

(u) *Required by law* means the same as the phrase ''required by law'' at 45 CFR 164.103.

■ 3. Section 401.713 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 401.713 Ensuring the privacy and security of data.

(a) Data Use Agreement between CMS and a qualified entity. A qualified entity must comply with the data requirements in its data use agreement with CMS (hereinafter the CMS DUA). Contractors of qualified entities that are anticipated to have access to the Medicare claims data or beneficiary identifiable data in the context of this program are also required to execute and comply with the CMS DUA. The CMS DUA will require the qualified entity to maintain privacy and security protocols throughout the duration of the agreement with CMS, and will ban the use or disclosure of CMS data or any derivative data for purposes other than those set out in this subpart. The CMS DUA will also prohibit the use of unsecured telecommunications to transmit such data, and will specify the circumstances under which such data must be stored and may be transmitted.

* * * * *

(d) Data Use Agreement between a qualified entity and an authorized user. In addition to meeting the other requirements of this subpart, and as a pre-condition of selling or disclosing any combined data or any Medicare claims data (or any beneficiary-identifiable derivative data of either kind) and as a pre-condition of selling or disclosing non-public analyses that include individually identifiable beneficiary data, the qualified entity must enter a DUA (hereinafter the QE DUA) with the authorized user. Among other things laid out in this subpart, such QE DUA must contractually bind the authorized user to the following:

(1)(i) The authorized user may be permitted to use such data and non-public analyses in a manner that a HIPAA Covered Entity could do under the following provisions:

(A) Activities falling under the first paragraph of the definition of ''health care operations'' under 45 CFR 164.501: Quality improvement activities, including care coordination activities and efforts to track and manage medical costs.

(B) Activities falling under the second paragraph of the definition of ''health care operations'' under 45 CFR 164.501: Population-based activities such as those aimed at improving patient safety, quality of care, or population health, including the development of new models of care, the development of means to expand coverage and improve access to healthcare, the development of means of reducing health care disparities, and the development or improvement of methods of payment or coverage policies.

(C) Activities that qualify as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(ii) All other uses and disclosures of such data and/or such non-public analyses must be forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

(2) The authorized user is prohibited from using or disclosing the data or non-public analyses for marketing purposes as defined at § 401.703(s).

(3) The authorized user is required to ensure adequate privacy and security protection for such data and non-public analyses. At a minimum, regardless of whether the authorized user is a HIPAA covered entity, such protections of beneficiary identifiable data must be at least as protective as what is required of covered entities regarding protected health information (PHI) under the HIPAA Privacy and Security Rules. In all cases, these requirements must be imposed for the life of such beneficiary identifiable data or non-public analyses and/or any derivative data, that is until all copies of such data or non-public analyses are returned or destroyed. Such duties must be written in such a manner as to survive termination of the QE DUA, whether for cause or not.

(4) Except as provided for in paragraph (d)(5) of this section, the authorized user must be prohibited from re-disclosing or making public any such data or non-public analyses.

(5)(i) At the qualified entity's discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose such data and non-public analyses as a covered entity would be permitted to disclose PHI under 45 CFR 164.506(c)(4)(i)), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

(6) Authorized users who/that receive the beneficiary de-identified combined data or Medicare data as contemplated

under § 401.718 are contractually prohibited from linking the beneficiary de-identified data to any other identifiable source of information, and must be contractually barred from attempting any other means of re-identifying any individual whose data is included in such data.

(7) The QE DUA must bind authorized user(s) to notifying the qualified entity of any violations of the QE DUA, and it must require the full cooperation of the authorized user in the qualified entity's efforts to mitigate any harm that may result from such violations, or to comply with the breach provisions governing qualified entities under this subpart.

■ 4. Section 401.716 is added to read as follows:

§ 401.716 Non-public analyses.

(a) *General.* So long as it meets the other requirements of this subpart, and subject to the limits in paragraphs (b) and (c) of this section, the qualified entity may use the combined data to create non-public analyses in addition to performance measures.

(b) *Limitations on a qualified entity.* In addition to meeting the other requirements of this subpart, a qualified entity must comply with the following limitations as a pre-condition of dissemination or selling non-public analyses to an authorized user:

(1) A qualified entity may only provide or sell a non-public analysis to a health insurance issuer as defined in § 401.703(l), after the health insurance issuer has provided the qualified entity with claims data that represents a majority of the health insurance issuer's covered lives for the time period and geographic region covered by the issuer-requested non-public analyses.

(2) Analyses that contain information that individually identifies one or more beneficiaries may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) when the following conditions are met:

(i) The analyses only contain identifiable information on beneficiaries with whom the provider or supplier have a patient relationship as defined at § 401.703(r), and

(ii) a QE DUA as defined at § 401.713(d) is executed between the qualified entity and the provider or supplier prior to making any individually identifiable beneficiary information available to the provider or supplier.

(3) Except as specified under paragraph (c)(2) of this section, all analyses must be limited to beneficiary de-identified data. Regardless of the HIPAA covered entity or business associate status of the qualified entity and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR 164.514(b).

(4) Analyses that contain information that individually identifies a provider or supplier may not be disclosed unless:

(i) The analysis only individually identifies the provider or supplier that is being supplied the analysis, or

(ii) Every provider or supplier individually identified in the analysis has been afforded the opportunity to appeal or correct errors using the process at § 401.717(f).

(c) *Non-public analyses agreement between a qualified entity and an authorized user for beneficiary de-identified non-public analyses disclosures.* In addition to the other requirements of this subpart, a qualified entity must enter a contractually binding non-public analyses agreement with the authorized user as a pre-condition to providing or selling de-identified analyses. Such non-public analyses agreement must contain the following provisions:

(1) The authorized user may not use the analyses or derivative data for the following purposes:

(i) Marketing, as defined at § 401.703(s).

(ii) Harming or seeking to harm patients or other individuals both within and outside the healthcare system regardless of whether their data are included in the analyses.

(iii) Effectuating or seeking opportunities to effectuate fraud and/or abuse in the health care system.

(2) If the authorized user is an employer as defined in § 401.703(k), the authorized user may only use the analyses or derivative data for purposes of providing health insurance to employees, retirees, or dependents of employees or retirees of that employer.

(3)(i) At the qualified entity's discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose the de-identified analyses or derivative data, as a covered entity would be permitted under 45 CFR 164.506(c)(4)(i), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

(4) If the authorized user is not a provider or supplier, the authorized user may not re-disclose or make public any non-public analyses or derivative data except as required by law.

(5) The authorized user may not link the de-identified analyses to any other identifiable source of information and may not in any other way attempt to identify any individual whose de-identified data is included in the analyses.

(6) The authorized user must notify the qualified entity of any DUA violations, and it must fully cooperate with the qualified entity's efforts to mitigate any harm that may result from such violations.

■ 5. Section 401.717 is amended by adding paragraph (f) to read as follows:

§ 401.717 Provider and supplier requests for error correction.

* * * * *

(f) A qualified entity also must comply with paragraphs (a) through (e) of this section before disclosing non-public analyses, as defined at § 401.716, that contain information that individually identifies a provider or supplier.

■ 6. Section 401.718 is added to read as follows:

§ 401.718 Dissemination of data.

(a) *General.* Subject to the other requirements in this subpart, the requirements in paragraphs (b) and (c) of this section and any other applicable laws or contractual agreements, a qualified entity may provide or sell combined data, or provide Medicare data at no cost to authorized users defined at § 401.703(b), (c), (m), and (n).

(b) *Data*—(1) *De-identification.* Except as specified in paragraph (b)(2) of this section, any data provided or sold by a qualified entity to an authorized user must be limited to beneficiary de-identified data. De-identification must be determined based on the de-identification standards for HIPAA covered entities found at § 164.514(b).

(2) *Exception.* If such disclosure would be consistent with all applicable laws, data that individually identifies a beneficiary may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) with whom the identifiable individuals in such data have a current patient relationship as defined at § 401.703(r).

(c) *Data Use Agreement between a qualified entity and an authorized user.* A qualified entity must contractually require an authorized user to comply with the requirements in § 401.713(d) prior to providing or selling data to an authorized user under § 401.718.

■ 7. Section 401.719 is amended by adding paragraphs (b)(3) and (4) and (d)(5) to read as follows:

§ 401.719 Monitoring and sanctioning of qualified entities.

* * * * *

(b) * * *

(3) Non-public analyses provided or sold to authorized users under this subpart, including the following information:

(i) A summary of the analyses provided or sold, including—

(A) The number of analyses.

(B) The number of purchasers of such analyses.

(C) The types of authorized users that purchased analyses.

(D) The total amount of fees received for such analyses.

(E) QE DUA or non-public analyses agreement violations.

(ii) A description of the topics and purposes of such analyses.

(4) Data provided or sold to authorized users under this subpart, including the following information:

(i) The entities who received data.

(ii) The basis under which each entity received such data.

(iii) The total amount of fees received for providing, selling, or sharing the data.

(iv) QE DUA violations.

* * * * *

(d) * * *

(5) In the case of a violation, as defined at § 401.703(t) of the CMS DUA or the QE DUA, CMS will impose an assessment on a qualified entity in accordance with the following:

(i) *Amount of Assessment.* CMS will calculate the amount of the assessment of up to $100 per individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under part B of such title whose data was implicated in the violation based on the following:

(A) *Basic Factors.* In determining the amount per impacted individual, CMS takes into account the following:

(*1*) The nature and the extent of the violation.

(*2*) The nature and the extent of the harm or potential harm resulting from the violation.

(*3*) The degree of culpability and the history of prior violations.

(B) *Criteria to be considered.* In establishing the basic factors, CMS considers the following circumstances, including:

(1) Aggravating Circumstances. Aggravating circumstances include the following:

(*i*) There were several types of violations occurring over a lengthy period of time.

(*ii*) There were many of these violations or the nature and circumstances indicate a pattern of violations.

(*iii*) The nature of the violation had the potential or actually resulted in harm to beneficiaries.

(2) Mitigating circumstances. Mitigating circumstances include the following:

(*i*) All of the violations subject to the imposition of an assessment were few in number, of the same type, and occurring within a short period of time.

(*ii*) The violation was the result of an unintentional and unrecognized error and the qualified entity took corrective steps immediately after discovering the error.

(C) *Effects of aggravating or mitigating circumstances.* In determining the amount of the assessment to be imposed under (d)(5)(i)(A) of this section.

(*1*) If there are substantial or several mitigating circumstance, the aggregate amount of the assessment is set at an amount sufficiently below the maximum permitted by (d)(5)(A) of this section to reflect the mitigating circumstances.

(*2*) If there are substantial or several aggravating circumstances, the aggregate amount of the assessment is set at an amount at or sufficiently close to the maximum permitted by (d)(5)(i)(A) of this section to reflect the aggravating circumstances.

(D) The standards set for the qualified entity in this paragraph are binding, except to the extent that—

(*1*) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(*2*) Nothing in this section limits the authority of CMS to settle any issue or case as provided by part 1005 of this title or to compromise any assessment as provided by (d)(5)(E) of this section.

(ii) *Notice of Determination.* CMS must propose an assessment in accordance with this paragraph, by notifying the qualified entity by certified mail, return receipt requested. Such notice must include the following information:

(A) The assessment amount.

(B) The statutory and regulatory bases for the assessment.

(C) A description of the violations upon which the assessment was proposed.

(D) Any mitigating or aggravating circumstances that CMS considered when it calculated the amount of the proposed assessment.

(E) Information concerning response to the notice, including:

(*1*) A specific statement of the respondent's right to a hearing in accordance with procedures established at Section 1128A of the Act and implemented in 42 CFR part 1005.

(*2*) A statement that failure to respond within 60 days renders the proposed determination final and permits the imposition of the proposed assessment.

(*3*) A statement that the debt may be collected through an administrative offset.

(*4*) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(F) The means by which the qualified entity may pay the amount if they do not intend to request a hearing.

(iii) *Failure to request a hearing.* If the qualified entity does not request a hearing within 60 days of receipt of the notice of proposed determination specified in the preceding paragraph, any assessment becomes final and CMS may impose the proposed assessment.

(A) CMS notifies the qualified entity, by certified mail with return receipt requested, of any assessment that has been imposed and of the means by which the qualified entity may satisfy the judgment.

(B) The qualified entity has no right to appeal an assessment for which the qualified entity has not requested a hearing.

(iv) *When an assessment is collectible.* An assessment becomes collectible after the earliest of the following:

(A) 60 days after the qualified entity receives CMS's notice of proposed determination under (d)(5)(ii) of this section, if the qualified entity has not requested a hearing.

(B) Immediately after the qualified entity abandons or waives its appeal right at any administrative level.

(C) 30 days after the qualified entity receives the ALJ's decision imposing an assessment under § 1005.20(d) of this title, if the qualified entity has not requested a review before the DAB.

(D) 60 days after the qualified entity receives the DAB's decision imposing an assessment if the qualified entity has not requested a stay of the decision under § 1005.22(b) of this title.

(v) *Collection of an assessment.* Once a determination by HHS has become final, CMS is responsible for the collection of any assessment.

(A) The General Counsel may compromise an assessment imposed under this part, after consulting with CMS or OIG, and the Federal government may recover the assessment in a civil action brought in the United

States district court for the district where the claim was presented or where the qualified entity resides.

(B) The United States or a state agency may deduct the amount of an assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing the qualified entity.

(C) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect an assessment.

■ 8. Section 401.721 is amended by adding paragraph (a)(7) to read as follows:

§ 401.721 Terminating an agreement with a qualified entity.

(a) * * *

(7) Fails to ensure authorized users comply with their QE DUAs or analysis use agreements.

* * * * *

Dated: October 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: January 27, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–01790 Filed 1–29–16; 11:15 am]

BILLING CODE 4120–01–P

Notices

Federal Register
Vol. 81, No. 21
Tuesday, February 2, 2016

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 COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating the five-year review (''Sunset Review'') of the antidumping and countervailing duty (''AD/CVD'') orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

DATES: *Effective Date:* February 1, 2016.

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping and countervailing duty orders: [1]

DOC Case No.	ITC Case No.	Country	Product	Department contact
A–570–896	731–TA–1071	PRC	Magnesium Metal (2nd Review)	David Goldberger. (202) 482-4136.
A–570–506	731–TA–282	PRC	Porcelain-On-Steel Cooking Ware (4th Review).	Matthew Renkey. (202) 482-2312.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Web site at the following address: *http://enforcement.trade.gov/sunset/.* All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''), can be found at 19 CFR 351.303.[2]

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[3] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in these segments.[4] The formats for the revised certifications are provided at the end of the *Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

On April 10, 2013, the Department modified two regulations related to AD/CVD proceedings: the definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301).[5] Parties are advised to review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in these segments. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied. Parties are also advised to review the final rule concerning the extension of time limits for submissions in AD/CVD proceedings, available at *http://enforcement.trade.gov/frn/2013/1309frn/2013-22853.txt,* prior to submitting factual information in these segments.[6]

[1] In addition, we note that in the sunset initiation notice that published on November 3, 2015 (80 FR 67705) the Department inadvertently listed an incorrect effective date. The effective date is November 2, 2015.

[2] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[3] *See* section 782(b) of the Act.

[4] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*'') (amending 19 CFR 351.303(g)).

[5] *See Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013).

[6] *See Extension of Time Limits,* 78 FR 57790 (September 20, 2013).

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (''APO'') to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.[7]

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews. Consult the Department's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: January 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–01999 Filed 2–1–16; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for National Marine Sanctuary Advisory Councils

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: ONMS is seeking applications for vacant seats for five of its 13 national marine sanctuary advisory councils (advisory councils). Vacant seats, including positions (*i.e.,* primary member and alternate), for each of the advisory councils are listed in this notice under **SUPPLEMENTARY INFORMATION**. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; views regarding the protection and management of marine or Great Lake resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members or alternates should expect to serve two or three year terms, pursuant to the charter of the specific national marine sanctuary advisory council.

DATES: Applications are due by February 29, 2016.

ADDRESSES: Application kits are specific to each advisory council. As such, application kits must be obtained from and returned to the council-specific addresses noted below.

- Flower Garden Banks National Marine Sanctuary Advisory Council: Kelly Drinnen, Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Building 216, Galveston, TX 77551; (409) 621–5151 extension 105; email *Kelly.Drinnen@noaa.gov;* or download application from *http://flowergarden.noaa.gov.*
- Hawaiian Islands Humpback Whale National Marine Sanctuary Advisory Council: Inouye Regional Center, ATTN: NOS/ONMS/Shannon Lyday, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818; (808) 725–5905; email *Shannon.Lyday@noaa.gov;* or download application from *http://hawaiihumpbackwhale.noaa.gov/council/council_app_accepting.html.*
- Monterey Bay National Marine Sanctuary Advisory Council: Nichole Rodriguez, Monterey Bay National Marine Sanctuary, 99 Pacific Street, Building 455A, Monterey, CA 93940; (831) 647–4206; email *Nichole.Rodriguez@noaa.gov;* or download application from *http://montereybay.noaa.gov/welcome.html.*
- National Marine Sanctuary of American Samoa Advisory Council: Joseph Paulin, National Marine Sanctuary of American Samoa, Tauese P.F. Sunia Ocean Center, P.O. Box 4318, Pago Pago, AS 96799 (Utelei, American Samoa); (684) 633–6500; email *Joseph.Paulin@noaa.gov;* or download application from *http://americansamoa.noaa.gov/about/samoa.html.*
- Stellwagen Bank National Marine Sanctuary Advisory Council: Elizabeth Stokes, Stellwagen Bank National Marine Sanctuary, 175 Edward Foster Road, Scituate, MA 02066; (781) 545–8026 extension 201; email *Elizabeth.Stokes@noaa.gov;* or download application from *http://stellwagen.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: For further information on a particular national marine sanctuary advisory council, please contact the individual identified in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION: ONMS serves as the trustee for a network of underwater parks encompassing more than 170,000 square miles of marine and Great Lakes waters from Washington state to the Florida Keys, and from Lake Huron to American Samoa. The network includes a system of 13 national marine sanctuaries and Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for

thriving communities and stable economies. One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. National marine sanctuary advisory councils are community-based advisory groups established to provide advice and recommendations to the superintendents of the national marine sanctuaries on issues including management, science, service, and stewardship; and to serve as liaisons between their constituents in the community and the sanctuary. Additional information on ONMS and its advisory councils can be found at *http://sanctuaries.noaa.gov.* Information related to the purpose, policies, and operational requirements for advisory councils can be found in the charter for a particular advisory council (*http://sanctuaries.noaa.gov/management/ac/council_charters.html*) and the National Marine Sanctuary Advisory Council Implementation Handbook (*http://sanctuaries.noaa.gov/management/pdfs/2010-ac-handbook-appendices-07162015.pdf*).

The following is a list of the vacant seats, including positions (*i.e.,* primary member or alternate), for each of the advisory councils currently seeking applications for members and alternates:

Flower Garden Banks National Marine Sanctuary Advisory Council: Conservation (primary); Education (primary); Recreational Fishing (primary); and Research (primary).

Hawaiian Islands Humpback Whale National Marine Sanctuary Advisory Council: Lāna'i Island (alternate); and Moloka'i Island (alternate).

Monterey Bay National Marine Sanctuary Advisory Council: Agriculture (primary); Agriculture (alternate); At-Large (two primaries); At-Large (alternate); Business/Industry (primary); Business/Industry (alternate); College (primary); College (alternate); Commercial Fishing (primary); Commercial Fishing (alternate); Conservation (primary); Recreation (primary); Recreation (alternate); Recreational Fishing (primary); Recreational Fishing (alternate); Research (primary); and Research (alternate).

National Marine Sanctuary of American Samoa Advisory Council: West Side of Tutuila (primary).

Stellwagen Bank National Marine Sanctuary Advisory Council: At-Large (alternate); Business/Industry (alternate); Mobile Gear Commercial Fishing (alternate); Whale Watch (alternate); and Youth (alternate).

Authority: 16 U.S.C. 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: December 23, 2015.

John Armor,

Acting Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–01976 Filed 2–1–16; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) will convene a meeting of its Coastal Pelagic Species (CPS) Subcommittee of the Scientific and Statistical Committee (SSC). The meeting is open to the public.

DATES: The meeting will be held Thursday, March 10, 2016, from 8 a.m. to 5 p.m. Pacific Standard Time.

ADDRESSES: The meeting will be held at the Doubletree by Hilton Sacramento, Yuba River Room, 2001 Point West Way, Sacramento, CA 95815.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is to review a stock assessment update of the Pacific sardine resource. The SSC CPS subcommittee will conduct the review, and one member each from the CPS Management Team and CPS Advisory Subpanel will serve as advisers. The Council will set harvest specifications and management measures at its April 9–14, 2016 meeting in Vancouver, WA.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (503) 820–2280 at least 5 days prior to the meeting date.

Dated: January 28, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–01843 Filed 2–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA165

Marine Mammals; File No. 15510

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

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that a major amendment to Permit No. 15510 has been issued to Jennifer Burns, Ph.D., University of Alaska Anchorage, CPISB 202C, 3101 Science Circle, Anchorage, AK 99508.

ADDRESSES: The permit amendment and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Rosa L. González or Amy Sloan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On December 8, 2015, notice was published in the **Federal Register** (80 FR 76276) that a request for an amendment Permit No. 15510 to collect, receive, import, and export specimens from marine mammals for scientific research had been submitted by the above-named applicant. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The original permit (No. 15510), issued on April 25, 2011 (76 FR 25308) authorized Dr. Burns to obtain samples from up to 50 animals of each of the following species: Harp (*Pagophilus*

groenlandica), hooded (*Cystophora cristata*), gray (*Halichoerus grypus*), bearded (*Erignathus barbatus*), ringed (*Phoca hispida*), harbor (*Phoca vitulina*), spotted (*Phoca largha*), and ribbon (*Histriophoca fasciata*) seals; and to obtain samples annually from up to 6 captive Northern fur seals, *Callorhinus ursinus;* and 6 captive Steller Sea lions, *Eumetopias jubatus,* through April 30, 2016.

Permit 15510–01 authorizes the Permit Holder to increase the number of harbor seals from which samples may be collected, received, imported, and exported from 50 to 100 annually; and, extends the duration of the permit through April 30, 2017.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, issuance of this permit was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: January 27, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–01826 Filed 2–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council), Sea Scallop Committee, Advisory Panel and PDT are scheduling an inshore Atlantic Sea Scallop Fishing Industry workshop to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: This meeting will be held on Monday, February 22 and Tuesday, February 23, 2016, beginning at 8:30 a.m. both days.

ADDRESSES: The workshop will be held at the Crowne Plaza, 801 Greenwich Ave., Warwick, RI 02886; telephone: (401) 732–6000.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Workshop Agenda

The Council is hosting a workshop to provide an opportunity for participants in the scallop fishery to discuss concerns raised by some about the consequences of inshore scallop fishing practices. The workshop will support constructive and open dialogue between all users of the resource, scientific experts, fishery managers, and interested members of the public. In accordance with section 302(g)(2) of the Magnuson-Stevens Act, this workshop is considered to be an ad hoc advisory panel. Any recommendations made by this panel will be forwarded to the Council's Scallop Advisory Panel and Oversight Committee for full consideration.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: January 28, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–01842 Filed 2–1–16; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (''PRA''), this notice announces that the Information Collection Request (''ICR'') abstracted below has been forwarded to the Office of Management and Budget (''OMB'') for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before March 3, 2016.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs in OMB, within 30 days of publication of the notice, by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0061. Please provide the Commission with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0061, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, and to the Commission through its Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581, or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://reginfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Tom Guerin, Division of Market Oversight, Commodity Futures Trading Commission, (202) 734–4194, email:

tguerin@cftc.gov, and refer to OMB Control No. 3038–0061.

SUPPLEMENTARY INFORMATION: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on December 3, 2015 (80 FR 75663).

Title: Daily Trade and Supporting Data Reports (OMB Control No. 3038–0061). This is a request for extension of a currently approved information collection.

Abstract: Commission Regulation 16.02 requires Reporting Markets, including Designated Contract Markets, to provide the Commission with trade and supporting data reports on a daily basis. The Commission analyzes the daily trade and supporting data reports to discharge its regulatory responsibilities, including the responsibilities to prevent market manipulations and commodity price distortions and ensure the financial integrity of its jurisdictional markets.

This ICR concerns the collections of information required by 17 CFR 16.02. Commission staff estimates that up to 30 reporting markets could provide this data to the Commission in the future. The Commission did not receive any comments regarding the burden estimate or any other aspect of this ICR.

Burden Statement: Commission staff estimate that the total annual time burden for this ICR is 15,000 hours. Commission staff estimates that the total annual cost for this ICR is $1,139,700. The time burden estimate represents the annual burden that Reporting Markets incur to operate and maintain automated reporting systems and processes that facilitate the reporting of trade and supporting data reports to the Commission on a daily basis. The electronic reporting required by Commission Rule 16.02 is generally accomplished in an automated manner by respondents' computer systems. Reporting entities have already incurred significant one-time costs to establish the capability to electronically report trade and supporting data to the Commission on a daily basis. The burden hours currently incurred by respondents to comply with Commission Rule 16.02 are primarily related to the hours necessary to oversee, maintain, and utilize respondents' existing automated reporting functionality.

Commission staff estimates that Reporting Markets expend an average of two hours per trading day to oversee, maintain, and utilize their systems and procesess to comply with Commission Rule 16.02. Commission staff calculated the estimated cost burden by multiplying the estimated time burden by an estimated appropriate hourly wage rate of $75.98. Commission staff derived the estimated appropriate hourly wage rate by averaging the salaries and bonuses of relevant professions reported in the SIFMA Report on Management & Professional Earnings in the Securities Industry 2013.

Respondents/Affected Entities: Reporting Markets.

Estimated Number of Respondents: 30.

Estimated Total Annual Burden on Respondents: 15,000 hours.

Estimated Total Annual Cost: $1,139,700.

Frequency of Collection: Ongoing.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: January 27, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–01774 Filed 2–1–16; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (''PRA''), this notice announces that the Information Collection Request (''ICR'') abstracted below has been forwarded to the Office of Management and Budget (''OMB'') for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before March 3, 2016.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs in OMB, within 30 days of the notice's publication, by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0084. Please provide the Commodity Futures Trading Commission (''CFTC'' or ''Commission'') with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0084, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, and to the Commission through its Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581 or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://RegInfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Adam Kezsbom, Special Counsel, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, (202) 418–5372, email: *akezsbom@cftc.gov,* and refer to OMB Control No. 3038–0084.

SUPPLEMENTARY INFORMATION:

Title: Regulations Establishing and Governing the Duties of Swap Dealers and Major Swap Participants (OMB Control No. 3038–0084). This is a request for an extension of a currently approved information collection.

Abstract: On April 3, 2012, the Commission adopted Commission regulations 23.600 (Risk Management Program), 23.601 (Monitoring of Position Limits), 23.602 (Diligent Supervision), 23.603 (Business Continuity and Disaster Recovery), 23.606 (General Information: Availability for Disclosure and Inspection), and 23.607 (Antitrust Considerations) [1] pursuant to section 4s(j) [2] of the Commodity Exchange Act (''CEA''). The above regulations adopted by the Commission require, among other things, swap dealers (''SD'') [3] and major

[1] 17 CFR 23.600, 23.601, 23.602, 23.603, 23.606, 23.607.

[2] 7 U.S.C. 6s(j).

[3] For the definition of SD, *see* section 1a(49) of the CEA and Commission regulation 1.3(ggg). 7 U.S.C. 1a(49) and 17 CFR 1.3(ggg).

swap participants (''MSP'') [4] to develop a risk management program (including a plan for business continuity and disaster recovery and policies and procedures designed to ensure compliance with applicable position limits). The Commission believes that the information collection obligations imposed by the above regulations are essential to ensuring that swap dealers and major swap participants maintain adequate and effective risk management programs and policies and procedures to ensure compliance with position limits. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The Commission did not receive any comments on the 60-day **Federal Register** notice, 80 FR 74766, dated November 30, 2015.

Burden Statement: The Commission is revising its estimate of the burden for this collection to reflect the current number of registered SDs and MSPs. Accordingly, the respondent burden for this collection is estimated to be as follows:

Number of Registrants: 105.[5]

Estimated Average Burden Hours per Registrant: 1,148.5.

Estimated Aggregate Burden Hours: 120,592.5.[6]

Frequency of Recordkeeping/Third-party Disclosure: As applicable.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: January 27, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–01773 Filed 2–1–16; 8:45 am]

BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0034]

Agency Information Collection Activities; Submission for OMB Review; Comment Request—Baby Bouncers and Walker-Jumpers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (''PRA'') of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission (''Commission'' or ''CPSC'') announces that the Commission has submitted to the Office of Management and Budget (''OMB'') a request for extension of approval of a collection of information relating to certain children's articles known as baby-bouncers and walker-jumpers, approved previously under OMB Control No. 3041–0019. In the **Federal Register** of October 26, 2015 (80 FR 65218), the CPSC published a notice to announce the agency's intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by March 3, 2016.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2012–0034.

FOR FURTHER INFORMATION CONTACT: For further information contact: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC has submitted the following currently approved collection of information to OMB for extension:

Title: Ban of Certain Articles Known as Baby-Bouncers or Walker-Jumpers.

OMB Number: 3041–0019.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of baby-bouncers or walker-jumpers.

Estimated Number of Respondents: 33 firms that supply baby-bouncers or walker-jumpers to the United States market have been identified; there are approximately 4 new models per firm annually.

Estimated Time per Response: 30 minutes/model associated with labeling requirements and 1 hour/model associated with recordkeeping requirements.

Total Estimated Annual Burden: 132 hours on recordkeeping (33 firms × 1 hour × 4 models) and 66 hours for labeling (33 firms × ½ hour × 4 models) for a total annual burden of 198 hours per year.

General Description of Collection: Under 16 CFR 1500.18(a)(6), certain articles known as ''baby-bouncers'' and ''walker-jumpers'' that are intended to support very young children while sitting, bouncing, jumping, and/or reclining, are banned if they are designed in such a way that exposed parts present hazards, such as amputation, crushing, laceration, fracture, hematoma, bruise, or other injury to fingers, toes, or other parts of the anatomy of young children. An exemption from the ban is provided at 16 CFR 1500.86(a)(4) if the products are designed to guard against or prevent those same injuries. Among other requirements, the regulations require manufacturers, including importers, to meet the collection of information requirements for labeling and recordkeeping requirements.

Products that are the subject of this information collection are distinguishable from the infant bouncer seats that are the subject of the Commission's recent proposed safety standard on infant bouncer seats at 80 FR 63168 (Oct. 19, 2015). Infant bouncer seats described in the Commission's proposed standard are intended to hold young infants that cannot sit up unassisted in a reclined position (approximately 0 to 6 months of age). The products subject to this information collection are typically described as doorway jumpers, and allow the child to jump in place. Such products are intended for use with children that are beginning to develop leg strength to aid in learning to walk.

Dated: January 27, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–01779 Filed 2–1–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

DoD Medicare-Eligible Retiree Health Care Board of Actuaries; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

[4] For the definitions of MSP, *see* section 1a(33) of the CEA and Commission regulation 1.3(hhh). 7 U.S.C. a(33) and 17 CFR 1.3(hhh).

[5] The 60-day notice indicated that there were 106 Swap Dealers and Major Swap Participants. The estimates have been adjusted to reflect the current number of 105 Swap Dealers and Major Swap Participants registered with the Commission.

[6] The estimated aggregate burden hour is adjusted to reflect the correct total burden hours based on the new number of Swap Dealers and Major Swap Participants registered with the Commission.

ACTION: Meeting notice.

SUMMARY: The Department of Defense announces that the following Federal Advisory Committee meeting of the DoD Medicare-Eligible Retiree Health Care Board of Actuaries will take place. This meeting will be open to the public.

DATES: Friday, July 29, 2016, from 10:00 a.m. to 12:00 p.m.

ADDRESSES: 4800 Mark Center Drive, Conference Room 19, Level B1, Alexandria, VA 22350.

FOR FURTHER INFORMATION CONTACT: Mrs. Kathleen Ludwig at the Defense Human Resource Activity, DoD Office of the Actuary, 4800 Mark Center Drive, STE 05E22, Alexandria, VA 22350–7000. Phone: 571–372–1993. Email: *Kathleen.A.Ludwig.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to execute the provisions of chapter 56, title 10, United States Code (10 U.S.C. 1114 et. seq.). The Board shall review DoD actuarial methods and assumptions to be used in the valuation of benefits under DoD retiree health care programs for Medicare-eligible beneficiaries.

Agenda:

1. Meeting Objective

Approve actuarial assumptions and methods needed for calculating:

i. FY 2018 per capita full-time and part-time normal cost amounts
ii. September 30, 2015, unfunded liability (UFL)
iii. October 1, 2016, Treasury UFL amortization and normal cost payments

2. Trust Fund Update

3. Medicare-Eligible Retiree Health Care Fund Update

4. September 30, 2014, Actuarial Valuation Results

5. September 30, 2015, Actuarial Valuation Proposals

6. Decisions

Actuarial assumptions and methods needed for calculating:

a. FY 2018 per capita full-time and part-time normal cost amounts
b. September 30, 2015, unfunded liability (UFL)
c. October 1, 2016, Treasury UFL amortization and normal cost payments

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and the availability of space, this meeting is open to the public. Seating is on a first-come basis. The Mark Center is an annex of the Pentagon. Those without a valid DoD Common Access Card must contact Kathleen Ludwig at 571–372–1993 no later than June 30, 2016. Failure to make the necessary arrangements will result in building access being denied. It is strongly recommended that attendees plan to arrive at the Mark Center at least 30 minutes prior to the start of the meeting.

Committee's Designated Federal Officer or Point of Contact: The Designated Federal Officer is Ms. Inger M. Pettygrove. Phone: 571–372–1998. Email: *inger.m.pettygrove.civ@mail.mil.* Persons desiring to attend the DoD Medicare-Eligible Retiree Health Care Board of Actuaries meeting or make an oral presentation or submit a written statement for consideration at the meeting, must notify Kathleen Ludwig at 571–372–1993, or *Kathleen.A.Ludwig.civ@mail.mil,* by June 30, 2016.

Dated: January 28, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–01854 Filed 2–1–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

DoD Board of Actuaries; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense announces that the following Federal Advisory Committee meeting of the DoD Board of Actuaries will take place. This meeting is open to the public.

DATES: Thursday, July 14, 2016, from 1:00 p.m. to 4:00 p.m. and Friday, July 15, 2016, from 10:00 a.m. to 1:00 p.m.

ADDRESSES: 4800 Mark Center Drive, Conference Room 18, Level B1, Alexandria, VA 22350.

FOR FURTHER INFORMATION CONTACT: Mrs. Kathleen Ludwig at the Defense Human Resources Activity, DoD Office of the Actuary, 4800 Mark Center Drive, STE 05E22, Alexandria, VA 22350–7000. Phone: 571–372–1993. Email: *Kathleen.A.Ludwig.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provision of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the meeting: The purpose of the meeting is for the Board to review DoD actuarial methods and assumptions to be used in the valuations of the Education Benefits Fund, the Military Retirement Fund, and the Voluntary Separation Incentive Fund, in accordance with the provisions of Section 183, Section 2006, Chapter 74 (10 U.S.C. 1464 et. seq.), and 10 U.S.C. 1175.

Agenda:

Education Benefits Fund (July 14, 1:00 p.m.–4:00 p.m.)

1. Briefing on Investment Experience
2. September 30, 2015, Valuation Proposed Economic Assumptions *
3. September 30, 2015, Valuation Proposed Methods and Assumptions—Reserve Programs *
4. September 30, 2015, Valuation Proposed Methods and Assumptions—Active Duty Programs *
5. Developments in Education Benefits

Military Retirement Fund (July 15, 10:00 a.m.–1:00 p.m.)

1. Briefing on Investment Experience
2. September 30, 2015, Valuation of the Military Retirement Fund *
3. Proposed Methods and Assumptions for September 30, 2016, Valuation of the Military Retirement Fund *
4. Proposed Methods and Assumptions for September 30, 2015, Voluntary Separation Incentive (VSI) Fund Valuation *
5. Recent and Proposed Legislation

* Board approval required

Public's accessibility to the meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. The Mark Center is an annex of the Pentagon. Those without a valid DoD Common Access Card must contact Kathleen Ludwig at 571–372–1993 no later than June 16, 2016. Failure to make the necessary arrangements will result in building access being denied. It is strongly recommended that attendees plan to arrive at the Mark Center at least 30 minutes prior to the start of the meeting.

Committee's Designated Federal Officer or Point of Contact: The Designated Federal Officer is Ms. Inger M. Pettygrove. Phone: 571–372–1998. Email: *inger.m.pettygrove.civ@mail.mil.*

Persons desiring to attend the DoD Board of Actuaries meeting or make an oral presentation or submit a written statement for consideration at the meeting must notify Kathleen Ludwig at 571–372–1993, or *Kathleen.A.Ludwig.civ@mail.mil,* by June 16, 2016.

Dated: January 28, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–01855 Filed 2–1–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Educational Opportunity Centers Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

Overview Information: Educational Opportunity Centers Program (EOC Program) Notice Inviting Applications for New Awards for Fiscal Year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.066A.

DATES: *Applications Available:* February 2, 2016.

Deadline for Transmittal of Applications: April 4, 2016.

Deadline for Intergovernmental Review: June 1, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of the EOC Program are to: provide information regarding financial and academic assistance available for qualified adults who want to enter or continue to pursue a program of postsecondary education; provide assistance to those individuals in applying for admission to institutions at which a program of postsecondary education is offered, including preparing necessary applications for use by admissions and financial aid officers; and assist in improving the financial and economic literacy of program participants.

An Educational Opportunity Centers project may provide the following services:

(1) Public information campaigns designed to inform the community regarding opportunities for postsecondary education and training;

(2) Academic advice and assistance in course selection;

(3) Assistance in completing college admission and financial aid applications;

(4) Assistance in preparing for college entrance examinations;

(5) Education or counseling services designed to improve the financial literacy and economic literacy of students;

(6) Guidance on secondary school reentry or entry to a general educational development (GED) program or other alternative education program for secondary school dropouts;

(7) Individualized personal, career, and academic counseling;

(8) Tutorial services;

(9) Career workshops and counseling;

(10) Mentoring programs involving elementary or secondary school teachers, faculty members at institutions of higher education (IHEs), students, or any combination of these persons; and

(11) Programs and activities as described in items (1) through (10) that are specially designed for students who are limited English proficient, students from groups that are traditionally underrepresented in postsecondary education, students with disabilities, students who are homeless children and youths, students who are in foster care or are aging out of the foster care system, or other disconnected students.

(12) Other activities designed to meet the purposes of the EOC Program.

Note: Consistent with 34 CFR 75.209, the Secretary will use the selection criteria outlined in 34 CFR 644.21 to evaluate the applications submitted for new grants under this program. In addition, consistent with the Department's increasing emphasis on promoting evidence-based practices through our grant competitions, the Secretary will also evaluate applications on the extent to which the components of the proposed project are supported by a logic model that meets the evidence standard of ''strong theory'' (as defined in this notice). We encourage applicants to read carefully the *Selection Criteria* section of this notice. Resources to assist applicants in creating a logic model can be found here: *http://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf.*

Priorities: This notice contains two competitive preference priorities. The competitive preference priorities 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 Priorities: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award an application up to two additional points for each priority, for a total of up to four additional points, depending on how well the application meets each of these priorities.

The competitive preference priorities are:

Competitive Preference Priority 1: Improving Parent, Family, and Community Engagement (up to 2 additional points).

The Secretary gives priority to projects that are designed to improve student outcomes through implementing initiatives that improve community engagement (as defined in this notice), the relationships between parents or families and school or program staff by cultivating sustained partnerships (as defined in this notice).

Competitive Preference Priority 2: Supporting Military Families and Veterans (up to 2 additional points).

The Secretary gives priority to projects that are designed to address the needs of military- or veteran-connected students (as defined in this notice).

Note: Applicants must include, in the one-page abstract submitted with the application, a statement indicating which, if any, of the competitive preference priorities are addressed. If the applicant has addressed the competitive preference priorities, this information must also be listed in the application package on the EOC Program Profile Form.

Definitions: These definitions are from the Supplemental Priorities and 34 CFR 77.1.

Community engagement means the systematic inclusion of community organizations as partners with State educational agencies (SEAs), local educational agencies (LEAs), or other educational institutions, or their school or program staff to accomplish activities that may include developing a shared community vision, establishing a shared accountability agreement, participating in shared data collection and analysis, or establishing community networks that are focused on shared community-level outcomes. These organizations may include faith- and community-based organizations, IHEs (including minority-serving institutions eligible to receive aid under title III or title V of the Higher Education Act of 1965 (HEA)), businesses and industries, labor organizations, State and local government entities, or Federal entities other than the Department.

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.

Military- or veteran-connected student means (a) A child participating in an early learning and development program, a student enrolled in preschool through grade 12, or a student enrolled in postsecondary education or career and technical training who has a parent or guardian who is a member of the uniformed services (as defined by 37 U.S.C. 101, in the Army, Navy, Air Force, Marine Corps, Coast Guard, National Guard, National Oceanic and Atmospheric Administration, or Public Health Service); (b) A student who is a member of the uniformed services, a veteran of the uniformed services, or the spouse of a service member or veteran; or (c) A child participating in an early learning and development program or a student enrolled in preschool through grade 12 who has a parent or guardian who is a veteran of the uniformed services (as defined by 37 U.S.C. 101).

Note: For the purpose of this competition, only subpart (b) of this definition is applicable, and the term ''students'' in this definition includes prospective students.

Parent and family engagement means the systematic inclusion of parents and families, working in partnership with SEAs, State lead agencies (under Part C of the Individuals with Disabilities Education Act or the State's race to the Top-Early Learning Challenge grant), LEAs, or other educational institutions, or their staff, in their child's education, which may include strengthening the ability of (a) parents and families to support their child's education; and (b) school or program staff to work with parents and families.

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model.

Sustained partnership means a relationship that has demonstrably adequate resources and other support to continue beyond the funding period and that consists of community organizations as partners with an LEA and one or more of its schools. These organizations may include faith- and community-based organizations, IHEs (including minority-serving institutions eligible to receive aid under title III or title V of the HEA), businesses and industries, labor organizations, State and local government entities, or Federal entities other than the Department.

Program Authority: 20 U.S.C. 1070a–11 and 20 U.S.C. 1070a–16.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75 (except for 75.215 through 75.221), 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Education Department debarment and suspension regulations as adopted in 2 CFR part 3485 and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards as adopted in 2 CFR part 3474. (c) The regulations for this program in 34 CFR part 644. (d) 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 IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $54,296,053.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2017 from the list of unfunded applications from this competition.

Estimated Range of Awards: $236,000–$1,207,694.

Estimated Average Size of Awards: $377,661.

Maximum Award:

- For an applicant that is not currently receiving an EOC Program grant, the maximum award amount is $236,000, based upon a per-participant cost of no more than $236 and a minimum of 1,000 participants.
- For an applicant that is currently receiving an EOC Program grant, the maximum award amount is an amount equal to 103 percent of the applicant's base award amount for FY 2015. The minimum number of participants an applicant proposes to serve must be at least the number of participants approved to serve in FY 2015.

We will reject any application that proposes a budget exceeding the applicable maximum amount listed above for a single budget period of 12 months. We will also reject any application that proposes a budget to serve fewer than 1,000 participants, or any application that proposes a budget that exceeds the maximum per-participant cost of $309.

Estimated Number of Awards: 151.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, public and private agencies and organizations including community-based organizations with experience in serving disadvantaged youth; combinations of such institutions, agencies, and organizations; and secondary schools.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other:* An applicant may submit more than one application for an EOC Program grant so long as each application describes a project that serves a different target area (34 CFR 644.10(a)). The term ''target area'' is defined as a geographic area served by a project (34 CFR 644.7(b)).

IV. Application and Submission Information

1. *Address to Request Application Package:* Rachael Couch, Ed.D., U.S. Department of Education, 400 Maryland Avenue SW., Room 7E311, Washington, DC 20202. Telephone: (202) 502–7655 or by email: *Rachael.Couch@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (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. *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 program.

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 must limit the application narrative, which includes the budget narrative, to no more than 60 pages using the following standards. However, any application addressing the competitive preference priorities may include up to 4 additional pages for each of the priorities that is addressed. Those additional pages must be used to discuss how the application meets the competitive preference priorities.

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides. Page numbers and an identifier may be within the 1″ margin.
- Each page on which there is text or graphics will be counted as one full page.
- Double space (no more than three lines per vertical inch) all text in the application narrative.
- Titles, headings, footnotes, quotations, references, and captions, as

well as all text in figures, charts, 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: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman and Arial Narrow) will not be accepted.

The page limit does not apply to Part I—the Application for Federal Assistance Face Sheet (SF 424); Part II—the Budget Information Summary form (ED Form 524); Part III—the EOC Program Profile form; Part III—the one-page Project Abstract form; and Part IV—the Assurances and Certifications. The page limit also does not apply to a table of contents, which you should include in the application narrative. If you include any attachments or appendices, these items will be counted as part of Part III—the application narrative for purpose of the page-limit requirement. You must include your complete response to the selection criteria in Part III—the application narrative.

We will reject your application if you exceed the page limit.

3. *Submission Dates and Times:*

Applications Available: February 2, 2016.

Deadline for Transmittal of Applications: April 4, 2016.

Applications for grants under this program 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.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in 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: June 1, 2016.

4. *Intergovernmental Review:* This program 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 program.

5. *Funding Restrictions:* We specify unallowable costs in 34 CFR 644.31. 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 Contractor 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 into 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 this program 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 the EOC Program, CFDA number 84.066A, 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 EOC 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 84.066, not 84.066A).

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 this program 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: 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 then 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 program contact 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 Grants.gov 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: Gaby Watts, U.S. Department of Education, 400 Maryland Avenue SW., Room 7E311, Washington, DC 20202. Fax: (202) 205–0063.

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 84.066A), 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 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 84.066A), 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 grant 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 following selection criteria for this competition total 105 points and are from 34 CFR 644.21 and 34 CFR 75.210:

(a) Need for the project (24 points). The Secretary evaluates the need for an EOC project in the proposed target area on the basis of the extent to which the application contains clear evidence of—

(1) A high number or percentage, or both, of low-income families residing in the target area;

(2) A high number or percentage, or both, of individuals residing in the target area with education completion levels below the baccalaureate level;

(3) A high need on the part of residents of the target area for further education and training from programs of postsecondary education in order to meet changing employment trends; and

(4) Other indicators of need for an EOC project, including the presence of unaddressed educational or socio-economic problems of adult residents in the target area.

(b) Objectives (8 points). The Secretary evaluates the quality of the applicant's objectives and proposed targets (percentages) in the following areas on the basis of the extent to which they are both ambitious, as related to the need data provided under paragraph (a) of this section, and attainable, given the project's plan of operation, budget, and other resources—

(1) Secondary school diploma or equivalent (2 points).

(2) Postsecondary enrollment (3 points).

(3) Financial aid applications (1.5 points).

(4) College admission applications (1.5 points).

(c) Plan of operation (30 points). The Secretary evaluates the quality of the applicant's plan of operation on the basis of the following—

(1) The plan to inform the residents, schools, and community organizations in the target area of the goals, objectives, and services of the project and the eligibility requirements for participation in the project (4 points);

(2) The plan to identify and select eligible participants and ensure their participation without regard to race, color, national origin, gender, or disability (4 points);

(3) The plan to assess each participant's need for services provided by the project (2 points);

(4) The plan to provide services that meet the participants' needs and achieve the objectives of the project (12 points); and

(5) The management plan to ensure the proper and efficient administration of the project including, but not limited to, the project's organizational structure, the time committed to the project by the project director and other personnel, and, where appropriate, its coordination with other projects for disadvantaged students (8 points).

(d) Applicant and community support (16 points). The Secretary evaluates the applicant and community support for the proposed project on the basis of the extent to which the applicant has made provision for resources to supplement the grant and enhance the project's services, including—

(1) Facilities, equipment, supplies, personnel, and other resources committed by the applicant (8 points); and

(2) Resources secured through written commitments from schools, community organizations, and others (8 points).

(e) Quality of personnel (9 points). (1) The Secretary evaluates the quality of the personnel the applicant plans to use in the project on the basis of the following—

(i) The qualifications required of the project director.

(ii) The qualifications required of each of the other personnel to be used in the project.

(iii) The plan to employ personnel who have succeeded in overcoming

disadvantages or circumstances like those of the population of the target area.

(2) In evaluating the qualifications of a person, the Secretary considers his or her experience and training in fields related to the objectives of the project.

(f) Budget (5 points). The Secretary evaluates the extent to which the project budget is reasonable, cost-effective, and adequate to support the project.

(g) Evaluation plan (8 points). The Secretary evaluates the quality of the evaluation plan for the project on the basis of the extent to which the applicant's methods of evaluation—

(1) Are appropriate to the project's objectives;

(2) Provide for the applicant to determine, using specific and quantifiable measures, the success of the project in—

(i) Making progress toward achieving its objectives (a formative evaluation); and

(ii) Achieving its objectives at the end of the project period (a summative evaluation); and

(3) Provide for the disclosure of unanticipated project outcomes, using quantifiable measures if appropriate.

(h) Quality of the project design (5 points). The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the extent to which the proposed project is supported by strong theory (as defined in this notice).

2. *Review and Selection Process:* 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 assistance from the Department of Education (34 CFR 100.4,104.5,106.4,108.8, and 110.23).

For this competition, a panel of non-Federal reviewers will review each application in accordance with the selection criteria in 34 CFR 644.21 and 34 CFR 75.210. The individual scores of the reviewers will be added and the sum divided by the number of reviewers to determine the peer review score received in the review process. Additionally, in accordance with 34 CFR 644.22, the Secretary will award prior experience points to applicants that conducted an EOC Program project during budget periods 2012–13, 2013–14, and 2014–15, based on their documented experience. Prior experience points, if any, will be added to the application's averaged reader score to determine the total score for each application.

If there are insufficient funds for all applications with the same total scores, the Secretary will choose among the tied applications so as to serve geographic areas and eligible populations that have been underserved by the EOC Program.

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 multi-year 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.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* The success of the EOC Program will be measured by the EOC Program participants' success in completing a secondary school diploma or its equivalent, completion of applications for student financial aid, submission of applications for postsecondary admission, and postsecondary enrollment. All EOC Program grantees will be required to submit annual performance reports.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, 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 management requirements, the performance targets in the grantee's approved application.

In making a continuation grant, 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 Contacts

FOR FURTHER INFORMATION CONTACT: Rachael Couch, Ed.D., U.S. Department of Education, 400 Maryland Avenue SW., room 7E311, Washington, DC 20202. Telephone: (202) 502–7655 or by email: *Rachael.Couch@ed.gov.*

If you use a TDD or a 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 computer 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 Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at this 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 feature at this site, you can limit your search to documents published by the Department.

Dated: January 27, 2016.

Lynn Mahaffie,

Deputy Assistant Secretary for Policy, Planning and Innovation Delegated the Duties of Assistant Secretary for Postsecondary Education.

[FR Doc. 2016–01832 Filed 2–1–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0012]

Agency Information Collection Activities; Comment Request; Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection

AGENCY: Office of Elementary and Secondary Education (OESE), 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 April 4, 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–0012. 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–115, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact John Cheek, 202–401–0274.

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: Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection.

OMB Control Number: 1810–0698.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 5,412.

Total Estimated Number of Annual Burden Hours: 2,728.

Abstract: ''Indian Education—Individual Reporting on Regulatory Compliance Related to the Indian Education Professional Development Program's Service Obligation and the Government Performance and Results Act of 1993 (GPRA).''

The Indian Education Professional Development program, authorized under title VII, part A of the Elementary and Secondary Education Act of 1965, as amended (ESEA), is designed to increase the number of, provide training to, and improve the skills of American Indian or Alaska Natives serving as teachers and school administrators in schools serving American Indian or Alaska Native students.

Section 7122(h) of the ESEA (20 U.S.C. 7442(h)) requires that individuals who receive financial assistance through the Indian Education Professional Development program subsequently complete a service obligation equivalent to the amount of time for which the participant received financial assistance. Participants who do not satisfy the requirements of the regulations must repay all or a pro-rated part of the cost of assistance, in accordance with 20 U.S.C. 7442(h) and 34 CFR 263.8(a)(3). The regulations in part 263 implement requirements governing, among other things, the service obligation and reporting requirements of the participants in the Indian Education Professional Development program, and repayment of financial assistance by these participants. In order for the Federal Government to ensure that the goals of the program are achieved, certain data collection, recordkeeping, and documentation are necessary.

In addition, GPRA requires Federal agencies to establish performance measures for all programs, and the Department has established performance measures for the Indian Education Professional Development program. Data collection from participants who have received financial assistance under the Indian Education Professional Development program is a necessary element of the Department's effort to evaluate progress on these measures.

The Department tracks participants who are receiving or have previously received support through the Indian Education Professional Development program. Participants must sign a payback agreement that includes contact

information. Additionally, the Department receives information about participants from institutions of higher education (IHEs) and other eligible grantees when participants are no longer receiving assistance through the Indian Education Professional Development program. When the performance period is complete, the participant data are collected from the grantee and also from the participants.

Dated: January 28, 2016.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–01844 Filed 2–1–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP16–301–000]

Iroquois Gas Transmission System, L.P.; Notice of Initiation of Section 5 Proceeding

On January 21, 2016, the Commission issued an order in Docket No. RP16–301–000, pursuant to section 5 of the Natural Gas Act, 15 U.S.C. 717d (2012), instituting an investigation into the justness and reasonableness of Iroquois Gas Transmission System, LP's (Iroquois) currently effective tariff rates. The Commission's order directs Iroquois to file a full cost and revenue study within 75 days of the issuance of the order. *Iroquois Gas Transmission System, L.P.,* 154 FERC ¶61,028 (2016).

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01797 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Half-Day Closing

Pursuant to the Office of Personnel Management announcement on January 22, 2016, all Federal Government offices in the District of Columbia metropolitan area will be closed at 12 noon.

In accordance with section 385.2007 of the Commission's Rules, 18 CFR 385.2007, filings and documents due to be filed on Friday, January 22, 2016 will be accepted as timely on the next official business day.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01806 Filed 2–1–16; 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 meeting 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

January 28, 2016, 10:00 a.m.–3:00 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/markets_operations/services/planning/index.jsp.*

The New York Independent System Operator, Inc. Joint Electric System Planning Working Group and Transmission Planning Advisory Meeting

February 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/markets_operations/services/planning/index.jsp.*

The New York Independent System Operator, Inc. Electric System Planning Working Group Meeting

February 25, 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/markets_operations/services/planning/index.jsp.*

The discussions at the meeting 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. ER16–120.

New York Transco, LLC, Docket No. ER15–572.

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: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01809 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2322–060]

Brookfield White Pine Hydro LLC; Notice of Intent To File License Application, Filing of Pre-Application Document (PAD), Commencement of Pre-Filing Process, and Scoping; Request for Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests; and Scoping Meeting

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Pre-Application Document (PAD) (including a proposed process plan and schedule), pursuant to 18 CFR 5.6 of the Commission's regulations.

b. *Project No.:* 2322–060.

c. *Date Filed:* September 21, 2015.

d. *Submitted By:* Brookfield White Pine Hydro LLC (White Pine Hydro).

e. *Name of Project:* Shawmut Hydroelectric Project.

f. *Location:* On the Kennebec River in the towns of Skowhegan, Fairfield, Clinton, and Benton, within Kennebec and Somerset Counties, Maine. The project does not occupy United States lands.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's Regulations.

h. *Potential Applicant Contact:* Frank Dunlap, Licensing Specialist, Brookfield White Pine Hydro LLC, 150 Main St., Lewiston, ME 04240; (207) 755–5603; *Frank.Dunlap@brookfieldrenewable.com.*

i. *FERC Contact:* Dustin Wilson at (202) 502–6528, or email at *dustin.wilson@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise

with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in paragraph o. below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (1) The U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and (2) the State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating White Pine Hydro as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. Commission staff issued a Scoping Document 1 (SD1) on November 20, 2015, which also asked for study requests.

n. A copy of the PAD and SD1 are available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's Web site (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter P–2322 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. A copy is also available for inspection and reproduction at the address in paragraph h.

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.

o. With this notice, we are soliciting public comments on the PAD and the SD1, as well as on issues and associated study requests. All comments and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission. Documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and five copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

All filings with the Commission must include on the first page, the project name (Shawmut Hydroelectric Project) and number (P–2322–060), and bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by March 21, 2016.

Study requests and comments on the PAD or SD1 that have been filed previously are part of the relicensing record and do not need to be refiled.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, the scoping meetings held December 16, 2015, and the scoping meeting to be held February 9, 2016, will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

Scoping Meeting

Commission staff held scoping meetings December 16, 2015. The transcripts for the meetings are in the public record for this project, and are available for review through the Commission's Web site, using the ''eLibrary'' link.

Commission staff will hold a third scoping meeting in the vicinity of the project at the time and place noted below. All interested individuals and entities, particularly those who were unable to attend the December 16 scoping meetings, are invited to attend the meeting, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. The time and location of the meeting is as follows:

Evening Scoping Meeting

Date: Tuesday, February 9, 2016.

Time: 6:00 p.m.

Location: Skowhegan Community Center, 39 Poulin Dr., Skowhegan, Maine 04976.

Phone: (207) 474–6901.

As noted in item m. of this notice, SD1 was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 will be available at the scoping meeting, or may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues.

Meeting Objectives

At the scoping meeting, Commission staff will: (1) Initiate scoping of the issues; (2) review and discuss existing conditions and resource management objectives; (3) review and discuss existing information and identify preliminary information and study needs; and (4) review and discuss the process plan and schedule for pre-filing activities.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meeting. Directions on how to obtain a copy of the PAD and SD1 are included in item n. of this notice.

Meeting Procedures

The meeting will be recorded by a stenographer. The transcript will be placed in the public record for the project.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01810 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–59–000.

Applicants: RE Astoria LLC.

Description: Clarification to January 11, 2016 Application for Authorization

Under Section 203 of the Federal Power Act and Request for Expedited Consideration, Confidential Treatment and Waivers of RE Astoria LLC.

Filed Date: 1/20/16.

Accession Number: 20160120–5161.

Comments Due: 5 p.m. ET 2/1/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2331–054; ER14–630–029; ER10–2319–045; ER10–2317–045; ER13–1351–027; ER10–2330–052.

Applicants: J.P. Morgan Ventures Energy Corporation, AlphaGen Power LLC, BE Alabama LLC, BE CA LLC, Florida Power Development LLC, Utility Contract Funding, L.L.C.

Description: Non-Material Change in Status of the J.P. Morgan Sellers.

Filed Date: 1/21/16.

Accession Number: 20160121–5189.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER12–2448–012.

Applicants: Chisholm View Wind Project, LLC.

Description: Notice of Change in Status of Chisholm View Wind Project, LLC.

Filed Date: 1/21/16.

Accession Number: 20160121–5155.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–277–001.

Applicants: Talen Energy Marketing, LLC.

Description: Tariff Amendment: Response to FERC Request for Additional Information to be effective 12/31/9998.

Filed Date: 1/21/16.

Accession Number: 20160121–5137.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–620–001.

Applicants: Safe Harbor Water Power Corporation.

Description: Tariff Amendment: Amendment to Pending Safe Harbor PPA eTariff Filing to be effective 12/31/2015.

Filed Date: 1/21/16.

Accession Number: 20160121–5180.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–743–000.

Applicants: ITC Great Plains, LLC.

Description: § 205(d) Rate Filing: Settlement Agreement to be effective 1/1/2016.

Filed Date: 1/19/16.

Accession Number: 20160119–5235.

Comments Due: 5 p.m. ET 2/9/16.

Docket Numbers: ER16–752–000.

Applicants: Carousel Wind Farm, LLC.

Description: Amendment to January 20, 2016 Carousel Wind Farm, LLC submits tariff filing.

Filed Date: 1/21/16.

Accession Number: 20160121–5167.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–757–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OATT re: Merchant Network Upgrades to be effective 5/1/2016.

Filed Date: 1/21/16.

Accession Number: 20160121–5211.

Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–758–000.

Applicants: New England Power Company.

Description: § 205(d) Rate Filing: NEP Sched III–B Integrated Facilities Provisions Amdts & Notice Waiver Request to be effective 1/1/2014.

Filed Date: 1/21/16.

Accession Number: 20160121–5215.

Comments Due: 5 p.m. ET 2/11/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01800 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP16–302–000]

Columbia Gulf Transmission, LLC; Notice of Initiation of Section 5 Proceeding

On January 21, 2016, the Commission issued an order in Docket No. RP16–302–000, pursuant to section 5 of the Natural Gas Act, 15 U.S.C. 717d (2012), instituting an investigation into the justness and reasonableness of Columbia Gulf Transmission, LLC's (Columbia Gulf) currently effective tariff rates. The Commission's order directs Columbia Gulf to file a full cost and revenue study within 75 days of the issuance of the order. *Columbia Gulf Transmission, LLC,* 154 FERC ¶ 61,027 (2016).

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01798 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–750–000]

Bethel Wind Farm 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 Bethel Wind Farm 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 February 10, 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: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01808 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2558–043]

Green Mountain Power Corporation; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Type of Application: Application to amend license.

b. Project No.: 2558–043.

c. Date Filed: December 15, 2015.

d. Applicant: Green Mountain Power Corporation.

e. Name of Project: Otter Creek Hydroelectric Project.

f. Location: The project is located on Otter Creek in Addison and Rutland counties, Vermont.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791a–825r.

h. Applicant Contact: Mr. Josh Castonguay, Director, Generation and Renewable Innovation, Green Mountain Power Corporation, 163 Acorn Ln., Colchester, VT 05446, (802) 655–8754.

i. FERC Contact: Mr. Steven Sachs, (202) 502–8666, or *steven.sachs@ferc.gov.*

j. Deadline for filing comments, motions to intervene, protests, and recommendations is 30 days from the date of issuance of this notice. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, or recommendations 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. Please include the project number (P–2558–043) on any comments, motions to intervene, protests, or recommendations filed.

k. Description of Request: The applicant requests a temporary amendment to release an interim bypass conservation flow of 48 cubic feet per second (cfs) into the bypassed reach of the Huntington Falls development at the project. The license, issued October 23, 2014, requires the applicant to release a bypass conservation flow of 66 cfs at the development; however, the applicant states it currently lacks the equipment to efficiently release the required flow and is requesting the temporary amendment while it builds a new gate to comply with the requirement. The applicant expects to construct the gate and release the required 66 cfs by the end of 2016.

l. Locations of the Application: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208- 3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions To Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents: Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading, the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license amendment. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: January 21, 2016.

Nathanial J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01811 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–206–000.
Applicants: South Central MCN, LLC.
Description: Response to Request for Further Information of South Central MCN LLC.
Filed Date: 1/20/16.
Accession Number: 20160120–5142.
Comments Due: 5 p.m. ET 2/3/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–2542–008.
Applicants: Prairie Rose Wind, LLC.
Description: Compliance filing: Prairie Rose Wind, LLC MBR Tariff to be effective 10/1/2012.
Filed Date: 1/22/16.
Accession Number: 20160122–5002.
Comments Due: 5 p.m. ET 2/12/16.

Docket Numbers: ER14–2752–004.
Applicants: Xcel Energy Transmission Development Company, LLC.
Description: Second Formula Rate Compliance Filing of Xcel Energy Transmission Development Company, LLC.
Filed Date: 1/21/16.
Accession Number: 20160121–5265.
Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER15–1405–002.
Applicants: The Empire District Electric Company.
Description: Compliance filing: Supplement to Compliance Filing re Reactive to be effective 6/1/2015.
Filed Date: 1/21/16.
Accession Number: 20160121–5225.
Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–759–000.
Applicants: Innovative Solar 43, LLC.
Description: Innovative Solar 43, LLC submits tariff filing per 35.12: Innovative Solar 43, LLC MBR Tariff to be effective 2/20/2016.
Filed Date: 1/21/16.
Accession Number: 20160121–5261.
Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–760–000.
Applicants: New England Power Company.
Description: § 205(d) Rate Filing: New England Power Filing of LGIA with Wheelabrator Saugus, Inc. to be effective 1/1/2016.
Filed Date: 1/21/16.
Accession Number: 20160121–5238.
Comments Due: 5 p.m. ET 2/11/16.

Docket Numbers: ER16–761–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2016–01–22_SA 2763 Termination of ATCLLC-Escanaba FCA to be effective 1/23/2016.
Filed Date: 1/22/16.
Accession Number: 20160122–5033.
Comments Due: 5 p.m. ET 2/12/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 22, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01801 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP16–300–000]

Empire Pipeline, Inc.; Notice of Initiation of Section 5 Proceeding

On January 21, 2016, the Commission issued an order in Docket No. RP16–300–000, pursuant to section 5 of the Natural Gas Act, 15 U.S.C. 717d (2012), instituting an investigation into the justness and reasonableness of Empire Pipeline, Inc.'s (Empire) currently effective tariff rates. The Commission's order directs Empire to file a full cost and revenue study within 75 days of the issuance of the order. *Empire Pipeline, Inc.,* 154 FERC ¶61,029 (2016).

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01796 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP16–299–000]

Tuscarora Gas Transmission Company; Notice of Initiation of Section 5 Proceeding

On January 21, 2016, the Commission issued an order in Docket No. RP16–299–000, pursuant to section 5 of the Natural Gas Act, 15 U.S.C. 717d (2012), instituting an investigation into the justness and reasonableness of Tuscarora Gas Transmission Company (Tuscarora) currently effective tariff rates. The Commission's order directs Tuscarora to file a full cost and revenue study within 75 days of the issuance of the order. *Tuscarora Gas Transmission Company,* 154 FERC ¶61,030 (2016).

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01795 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–59–000]

Cheniere Corpus Christi Pipeline, L.P.; Notice of Request Under Blanket Authorization

Take notice that on January 15, 2016, Cheniere Corpus Christi Pipeline, L.P. (Cheniere Corpus Christi), 700 Milam Street, Suite 1900, Houston, Texas 77002, filed in Docket No. CP16–59–000 a prior notice request pursuant to sections 157.205, 157.208 and 157.210 of the Commission's regulations under the Natural Gas Act (NGA) as amended, requesting authorization to install two electric motor drive (EMD) compressors and associated facilities at the previously authorized Sinton Compressor Station site at San Patricio County, Texas (Sinton Compressor Station EMD Project).

Cheniere Corpus Christi was granted authorization in Docket No. CP12–508–000 [1] to construct its Corpus Christi Pipeline Project which included two compressor stations. Cheniere Corpus Christi states that the Taft Compressor Station is no longer needed and proposes to install approximately 29,600 horsepower (HP) of additional compression via two Solar EMD compressor units (14,800 HP each) at

[1] 149 FERC ¶61,283 (2014).

the Sinton Compressor Station. Cheniere Corpus Christi states that, as a result of the relocation of compression, neither the capacity nor the maximum allowable operating pressure of the Corpus Christi Pipeline will differ from what was authorized by the Commission in the Certificate.

Cheniere Corpus Christi estimates the cost of the Sinton Compressor Station EMD Project to be approximately $30 million, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Patricia Outtrim, Cheniere Energy Inc., 700 Milam Street, Suite 1900, Houston, Texas 77002, by telephone at (713) 375–5000, by facsimile at (713) 375–6485, or by email at *pat.outtrim@cheniere.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and seven copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01803 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice Of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2331–053; ER14–630–028; ER10–2319–044; ER10–2317–044; ER13–1351–026; ER10–2330–051.

Applicants: J.P. Morgan Ventures Energy Corporation, AlphaGen Power LLC, BE Alabama LLC, BE CA LLC, Florida Power Development LLC, Utility Contract Funding, L.L.C.

Description: Non-Material Change in Status of the J.P. Morgan Sellers.

Filed Date: 1/19/16.

Accession Number: 20160119–5455.

Comments Due: 5 p.m. ET 2/9/16.

Docket Numbers: ER11–4073–003.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Complaince Filing for Service Agreement No. 2962 to be effective 6/17/2011.

Filed Date: 1/20/16.

Accession Number: 20160120–5122.

Comments Due: 5 p.m. ET 2/10/16.

Docket Numbers: ER14–325–007; ER13–2409–007; ER11–4498–011; ER11–4499–011; ER11–4500–010; ER11–4507–009; ER12–128–008; ER11–4501–012; ER12–979–011; ER14–2858–006; ER11–4363–007; ER12–2448–011; ER12–2542–007.

Applicants: Enel Cove Fort, LLC, Buffalo Dunes Wind Project, LLC, Smoky Hills Wind Farm, LLC, Smoky Hills Wind Project II, LLC, Enel Stillwater, LLC, Canastota Windpower, LLC, EGP Stillwater Solar, LLC, Caney River Wind Project, LLC, Rocky Ridge Wind Project, LLC, Origin Wind Energy, LLC, Osage Wind, LLC, Chisholm View Wind Project, LLC, Prairie Rose Wind, LLC.

Description: Notice of Change in Status of Enel Cove Fort, LLC, et. al. under ER14–325, et. al.

Filed Date: 1/19/16.

Accession Number: 20160119–5448.

Comments Due: 5 p.m. ET 2/9/16.

Docket Numbers: ER16–457–001.

Applicants: California Independent System Operator Corporation.

Description: Tariff Amendment: 20160120-Errata_Pearblossom Certificate of Concurrence-SvcAgmt3480 to be effective 12/2/2015.

Filed Date: 1/20/16.

Accession Number: 20160120–5139.

Comments Due: 5 p.m. ET 2/1/16.

Docket Numbers: ER16–754–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Tri-State NITSA Rev 7 to be effective 1/1/2016.

Filed Date: 1/20/16.

Accession Number: 20160120–5141.

Comments Due: 5 p.m. ET 2/10/16.

Docket Numbers: ER16–755–000.

Applicants: Frontier El Dorado Refining LLC.

Description: § 205(d) Rate Filing: HollyFrontier El Dorado Refining LLC Notice of Succession Filing to be effective 1/21/2016.

Filed Date: 1/20/16.

Accession Number: 20160120–5148.

Comments Due: 5 p.m. ET 2/10/16.

Docket Numbers: ER16–756–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3320, Queue No. X3–043 to be effective 3/7/2016.

Filed Date: 1/21/16.

Accession Number: 20160121–5070.

Comments Due: 5 p.m. ET 2/11/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01799 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–58–000]

Iroquois Gas Transmission System, L.P.; Notice of Application

Take notice that on January 15, 2016, Iroquois Gas Transmission System, L.P. (Iroquois), One Corporate Drive, Shelton, Connecticut 06484, filed an application pursuant to section 7 of the Natural Gas Act and Part 157 of the Commission's regulations for authorization to enter into a payment-in-lieu-of-taxes (PILOT) transaction, including a lease and leaseback arrangement, with the Schoharie County Industrial Development Agency (Agency) in the State of New York. Specifically, Iroquois requests that the Commission (i) grant Iroquois authority to abandon passive leasehold interests in certain jurisdictional facilities located in Schoharie County, New York, by transferring such passive leasehold interests to the Agency; (ii) issue a certificate of public convenience and necessity to Iroquois to simultaneously lease back the leasehold interests from the Agency; and (3) grant Iroquois' request for pre-granted authorization to reacquire the leasehold interests from the Agency at the time the lease/leaseback agreements terminate.

The filing may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Helen M. Gallagher, Director of Legal Services and Secretary, Iroquois Pipeline Operating Company, One Corporate Drive, Suite 600, Shelton, CT 06484, phone: (203) 925–7201, or email: *helen_gallagher@iroquois.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on February 1, 2016.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01802 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–28–000]

NRG Wholesale Generation LP; Seward Generation, LLC: Notice of Institution of Section 206 Proceeding and Refund Effective Date

On January 14, 2016, the Commission issued an order in Docket No. EL16–28–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of NRG Wholesale Generation LP's reactive power rates for the Seward Generation Facility. *NRG Wholesale Generation LP,* 154 FERC ¶ 61,017 (2016).

The refund effective date in Docket No. EL16–28–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: January 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01804 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice Concerning Submissions Made During Federal Government Closures

Take notice that the Commission is adopting the following practice with respect to submittals to the Commission during Federal government office closures.

Effective January 22, 2016, the Commission will not accept submittals—either in electronic format submitted through ''FERC Online'' (including through eFiling and eTariff) or in hardcopy format—when the Commission is closed at the direction of

the Office of Personnel Management (OPM) or Presidential Executive Order closing Federal government offices in Washington, DC.[1]

At such time as the Commission reopens, it will again accept submittals both in electronic format through ''FERC Online'' (including through eFiling and eTariff) and in hardcopy format.

Dated: January 22, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–01805 Filed 2–1–16; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0265]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 4, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0265.

Title: Section 80.868, Card of Instructions.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 4,506 respondents; 4,506 responses.

Estimated Time per Response: 10 minutes (0.167 hours).

Frequency of Response: Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154, 303, 307(e), 309 and 332.

Total Annual Burden: 753 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The third party disclosure requirement contained in 47 CFR 80.868 of the Commission's rules is necessary to ensure that radiotelephone distress procedures must be securely mounted and displayed in full view of the principal operating position on board certain vessels (300 gross tons) required by the Communications Act or the International Convention for Safety of Life at Sea to be equipped with a radiotelephone station.

The information is used by a vessel radio operator during an emergency situation, and is designed to assist the radio operator to utilize proper distress procedures during a time when he or she may be subject to considerable stress or confusion.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–01822 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 4, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

[1] On January 22, 2016, OPM announced that all Federal Government offices in the District of Columbia metropolitan area will be closed at 12 noon. The above-described practice will be in effect that day.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0678.

Title: Part 25 of the Federal Communications Commission's Rules: Governing the Licensing of, and Spectrum Usage by, Commercial Earth Stations and Space Stations.

Form Nos.: FCC Form 312; Schedule A; Schedule B; Schedule S; FCC Form 312–EZ; FCC Form 312–R.

Type of Review: Revision of a currently approved information collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 4,924 respondents; 4,972 responses.

Estimated Time per Response: 0.5–80 hours per response.

Frequency of Response: On occasion, one time, and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721.

Total Annual Burden: 34,099 hours.

Annual Cost Burden: $10,617,860.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information. Certain information collected regarding international coordination of satellite systems is not routinely available for public inspection pursuant to 5 U.S.C. 552(b) and 47 CFR 0.457(d)(vii).

Needs and Uses: On December 17, 2015, the Commission released a Second Report and Order, FCC 15–167, titled, ''In the Comprehensive Review of Licensing and Operating Rules for Satellite Services.'' In this Report and Order, the Commission adopted comprehensive changes to 47 CFR part 25, which governs licensing and operation of space stations and earth stations for the provision of satellite communication services. Many of the amendments are substantive changes intended to give licensees greater operational flexibility.

The information collection requirements in this collection are needed to determine the technical, legal, and other qualifications of applicants and licensees to operate a radio station and to determine whether grant of an authorization serves the public interest, convenience and necessity. Without such information, the Commission could not determine whether to permit respondents to provide communications services in the United States. Therefore, the Commission would not be able to fulfill its statutory responsibilities in accordance with the Communications Act of 1934, as amended, and the obligations imposed on parties to the World Trade Organization Basic Telecom Agreement.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–01824 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[AU Docket No. 14–252; GN Docket No. 12–268; WT Docket No. 12–269; DA 16–89]

Revised Filing Window Dates for FCC Form 175 Application To Participate in the Forward Auction (Auction 1002)

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces revised filing window dates for FCC Form 175, the application for parties seeking to participate in the forward auction phase (Auction 1002) of the broadcast incentive auction (Auction 1000).

DATES: The forward auction FCC Form 175 filing window opened at 12:00 p.m. Eastern Time (ET) on January 27, 2016, and will close at 6:00 p.m. ET on February 10, 2016.

FOR FURTHER INFORMATION CONTACT: *Wireless Telecommunications Bureau, Auctions and Spectrum Access Division:* for general forward auction questions Leslie Barnes or Valerie Barrish at (202) 418–0660.

SUPPLEMENTARY INFORMATION: This is a summary of the *Forward Auction Application Filing Window Opens Today at Noon After One-Day Weather Delay; FCC Form 175 Deadline Extended to February 10, 2016 (Forward Auction 1002 FCC Form 175 Revised Filing Window Dates Public Notice),* AU Docket No. 14–252, GN Docket No. 12–268, WT Docket No. 12–269, DA 16–89, released on January 27, 2016. The complete text of the *Forward Auction 1002 FCC Form 175 Revised Filing Window Dates Public Notice* is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. ET Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text is also available on the Commission's Web site at *http://wireless.fcc.gov,* the Auction 1002 Web site at *http://www.fcc.gov/auctions/1002,* or by using the search function on the ECFS Web page at *http://www.fcc.gov/cgb/ecfs/.* Alternative formats are available to persons with disabilities by sending an email to *FCC504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

General Information

The *Forward Auction 1002 FCC Form 175 Revised Filing Window Dates Public Notice* announced that the filing window for the FCC Form 175, the application to participate in the forward auction phase of the broadcast incentive auction, opened on January 27, 2016, after a one-day delay due to severe weather in the Washington, DC area. In addition, the closing of the filing window will be extended for one day from its originally scheduled date. Specifically, the FCC Form 175 filing window opened at 12:00 p.m. ET on January 27, 2016, and will close at 6:00 p.m. ET on February 10, 2016. Applications must be filed prior to the closing of the filing window. All other procedures, terms and requirements as set out in the *Auction 1000 Application Procedures Public Notice,* 80 FR 66429, October 29, 2015, remain unchanged. Additional information for potential broadcast incentive auction participants is available on the Auction 1000 Web site at *www.fcc.gov/auctions/1000.*

Federal Communications Commission.

Gary D. Michaels,

Deputy Chief, Auctions and Spectrum Access Division, WTB.

[FR Doc. 2016–01980 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0937]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as

required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 4, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0937.

Title: Establishment of a Class A Television Service, MM Docket No. 00–10.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion and quarterly reporting requirements.

Number of Respondents and Responses: 430 respondents; 10,850 responses.

Estimated Time per Response: 0.017 hours–52 hours.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i), 307, 308, 309 and 319 of the Communications Act of 1934, as amended.

Total Annual Burden: 202,133 hours.

Total Annual Cost: $1,911,000.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On November 29, 1999, the Community Broadcasters Protection Act of 1999 (CBPA), Public Law 106–113, 113 Stat. Appendix I at pp. 1501A–594–1501A–598 (1999), codified at 47 U.S.C. 336(f), was enacted. That legislation provided that a low power television (LPTV) licensee should be permitted to convert the secondary status of its station to the new Class A status, provided it can satisfy certain statutorily-established criteria. The CBPA directs that Class A licensees be subject to the same license terms and renewal standards as full-power television licenses and that Class A licensees be accorded primary status as television broadcasters as long as they continue to meet the requirements set forth in the statute for a qualifying low power station.

The CBPA sets out certain certification and application procedures for LPTV licensees seeking Class A designation, prescribes the criteria LPTV licensees must meet to be eligible for Class A licenses, and outlines the interference protection Class A applicants must provide to analog, digital, LPTV and TV translator stations.

The CBPA directs that Class A stations must comply with the operating requirements for full-service television broadcast stations. Therefore, beginning on the date of its application for a Class A license and thereafter, a station must be ''in compliance'' with the Commission's operating rules for full-service television stations, contained in 47 CFR part 73.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–01821 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0998]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 4, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0998.

Title: Section 87.109, Station logs.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5 respondents and 5 responses.

Estimated Time per Response: 100 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. 154, 303 and 307(e) unless otherwise noted.

Total Annual Burden: 500 hours.

Annual Cost Burden: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Section 87.109 of the Commission's rules require that a station at a fixed location in the international aeronautical mobile service (IAMS) must maintain a log (written or automatic log) in accordance with the Annex 10 provisions of the International Civil Aviation Organization (ICAO) Convention. This log is necessary to document the quality of service provided by fixed stations, including the harmful interference, equipment failure, and logging of distress and safety calls where applicable. This information is used by the Commission to ensure that particular stations are licensed and operated in compliance with applicable rules, statutes, and treaties.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–01823 Filed 2–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

[Docket No. 9357]

LabMD, Inc. Oral Argument Before the Commission

AGENCY: Federal Trade Commission.

ACTION: Oral argument; open meeting.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') will meet on Tuesday, March 8, 2016, in Room 532 of the FTC Building for an Oral Argument In the Matter of LabMD, Inc. The public is invited to attend and observe the open portion of the meeting, which is scheduled to begin at 1:00 p.m. The remainder of the meeting will be closed to the public.

DATES: Oral argument is scheduled for March 8, 2016 at 1:00 p.m.

ADDRESSES: Federal Trade Commission Building, 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Donald S. Clark, Secretary, Office of the Secretary, 600 Pennsylvania Avenue NW., Washington, DC 20580, 202–326–2515.

SUPPLEMENTARY INFORMATION:

Open Meeting

(1) Oral Argument In the Matter of LabMD, Inc., Docket No. 9357.

Closed Meeting

(2) Executive Session to follow Oral Argument In the Matter of LabMD, Inc., Docket No. 9357.

Record of Commission's Vote

On January 20, 2016, Commissioners Ramirez, Ohlhausen, and McSweeny were recorded as voting in the affirmative to close Matter Number (2), and to withhold from this meeting notice such information as is exempt from disclosure under 5 U.S.C. 552b(c)(10). Commissioner Brill was recorded as not participating.

Commission's Explanation of Closing

The Commission has determined that Matter Number (2) may be closed under 5 U.S.C. 552b(c)(10), and that the public interest does not require the matter to be open.

General Counsel Certification

The General Counsel has certified that Matter Number (2) may properly be closed, citing the following relevant provision: 5 U.S.C. 552b(c)(10).

Expected Attendees

Expected to attend the closed meeting are the Commissioners themselves, an advisor to one of the Commissioners, and such other Commission staff as may be appropriate.

By direction of the Commission, Commissioner Brill not participating.

Donald S. Clark,

Secretary.

[FR Doc. 2016–01852 Filed 2–1–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 81 FR 4912–4913, dated January 28, 2016) is amended to reflect the reorganization of the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and function statements for the *Division of Birth Defects and Developmental Disabilities (CUBB)* and insert the following:

Division of Congenital and Developmental Disorders (CUBB). (1) Conducts research to determine the causes and prevention of birth defects and developmental disabilities; (2) maintains and expands support for state-based surveillance; (3) evaluates the effectiveness of efforts to prevent birth defects and developmental disabilities; (4) conducts and disseminates findings of epidemiologic research, investigations, demonstrations, and programs directed toward the prevention of selected adverse reproductive outcomes that are environmentally related; (5) provides assistance to State and local health departments on community exposures to terotogenic, mutagenic, embryotoxic, other environmental agents, and genetic influences adversely interfering with normal growth and development; (6) conducts research and develops programs to identify women at high risk of an alcohol-exposed pregnancy and to fund epidemiologic and clinical research studies aimed at early identification and intervention of children affected by prenatal alcohol exposure; (7) works closely with international organizations and entities in developing strategies and programs for reducing the number of birth defects and developmental disabilities; (8) develops and evaluates prevention strategies and provides training, technical consultation, and assistance to States and localities in developing their

capacity for planning, establishing, and maintaining surveillance and prevention programs; (9) maintains and oversees funding and technical assistance to state-based institutions (*e.g.,* the Centers for Birth Defects Research and Prevention that seek causes and promotes prevention of birth defects); (10) plans, develops, establishes, and maintains systems of surveillance including registries for monitoring, evaluating and disseminating information; (11) assists in increasing the capacity of States to prevent and control birth defects and developmental disabilities through training, technology transfer, grants, cooperative agreements, contracts, and other means; (12) provides information and education to the public; (13) provides services, consultation, technical assistance, and information to States, localities, other Federal agencies, international organizations, and other public and private organizations; (14) provides training in the epidemiology to professionals throughout the U.S. and abroad; and (15) collaborates and coordinates activities with other CIOs and HHS agencies.

Office of the Director (CUBB1). (1) Manages, directs, and coordinates the research agenda and activities of the division; (2) provides leadership and guidance on strategic planning, policy, program and project priority planning and setting, program management, and operations; (3) establishes division goals, objectives, and priorities; (4) monitors progress in implementation of projects and achievement of objectives; (5) plans, allocates, and monitors resources; (6) provides management, administrative, and support services, and coordinates with appropriate NCBDDD offices on program and administrative matters; (7) provides liaison with other CDC organizations, other governmental agencies, international organizations, and other outside groups; (8) provides support for internal scientific advisory groups; (9) provides scientific leadership and guidance to the division to assure highest scientific quality and professional standards; and (10) provides coordinative support for CDC's efforts to reduce adverse consequences from birth defects, developmental disabilities, and pediatric genetic conditions.

Birth Defects Branch (CUBBB). (1) Designs and conducts epidemiologic and genetic research to identify causes and risk factors of birth defects; (2) conducts and evaluates interventions to improve infant and child health by preventing or reducing the adverse consequences of birth defects; (3) designs and conducts surveillance of selected birth defects to identify rates, trends, and patterns of occurrence, and to evaluate the effectiveness of prevention programs; (4) disseminates findings of studies to the scientific and public health communities, and to the general public; (5) provides technical assistance to state and local agencies on surveillance of birth defects, epidemiologic research, prevention program design and evaluation, and prevention effectiveness research; (6) funds and coordinates grant and cooperative agreement programs and other extramural activities to improve the knowledge base for the prevention of birth defects through surveillance, epidemiologic research, and applies research of preventive interventions; (7) coordinates activities with other CDC functional units, HHS, other federal agencies, and appropriate private organizations regarding research and prevention programs for birth defects; (8) works with international organizations in developing strategies for the prevention of birth defects; and (9) disseminates findings of research through direct contact with health authorities, publication and distribution of special reports, publication in scientific and technical journals, conference presentations, and other appropriate means.

Prevention Research and Translation Branch (CUBBC). (1) Modifies the impact of prenatal exposures leading to adverse physical and developmental impairments in infants, children, and adults including integrating successful prevention programs into social and medical environments, and evaluating innovative, effective, and strategic health promotion programs; (2) develops, implements, evaluates, and disseminates education and communication interventions that lead to the prevention of birth defects and developmental disabilities; (3) designs and conducts surveillance of preventable birth defects and developmental disabilities to identify rates, trends, and patterns of occurrence, and to evaluate the effectiveness of prevention programs; (4) disseminates findings of epidemiologic studies to the scientific and public health communities, and to the general public; (5) conducts prevention effectiveness research to evaluate interventions strategies for the prevention of birth defects and developmental disabilities; (6) identifies and monitors major preconception, prenatal and perinatal risks, and protective factors for fetal alcohol spectrum disorders (FASD) and other prenatal alcohol attributable conditions; (7) provides technical assistance to state and local agencies on surveillance, epidemiologic research, prevention program design and evaluation, and prevention effectiveness research; (8) funds and coordinates grant and cooperative agreement programs and other extramural activities to improve the knowledge base for the prevention of birth defects and developmental disabilities through surveillance, epidemiologic research, and applies research of preventive interventions; (9) coordinates activities with other CDC functional units, HHS, other federal agencies and appropriate private organizations regarding research and prevention programs for birth defects and developmental disabilities; (10) works with international organizations in developing strategies for the prevention of birth defects and developmental disabilities; and (11) disseminates finding of research through direct contact with health authorities, publication and distribution of special reports, publication in scientific and technical journals, conference presentations, and other appropriate means.

Developmental Disabilities Branch (CUBBD). (1) Designs and conducts surveillance of developmental disabilities to identify rates, trends, and patterns of occurrence, and to evaluate the effectiveness of prevention programs; (2) conducts epidemiologic studies of developmental disabilities to identify causes and risk factors for these conditions; (3) disseminates findings of epidemiologic studies to the scientific and public health communities and to the general public; (4) conducts prevention effectiveness research to evaluate interventions strategies for the prevention of developmental disabilities; (5) conducts epidemiologic studies to identify and describe specific conditions and long-term outcomes of developmental disabilities; (6) provides technical assistance to state and local agencies on surveillance of developmental disabilities, epidemiologic research, prevention program design and evaluation, and prevention effectiveness research; (7) funds and coordinates grant and cooperative agreement programs and other extramural activities to improve the knowledge base for the prevention of developmental disabilities through surveillance, epidemiologic research, and applies research of preventive interventions; (8) coordinates activities with other CDC functional units, HHS, other federal agencies and appropriate private organizations regarding research and prevention programs for

developmental disabilities; (9) collaborates with international organizations in developing strategies for the prevention of developmental disabilities; (10) disseminates findings of research through direct contact with health authorities, publication and distribution of special reports, publication in scientific and technical journals, conference presentations, and other appropriate means; and (11) provides training in the epidemiology of developmental disabilities to professionals throughout the United States and abroad.

Delete in its entirety the title and function statement for the *Epidemiology and Surveillance Branch (CUBDB)* and insert the following:

Epidemiology and Surveillance Branch (CUBDB). (1) Provides scientific leadership in the design and implementation of monitoring systems as well as designs and conducts epidemiologic and genetic research to identify causes, risk factors and complications of blood disorders in affected populations; (2) designs and manages surveillance systems to evaluate the incidence, morbidity, and mortality associated with blood diseases and disorders; (3) plans, develops and coordinates special surveys and populations studies to monitor and assess the complications of blood disorders; (4) designs and implements studies using surveillance data to identify risk factors for the complications of blood disorders, and evaluating the effectiveness of the prevention activities; (5) provides epidemiologic and medical consultation and technical assistance, including epidemic aids to state and local health departments, other governmental agencies, and other public and private institutions in the investigation of blood disorders and related complications; (6) designing and implements studies to evaluate the effectiveness of implemented prevention strategies in the treatment centers, (7) works closely with internal and external organizations in applying prevalence and incidence data to target and evaluate programs to prevent the complications of blood diseases and chronic hereditary disorders, (8) publishes findings and advances arising out of surveillance and epidemiologic research to the scientific and public health communities; (9) provides training services to states, localities, and other countries in investigation, diagnosis, prevention, and control of blood diseases and chronic hereditary disorders; (10) assists in designing, implementing, and evaluating prevention and counseling programs for persons and their families with chronic blood diseases and selected chronic hereditary disorders; (11) designs, implements and coordinates the prevention and surveillance activities of specialized federally funded prevention centers organized to prevent the complications of blood diseases and chronic hereditary disorders; (12) conducts and supports both qualitative and quantitative research to expand the knowledge base related to blood disorders across the lifespan; (13) collaborates with hemostasis laboratory branch and incorporates the findings of these branches' activities which leads to prevention of complications of blood disorders; (14) supports public health analysis to include facilitating data collection, data management, data manipulation, analysis, project reporting and presentation; and (15) conducts applied research to develop, evaluate, improve and standardize public information systems and educational modules which support the prevention of complications from blood disorders.

Delete in its entirety the title and function statement for the *Laboratory Research Branch (CUBDC)* and insert the following:

Hemostasis Laboratory Branch (CUBDC). (1) Identifies new genetic markers of risk factors and clotting defects for affected groups; (2) provides reference laboratory diagnosis for multi-site epidemiologic and surveillance studies; (3) develops techniques and interpretation methods to improve molecular and coagulation diagnosis; (4) provides diagnostic support for epidemiologic studies and epidemic aids on emerging blood disorders and chronic hereditary disorders; (5) determines the mechanisms of pathogenesis and complications of blood disorders and chronic hereditary disorders;

(6) conducts research and providing reference services on diagnostic techniques for blood disorders and chronic hereditary disorders; (7) conducts research to improve laboratory methodologies and materials; (8) where appropriate, maintains the national reference laboratory for blood disorders and chronic hereditary disorders; (9) works closely with entities and organizations within the agency and organizations external to the agency to provide laboratory services in support of projects whose primary aim is to prevent and reduce complications associated with blood disorders and chronic hereditary disorders; and (10) publishes findings and advances arising out of surveillance and epidemiologic research to the scientific and public health communities.

Delete in its entirety the title and function statement for the *Prevention Research and Informatics Branch (CUBDD).*

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2016–01833 Filed 2–1–16; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6059–N4]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extended Temporary Moratoria on Enrollment of Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

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

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of temporary moratoria on the enrollment of new Medicare Part B ground ambulance suppliers and Medicare home health agencies, subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. These moratoria also apply to the enrollment of home health agencies and ground ambulance suppliers in Medicaid and the Children's Health Insurance Program.

DATES: *Effective Date:* January 29, 2016.

FOR FURTHER INFORMATION CONTACT: Belinda Gravel, (410) 786–8934. News media representatives must contact CMS' Public Affairs Office at (202) 690–6145 or email them at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Imposition of Temporary Enrollment Moratoria

Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid, or Children's Health Insurance Program

(CHIP) providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. For a more detailed explanation of these authorities, please see the July 31, 2013 notice (78 FR 46339) that first established temporary moratoria in certain geographic locations, or the February 4, 2014 (79 FR 6475) document that extended and expanded such moratoria (hereinafter referred to as the February 4, 2014 moratoria document).

Based on this authority and our regulations at § 424.570, we initially imposed moratoria to prevent enrollment of new home health agencies, subunits, and branch locations [1] (hereafter referred to as HHAs) in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Medicare Part B ground ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339). We exercised this authority again in a document published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded it to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties. Then, we further extended these moratoria in documents issued on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), and July 28, 2015 (80 FR 44967).

B. Determination of the Need for Moratoria

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. CMS' determination of a high risk of fraud, waste, or abuse in these provider and supplier types within these geographic locations was then confirmed by CMS' data analysis, which relied on factors the agency identified as strong indicators of risk. (For a more detailed explanation of this determination process and of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

1. Consultation With Law Enforcement

In consultation with the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS identified two provider and supplier types in nine geographic locations that warrant a temporary enrollment moratorium. For a more detailed discussion of this consultation process, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475).

2. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its state partners, and CMS carefully evaluated access for the target moratorium locations. Prior to imposing these moratoria, CMS reviewed Medicare data for these areas and found no concerns with beneficiary access to HHAs or ground ambulance suppliers. CMS also consulted with the appropriate State Medicaid Agencies and with the appropriate State Departments of Emergency Medical Services to determine if the moratoria would create access to care concerns for Medicaid and CHIP beneficiaries in the targeted locations and surrounding counties. All of CMS' state partners were supportive of CMS' analysis and proposals, and together with CMS, determined that these moratoria would not create access to care issues for Medicaid or CHIP beneficiaries.

3. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended or lifted, CMS will publish a document to that effect in the **Federal Register**.

Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be designated to CMS' high screening level under § 424.518(c)(3)(iii) and § 455.450(e)(2) for 6 months from the date the moratorium is lifted.

II. Extension of Home Health and Ambulance Moratoria—Geographic Locations

As noted earlier, we previously imposed moratoria on the enrollment of new HHAs in the Florida counties of Broward, Miami-Dade, and Monroe; the Illinois counties of Cook, DuPage, Kane, Lake, McHenry, and Will; the Michigan counties of Macomb, Monroe, Oakland, Washtenaw, and Wayne; and the Texas counties of Brazoria, Chambers, Collin, Fort Bend, Galveston, Dallas, Harris, Liberty, Denton, Ellis, Kaufman, Montgomery, Rockwall, Tarrant, and Waller. Further, we previously imposed moratoria on the enrollment of new ground ambulance suppliers in the Texas counties of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller; the Pennsylvania counties of Bucks, Delaware, Montgomery, and Philadelphia; and the New Jersey counties of Burlington, Camden, and Gloucester. These moratoria became effective upon publication of the notice in the **Federal Register** on July 31, 2013 (78 FR 46339) and the moratoria document on February 4, 2014 (79 FR 6475), and were subsequently extended by documents published in the **Federal Register** on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), and July 28, 2015 (80 FR 44967).

As provided in § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under this authority, CMS is extending the temporary moratoria on the Medicare enrollment of HHAs and ground ambulance suppliers in the geographic locations discussed herein. Under regulations at §§ 455.470 and 457.990, these moratoria also apply to the enrollment of HHAs and ground ambulance suppliers in Medicaid and CHIP. Under § 424.570(b), CMS is required to publish a document in the **Federal Register** announcing any extension of a moratorium, and this extension of moratoria document fulfills that requirement.

CMS consulted with the HHS OIG regarding the extension of the moratoria on new HHAs and ground ambulance suppliers in all of the moratoria counties, and the HHS OIG agrees that a significant potential for fraud, waste, and abuse continues to exist in these geographic areas. The circumstances warranting the imposition of the moratoria have not yet abated, and CMS has determined that the moratoria are still needed as we monitor the indicators and continue with administrative actions, such as payment suspensions and revocations of

[1] As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, CMS–6028–FC (76 FR 5870), home health agency subunits and branch locations are subject to the moratoria to the same extent as any other newly enrolling home health agency.

provider/supplier numbers. (For more information regarding the monitored indicators, see the February 4, 2014 moratoria document (79 FR 6475)).

Based upon CMS' consultation with the relevant State Medicaid Agencies, CMS has concluded that extending these moratoria will not create an access to care issue for Medicaid or CHIP beneficiaries in the affected counties at this time. CMS also reviewed Medicare data for these areas and found there are no current problems with access to HHAs or ground ambulance suppliers. Nevertheless, the agency will continue to monitor these locations to make sure that no access to care issues arise in the future.

Based upon our consultation with law enforcement and consideration of the factors and activities described previously, CMS has determined that the temporary enrollment moratoria should be extended for an additional 6 months.

III. Summary of the Moratoria Locations

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to extend the enrollment moratoria in the following counties for HHAs and ground ambulance suppliers:

TABLE 1—HHA MORATORIA

State	City/metropolitan area	Counties
FL	Fort Lauderdale	Broward.
FL	Miami	Monroe Miami-Dade.
IL	Chicago	Cook. DuPage. Kane. Lake. McHenry. Will.
MI	Detroit	Macomb. Monroe. Oakland. Washtenaw. Wayne.
TX	Dallas	Collin. Dallas. Denton. Ellis. Kaufman. Rockwall. Tarrant.
TX	Houston	Brazoria. Chambers. Fort Bend. Galveston. Harris. Liberty. Montgomery. Waller.

TABLE 2—GROUND AMBULANCE MORATORIA

State	City/metropolitan area	Counties
PA/NJ	Philadelphia	Bucks. Burlington (NJ). Camden (NJ). Delaware. Gloucester (NJ). Montgomery. Philadelphia.
TX	Houston	Brazoria. Chambers. Fort Bend. Galveston. Harris. Liberty. Montgomery. Waller.

IV. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act states that there shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed on the enrollment of new providers of services and suppliers if the Secretary determines that the moratorium is necessary to prevent or combat fraud, waste, or abuse. Accordingly, our regulations at 42 CFR 498.5(l)(4) state that for appeals of denials based on a temporary moratorium, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review. Our regulations do not limit the right to seek judicial review of a final agency decision that the temporary moratorium applies to a particular provider or supplier. In the preamble to the February 2, 2011 (76 FR 5918) final rule with comment period establishing this regulation, we explained that ''a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review.'' We are clarifying that providers and suppliers that have received unfavorable decisions in accordance with the limited scope of review described in § 498.5(l)(4) may seek judicial review of those decisions after they exhaust their administrative appeals. We reiterate, however, that section 1866(j)(7)(B) of the Act precludes judicial review of the agency's basis for imposing a temporary moratorium.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

CMS has examined the impact of this document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects ($100 million or more in any one year). This document will prevent the enrollment of new home health providers and ground ambulance suppliers in Medicare and new home health providers and ground ambulance suppliers in Medicaid and CHIP. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. After the imposition of the initial moratoria on July 31, 2013, 848 HHAs and 14 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small

governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $35.5 million in any one year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this document.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Dated: December 7, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–01835 Filed 1–29–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3323–N]

Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs; Extension of Comment Period

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

ACTION: Request for information; extension of comment period.

SUMMARY: This document extends the comment period for the December 31, 2015 request for information entitled ''Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs'' (80 FR 81824) (referred to in this document as December 31 RFI). The comment period for the December 31 RFI, which would have ended on February 1, 2016, is extended for 15 days.

DATES: The comment period is extended to February 16, 2016. To be assured consideration, written or electronic comments on the December 31 RFI must be received at one of the addresses provided below no later than February 16, 2016.

ADDRESSES: In commenting on the December 31 RFI, please refer either to file code CMS–3323–NC and comment as indicated in that document (80 FR 81824) or file code CMS–3323–N and comment as provided in this document. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3323–N, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3323–N, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments. Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through

Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

FOR FURTHER INFORMATION CONTACT: Lisa Marie Gomez, (410) 786–1175.

SUPPLEMENTARY INFORMATION: On December 31, 2015, we published a request for information in the **Federal Register** (80 FR 81824) entitled, ''Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs'' (referred to in this document as ''the December 31 RFI''). That request for information seek public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS). In addition, it requested feedback on how often to require recertification, the number of clinical quality measures (CQMs) a certified Health IT Module should be required to certify to, and testing of certified Health IT Module(s).

We have received inquiries from stakeholders regarding the 30-day comment period to submit comments regarding the December 31 RFI. The stakeholders stated that they need additional time to respond to the questions posed in the December 31 RFI. Since we requested the public's comments on several options, we believe that it is important to allow ample time for the public to prepare their comments. Therefore, we have decided to extend the comment period for an additional 15 days. This document announces the extension of the public comment period to February 16, 2016.

Dated: January 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–01937 Filed 2–1–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2398–N]

RIN 0983–ZB24

Medicaid Program; Final FY 2013 and Preliminary FY 2015 Disproportionate Share Hospital Allotments, and Final FY 2013 and Preliminary FY 2015 Institutions for Mental Diseases Disproportionate Share Hospital Limits

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

ACTION: Notice.

SUMMARY: This notice announces the final federal share disproportionate share hospital (DSH) allotments for federal fiscal year (FY) 2013 and the preliminary federal share DSH allotments for FY 2015. This notice also announces the final FY 2013 and the preliminary FY 2015 limitations on aggregate DSH payments that states may make to institutions for mental disease and other mental health facilities. In addition, this notice includes background information describing the methodology for determining the amounts of states' FY DSH allotments.

DATES: This notice is effective March 3, 2016. The final allotments and limitations set forth in this notice are effective for the fiscal years specified.

FOR FURTHER INFORMATION CONTACT: Stuart Goldstein, (410) 786–0694 and Richard Cuno, (410) 786–1111.

SUPPLEMENTARY INFORMATION:

I. Background

A. Fiscal Year DSH Allotments

A state's federal fiscal year (FY) disproportionate share hospital (DSH) allotment represents the aggregate limit on the federal share amount of the state's payments to DSH hospitals in the state for the FY. The amount of such allotment is determined in accordance with the provisions of section 1923(f)(3) of the Social Security Act (the Act). Under such provisions, in general a state's FY DSH allotment is calculated by increasing the amount of its DSH allotment for the preceding FY by the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the previous FY.

The Affordable Care Act amended Medicaid DSH provisions, adding section 1923(f)(7) of the Act which would have required reductions to states' FY DSH allotments beginning with FY 2014, the calculation of which was described in the Disproportionate Share Hospital Payment Reduction final rule published in the September 18, 2013 **Federal Register** (78 FR 57293). Under the DSH reduction methodology, first, each state's unreduced FY DSH allotment would have been calculated in accordance with the provisions of section 1923(f) of the Act, excluding section 1923(f)(7) of the Act; then, the reduction amount for each state would have been determined under the provisions of section 1923(f)(7) of the Act and implementing regulations at 42 CFR 447.294; and, finally, the net FY DSH allotment for each state would have been determined by subtracting the DSH reduction amount for the state from its unreduced FY 2014 DSH allotment.

The reductions under section 1923(f)(7) of the Act were most recently delayed and modified by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), enacted on April 16, 2015. The reductions of states' fiscal year DSH allotments under section 1923(f)(7) of the Act that were applicable to FY 2017 were repealed, and are instead scheduled to begin in FY 2018 at modified levels. MACRA also extended DSH allotment reductions through 2025.

Because there is no reduction to DSH allotments for FY 2015 under section 1923(f)(7) of the Act, this notice contains only the state-specific preliminary FY 2015 DSH allotments, as calculated under the statute without application of the reductions that would have otherwise been imposed. This notice also provides information on the calculation of such FY DSH allotments, the calculation of the states' IMD DSH limits, and the amounts of states' preliminary FY 2015 IMD DSH limits.

B. Determination of Fiscal Year DSH Allotments

Generally, in accordance with the methodology specified under section 1923(f)(3) of the Act, a state's FY DSH allotment is calculated by increasing the amount of its DSH allotment for the preceding FY by the percentage change in the CPI–U for the previous FY. Also in accordance with section 1923(f)(3) of the Act, a state's DSH allotment for a FY is subject to the limitation that an increase to a state's DSH allotment for a FY cannot result in the DSH allotment exceeding the greater of the state's DSH allotment for the previous FY or 12 percent of the state's total medical assistance expenditures for the allotment year (this is referred to as the 12 percent limit).

Furthermore, under section 1923(h) of the Act, federal financial participation

(FFP) for DSH payments to institutions for mental diseases (IMDs) and other mental health facilities is limited to state-specific aggregate amounts. Under this provision, the aggregate limit for DSH payments to IMDs and other mental health facilities is the lesser of a state's FY 1995 total computable (state and federal share) IMD and other mental health facility DSH expenditures applicable to the state's FY 1995 DSH allotment (as reported on the Form CMS–64 as of January 1, 1997), or the amount equal to the product of the state's current year total computable DSH allotment and the applicable percentage specified in section 1902(h) of the Act (the applicable percentage is the IMD share of DSH total computable expenditures as of FY 1995).

In general, we determine states' DSH allotments for a FY and the IMD DSH limits for the same FY using the most recent available estimates of or actual medical assistance expenditures, including DSH expenditures in their Medicaid programs and the most recent available change in the CPI–U used for the FY in accordance with the methodology prescribed in the statute. The indicated estimated or actual expenditures are obtained from states for each relevant FY from the most recent available quarterly Medicaid budget reports (Form CMS–37) or quarterly Medicaid expenditure reports (Form CMS–64), respectively, submitted by the states. For example, as part of the initial determination of a state's FY DSH allotment (referred to as the preliminary DSH allotments) that is determined before the beginning of the FY for which the DSH allotments and IMD DSH limits are being determined, we use estimated expenditures for the FY obtained from the August submission of the CMS–37 submitted by states prior to the beginning of the FY; such estimated expenditures are subject to update and revision during the FY before such actual expenditure data become available. We also use the most recent available estimated CPI–U percentage change that is available before the beginning of the FY for determining the states' preliminary FY DSH allotments; such estimated CPI–U percentage change is subject to update and revision during the FY before the actual CPI–U percentage change becomes available. In determining the final DSH allotments and IMD DSH limits for a FY we use the actual expenditures for the FY and actual CPI–U percentage change for the previous FY.

II. Provisions of the Notice

A. Calculation of the Final FY 2013 Federal Share State DSH Allotments and the Preliminary FY 2015 Federal Share State DSH Allotments

1. Final FY 2013 Federal Share State DSH Allotments

Addendum 1 to this notice provides the states' final FY 2013 DSH allotments determined in accordance with section 1923(f)(3) of the Act. As described in the background section of this notice, in general, the DSH allotment for a FY is calculated by increasing the FY DSH allotment for the preceding FY by the CPI–U increase for the previous fiscal year. For purposes of calculating the states' final FY 2013 DSH allotments, the preceding final fiscal year DSH allotments (for FY 2012) were published in the July 26, 2013 **Federal Register** (78 FR 45217). For purposes of calculating the states' final FY 2013 DSH allotments we are using the actual Medicaid expenditures for FY 2013. Finally, for purposes of calculating the states' final FY 2013 DSH allotments, the applicable historical percentage change in the CPI–U for the previous FY (FY 2012) was 2.4 percent; we note that this is the same as the estimated 2.4 percentage change in the CPI–U for FY 2012 that was available and used in the calculation of the preliminary FY 2013 DSH allotments which were published in the July 26, 2013 **Federal Register** (78 FR 45217).

2. Calculation of the Preliminary FY 2015 Federal Share State DSH Allotments

Addendum 2 to this notice provides the preliminary FY 2015 DSH allotments determined in accordance with section 1923(f)(3) of the Act. The preliminary FY 2015 DSH allotments contained in this notice were determined based on the most recent available estimates from states of their FY 2015 total computable Medicaid expenditures. Also, the preliminary FY 2015 allotments contained in this notice were determined by increasing the preliminary FY 2014 DSH allotments as contained in the notice published in the February 28, 2014 **Federal Register** (79 FR 11436) by 1.6 percent, representing the most recent available estimate of the percentage increase in the CPI–U for FY 2014 (the previous FY to FY 2015).

We will publish states' final FY 2015 DSH allotments in future notices based on the states' four quarterly Medicaid expenditure reports (Form CMS–64) for FY 2015 available following the end of FY 2015 and the actual change in the CPI–U for FY 2014.

B. Calculation of the Final FY 2013 and Preliminary FY 2015 IMD DSH Limits

Section 1923(h) of the Act specifies the methodology to be used to establish the limits on the amount of DSH payments that a state can make to IMDs and other mental health facilities. FFP is not available for IMD or DSH payments that exceed the IMD limits. In this notice, we are publishing the final FY 2013 and the preliminary FY 2015 IMD DSH Limits determined in accordance with the provisions discussed above.

Addendums 3 and 4 to this notice detail each state's final FY 2013 and preliminary FY 2015 IMD DSH Limit, respectively, determined in accordance with section 1923(h) of the Act.

III. Collection of Information Requirements

This notice does not impose any new or revised information collection or recordkeeping requirements. The requirements and burden associated with form CMS–37 (OMB control number 0938–1265) and form CMS–64 (OMB control number 0938–1265) are unaffected by this notice. As it pertains to the content of this notice, CMS–37 and CMS–64 are not subject to formal Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This notice reaches the $100 million economic threshold and thus is considered a major rule under the Congressional Review Act.

The final FY 2013 DSH allotments being published in this notice are equal

to the preliminary FY 2013 DSH allotments published in the July 26, 2013 **Federal Register** (78 FR 45217). This is due to the actual percentage change in the CPI–U for FY 2012 used in the calculation of the final FY 2013 allotments (2.4 percent) being equal to the estimated percentage change in the CPI–U for FY 2012 used in the calculation of the preliminary FY 2013 allotments (2.4 percent). The final FY 2013 IMD DSH limits being published in this notice are also equal to the preliminary FY 2013 IMD DSH limits published in the July 26, 2013 **Federal Register** (78 FR 45217). Since the final FY 2013 DSH allotments were equal to the preliminary FY 2013 DSH allotments, the associated FY 2013 IMD DSH limits also remained the same.

The preliminary FY 2015 DSH allotments being published in this notice are about $240 million more than the preliminary FY 2014 DSH allotments published in the February 28, 2014 **Federal Register** (79 FR 11436). The increase in the DSH allotments is due to the application of the statutory formula for calculating DSH allotments under which the prior fiscal year allotments are increased by the percentage increase in the CPI–U for the prior fiscal year. The preliminary FY 2015 IMD DSH limits being published in this notice are about $14 million more than the preliminary FY 2014 IMD DSH limits published in the February 28, 2014 **Federal Register** (79 FR 11436). The increase in the IMD DSH limits is because the DSH allotment for a FY is a factor in the determination of the IMD DSH limit for the FY. Since the preliminary FY 2015 DSH allotments are greater than the preliminary FY 2014 DSH allotments, the associated preliminary FY 2015 IMD DSH limits for some states also increased.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have significant economic impact on a substantial number of small entities. Specifically, any impact on providers is due to the effect of the various controlling statutes; providers are not impacted as a result of the independent regulatory action in publishing this notice. The purpose of the notice is to announce the latest distributions as required by the statute.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area for Medicaid payment regulations and has fewer than 100 beds. We are not preparing analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

The Medicaid statute specifies the methodology for determining the amounts of states' DSH allotments and IMD DSH limits; and as described previously, the application of the methodology specified in statute results in the decreases or increases in states' DSH allotments and IMD DSH limits for the applicable FYs. The statute applicable to these allotments and limits does not apply to the determination of the amounts of DSH payments made to specific DSH hospitals; rather, these allotments and limits represent an overall limit on the total of such DSH payments. In this regard, we do not believe that this notice will have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately $144 million. This notice will have no consequential effect on state, local, or tribal governments, in the aggregate, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of E.O. 13132 are not applicable.

A. Alternatives Considered

The methodologies for determining the states' fiscal year DSH allotments and IMD DSH Limits, as reflected in this notice, were established in accordance with the methodologies and formula for determining states' allotments as specified in the statute. This notice does not put forward any further discretionary administrative policies for determining such allotments.

B. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the Table 1, we have prepared an accounting statement showing the classification of the estimated expenditures associated with the provisions of this notice. Table 1 provides our best estimate of the change (decrease) in the federal share of states' Medicaid DSH payments resulting from the application of the provisions of the Medicaid statute relating to the calculation of states' FY DSH allotments and the increase in the FY DSH allotments from FY 2014 to FY 2015.

TABLE 1—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE FY 2014 TO FY 2015

[In millions]

Category	Transfers
Annualized Monetized Transfers.	$240.
From Whom To Whom?	Federal Government to States.

Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: December 3, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: January 20, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

KEY TO ADDENDUM 1—FINAL DSH ALLOTMENTS FOR FY 2013

[The Final FY 2013 DSH Allotments for the NON-Low DSH States are presented in the top section of this addendum, and the Final FY 2013 DSH Allotments for the Low-DSH States are presented in the bottom section of this addendum]

Column	Description
Column A	State.
Column B	FY 2013 FMAPs. This column contains the States' FY 2013 Federal Medical Assistance Percentages.
Column C	Prior FY (2012) DSH Allotments This column contains the States' prior FY 2012 DSH Allotments.
Column D	Prior FY (2012) DSH Allotments (Col C) × (100 percent + Percentage Increase in CPIU): 102.4 percent. This column contains the amount in Column C increased by 1 plus the percentage increase in the CPI–U for the prior FY (102.4 percent).
Column E	FY 2013 TC MAP Exp. Including DSH. This column contains the amount of the States' FY 2013 total computable (TC) medical assistance expenditures including DSH expenditures.
Column F	FY 2013 TC DSH Expenditures. This column contains the amount of the States' FY 2013 total computable DSH expenditures.
Column G	FY 2013 TC MAP Exp. Net of DSH. This column contains the amount of the States' FY 2013 total computable medical assistance expenditures net of DSH expenditures, calculated as the amount in Column E minus the amount in Column F.
Column H	12 percent Amount. This column contains the amount of the ''12 percent limit'' in Federal share, determined in accordance with the provisions of section 1923(f)(3) of the Act.
Column I	Greater of FY 2012 Allotment or 12 percent Limit. This column contains the greater of the State's prior FY (FY 2012) DSH allotment or the amount of the 12 percent Limit, determined as the maximum of the amount in Column C or Column H
Column J	FY 2013 DSH Allotment. This column contains the States' final FY 2013 DSH allotments, determined as the minimum of the amount in Column I or Column D. For states with ''na'' in Columns I or D, refer to the footnotes in the addendum.

ADDENDUM 1—FINAL DSH ALLOTMENTS FOR FY 2013

State	FY 2013 FMAPs (percent)	Prior FY (2012) DSH allotments	Prior FY (2012) DSH allotment (Col C) × 100% + Pct increase in CPIU: 102.4%	FY 2013 TC MAP Exp. including DSH	FY 2013 TC DSH expenditures	FY 2013 TC MAP EXP. net of DSH Col E–F	"12% Amount" = Col G × .12/(1–.12/Col B)* (in FS)	Greater of Col H or Col C (12% limit, FY 2012 Allotment)	FY 2013 DSH allotment MIN Col I, Col D
A	B	C	D	E	F	G	H	I	J
ALABAMA	68.53	$315,520,769	$323,093,267	$4,999,646,843	$470,923,104	$4,528,723,739	$658,807,935	$658,807,935	$323,093,267
ARIZONA	65.68	103,890,985	106,384,369	8,437,380,837	173,082,813	8,264,298,024	1,213,410,792	1,213,410,792	106,384,369
CALIFORNIA	50.00	1,124,844,365	1,151,840,630	61,425,894,719	2,119,710,409	59,306,184,310	9,364,134,365	9,364,134,365	1,151,840,630
COLORADO	50.00	94,912,751	97,190,657	5,048,193,724	194,191,858	4,854,001,866	766,421,347	766,421,347	97,190,657
CONNECTICUT	50.00	205,216,760	210,141,962	6,415,388,481	272,860,246	6,142,528,235	969,872,879	969,872,879	210,141,962
DISTRICT OF COLUMBIA	70.00	62,847,632	64,355,975	2,275,681,171	56,387,767	2,219,293,404	321,414,907	321,414,907	64,355,975
FLORIDA	58.08	205,216,760	210,141,962	18,411,438,180	335,009,637	18,076,428,543	2,734,059,817	2,734,059,817	210,141,962
GEORGIA	65.56	275,760,021	282,378,262	8,887,641,041	429,964,548	8,457,676,493	1,242,312,033	1,242,312,033	282,378,262
ILLINOIS	50.00	220,608,017	225,902,609	15,493,580,784	447,072,185	15,046,508,599	2,375,764,516	2,375,764,516	225,902,609
INDIANA	67.16	219,325,413	224,589,223	7,930,553,510	337,536,579	7,593,016,931	1,109,384,374	1,109,384,374	224,589,223
KANSAS	56.51	42,325,957	43,341,780	2,544,769,057	76,622,785	2,468,146,272	376,027,713	376,027,713	43,341,780
KENTUCKY	70.55	148,782,151	152,352,923	5,726,056,802	216,263,666	5,509,793,136	796,685,033	796,685,033	152,352,923
LOUISIANA/1	na	na	na	na	na	na	na	na	731,960,000
MAINE	62.57	107,738,799	110,324,530	2,826,874,563	37,489,437	2,789,385,126	414,155,018	414,155,018	110,324,530
MARYLAND	50.00	78,238,890	80,116,623	7,688,146,740	134,340,816	7,553,805,924	1,192,706,199	1,192,706,199	80,116,623
MASSACHUSETTS	50.00	312,955,559	320,466,492	12,999,170,453	0	12,999,170,453	2,052,500,598	2,052,500,598	320,466,492
MICHIGAN	66.39	271,912,207	278,438,100	12,308,409,960	387,951,247	11,920,458,713	1,746,054,614	1,746,054,614	278,438,100
MISSISSIPPI	73.43	156,477,779	160,233,246	4,708,563,005	217,999,554	4,490,563,451	644,132,328	644,132,328	160,233,246
MISSOURI	61.37	486,107,200	497,773,773	8,863,322,084	703,393,659	8,159,928,425	1,217,196,210	1,217,196,210	497,773,773
NEVADA	59.74	47,456,375	48,595,328	1,797,228,664	81,373,600	1,715,855,064	257,658,605	257,658,605	48,595,328
NEW HAMPSHIRE	50.00	164,274,500	168,217,088	1,188,634,372	40,923,914	1,147,710,458	181,217,441	181,217,441	168,217,088
NEW JERSEY	50.00	660,541,446	676,394,441	10,480,866,440	1,298,115,161	9,182,751,279	1,449,908,097	1,449,908,097	676,394,441
NEW YORK	50.00	1,648,147,103	1,687,702,633	52,489,778,879	3,423,365,423	49,066,413,456	7,747,328,440	7,747,328,440	1,687,702,633
NORTH CAROLINA	65.51	302,694,721	309,959,394	11,721,921,735	617,376,633	11,104,545,102	1,631,378,246	1,631,378,246	309,959,394
OHIO	63.58	416,846,544	426,850,861	16,628,494,101	649,120,744	15,979,373,357	2,363,633,714	2,363,633,714	426,850,861
PENNSYLVANIA	54.28	575,889,532	589,710,881	20,922,389,122	847,055,684	20,075,333,438	3,092,778,900	3,092,778,900	589,710,881
RHODE ISLAND	51.26	66,695,447	68,296,138	1,909,141,351	129,846,057	1,779,295,294	278,777,412	278,777,412	68,296,138
SOUTH CAROLINA	70.43	336,042,444	344,107,463	4,690,094,944	457,173,209	4,232,921,735	612,270,432	612,270,432	344,107,463
TENNESSEE/2	na	na	na	na	na	na	na	na	53,100,000
TEXAS	59.30	981,192,634	1,004,741,257	27,752,018,303	226,747,941	27,525,270,362	4,141,011,076	4,141,011,076	1,004,741,257
VERMONT	56.04	23,086,886	23,640,971	1,452,095,084	37,448,781	1,414,646,303	216,013,021	216,013,021	23,640,971
VIRGINIA	50.00	89,892,713	92,050,138	7,218,485,856	186,468,433	7,032,017,423	1,110,318,540	1,110,318,540	92,050,138
WASHINGTON	50.00	189,825,503	194,381,315	7,805,501,929	366,733,930	7,438,767,999	1,174,542,316	1,174,542,316	194,381,315
WEST VIRGINIA	72.04	69,260,656	70,922,912	3,007,417,198	75,434,137	2,931,983,061	422,158,680	422,158,680	70,922,912
Total	0.00	10,004,528,519	10,244,637,203	366,054,779,932	15,047,983,957	351,006,795,975	53,874,035,598	53,874,035,598	11,029,697,203
LOW DSH STATES									
ALASKA	50.00	20,901,012	21,402,636	1,340,719,400	21,706,474	1,319,012,926	208,265,198.84	208,265,199	21,402,636
ARKANSAS	70.17	44,262,980	45,325,292	4,156,350,929	61,000,000	4,095,350,929	592,822,640	592,822,640	45,325,292
DELAWARE	55.67	9,289,338	9,512,282	1,557,544,100	10,874,669	1,546,669,431	236,601,110	236,601,110	9,512,282
HAWAII	51.86	10,000,000	10,240,000	1,586,220,307	24,971,280	1,561,249,027	243,752,256.52	243,752,257	10,240,000
IDAHO	71.00	16,866,254	17,271,044	1,641,925,393	23,708,980	1,618,216,413	233,681,421.00	233,681,421	17,271,044
IOWA	59.59	40,408,349	41,378,149	3,622,873,642	54,606,370	3,568,267,272	536,162,337	536,162,337	41,378,149
MINNESOTA	50.00	76,637,045	78,476,334	8,781,239,289	46,287,099	8,734,952,190	1,379,202,977	1,379,202,977	78,476,334
MONTANA	66.00	11,646,847	11,926,371	996,801,715	17,703,206	979,098,509	143,601,115	143,601,115	11,926,371
NEBRASKA	55.76	29,036,347	29,733,219	1,790,372,947	45,313,162	1,745,059,785	266,831,445	266,831,445	29,733,219
NEW MEXICO	69.07	20,901,012	21,402,636	3,280,561,202	25,164,146	3,255,397,056	472,788,382	472,788,382	21,402,636
NORTH DAKOTA	52.27	9,801,133	10,036,360	775,035,726	1,265,931	773,769,795	120,521,323	120,521,323	10,036,360
OKLAHOMA	64.00	37,157,353	38,049,129	4,481,944,280	41,759,650	4,440,184,630	655,781,115	655,781,115	38,049,129
OREGON	62.44	46,446,693	47,561,414	5,070,815,864	76,536,235	4,994,279,629	741,894,100	741,894,100	47,561,414
SOUTH DAKOTA	56.19	11,332,733	11,604,719	758,090,042	1,441,151	756,648,891	115,454,450	115,454,450	11,604,719
UTAH	69.61	20,129,695	20,612,808	2,087,187,059	28,794,708	2,058,392,351	298,457,958	298,457,958	20,612,808
WISCONSIN	59.74	96,998,597	99,326,563	7,034,898,860	581,325	7,034,317,535	1,056,296,932	1,056,296,932	99,326,563
WYOMING	50.00	232,233	237,807	546,576,901	463,560	546,113,341	86,228,422	86,228,422	237,807

Total Low DSH States	0.00	502,047,621	514,096,764	49,509,157,656	482,177,946	49,026,979,710	7,388,343,182	7,388,343,182	514,096,763
Total	0.00	10,506,576,140	10,758,733,967	415,563,937,588	15,530,161,903	400,033,775,685	61,262,378,780	61,262,378,780	11,543,793,966

[1] FY 2013 DSH allotment for Louisiana determined under the provisions of section 1903(f)(3)(C) and (D) of the Act.
[2] Tennessee's DSH allotments are determined under section 1923(f)(6)(A)(v)(II) of the Act. Under this provision, Tennessee's DSH payments for FY 2013 are limited to $53,100,000.
[3] Beginning FY 2013, under section 1923(f)(6)(B)(II) of the Act, Hawaii's DSH allotments are determined as for low-DSH states. This means its allotments are determined as for all States, by increasing the previous fiscal year allotment by the CPIU for the previous fiscal year.

KEY TO ADDENDUM 2—PRELIMINARY DSH ALLOTMENTS FOR FY 2015

[The Preliminary FY 2015 DSH Allotments for the NON-Low DSH States are presented in the top section of this addendum, and the Preliminary FY 2015 DSH Allotments for the Low-DSH States are presented in the bottom section of this addendum]

Column	Description
Column A	State.
Column B	FY 2015 FMAPs. This column contains the States' FY 2015 Federal Medical Assistance Percentages.
Column C	Prior FY (2014) DSH Allotments. This column contains the States' prior FY 2014 DSH Allotments
Column D	Prior FY (2014) DSH Allotments (Col C) × (100 percent + Percentage Increase in CPIU): 101.6 percent. This column contains the amount in Column C increased by 1 plus the estimated percentage increase in the CPI–U for the prior FY (101.6 percent).
Column E	FY 2015 TC MAP Exp. Including DSH. This column contains the amount of the States' projected FY 2015 total computable (TC) medical assistance expenditures including DSH expenditures.
Column F	FY 2015 TC DSH Expenditures. This column contains the amount of the States' projected FY 2015 total computable DSH expenditures.
Column G	FY 2015 TC MAP Exp. Net of DSH. This column contains the amount of the States' projected FY 2015 total computable medical assistance expenditures net of DSH expenditures, calculated as the amount in Column E minus the amount in Column F.
Column H	12 percent Amount. This column contains the amount of the ''12 percent limit'' in Federal share, determined in accordance with the provisions of section 1923(f)(3) of the Act.
Column I	Greater of FY 2014 Allotment or 12 percent Limit. This column contains the greater of the State's prior FY (FY 2014) DSH allotment or the amount of the 12 percent Limit, determined as the maximum of the amount in Column C or Column H.
Column J	FY 2015 DSH Allotment. This column contains the States' preliminary FY 2015 DSH allotments, determined as the minimum of the amount in Column I or Column D. For states with ''na'' in Columns I or D, refer to the footnotes in the addendum.

ADDENDUM 2—PRELIMINARY DSH ALLOTMENTS FOR FY 2015

State	FY 2015 FMAPs (percent)	Prior FY (2014) DSH allotments	Prior FY (2014) DSH Allotment (Col C) × 100% + Pct increase in CPIU: 101.6%	FY 2015 TC MAP Exp. Including DSH [4]	FY 2015 TC DSH Expenditures [4]	FY 2015 TC MAP EXP. Net Of DSH Col E–F	"12% Amount" = Col G × .12/(1–.12/Col B)* (in FS)	Greater of Col H or Col C (12% Limit, FY 2014 allotment)	FY 2015 DSH Allotment Min Col I, Col D
A	B	C	D	E	F	G	H	I	J
ALABAMA	68.99	$327,939,666	$333,186,701	$5,727,646,000	$507,528,000	$5,220,118,000	$758,313,966	$758,313,966	$333,186,701
ARIZONA	68.46	107,980,135	109,707,817	11,262,757,000	167,012,000	11,095,745,000	1,614,483,959	1,614,483,959	109,707,817
CALIFORNIA	50.00	1,169,118,239	1,187,824,131	96,031,140,000	597,609,000	95,433,531,000	15,068,452,263	15,068,452,263	1,187,824,131
COLORADO	51.01	98,648,517	100,226,893	6,927,502,000	204,899,000	6,722,603,000	1,054,867,918	1,054,867,918	100,226,893
CONNECTICUT	50.00	213,294,091	216,706,796	7,094,230,000	125,646,000	6,968,584,000	1,100,302,737	1,100,302,737	216,706,796
DISTRICT OF COLUMBIA	70.00	65,321,315	66,366,456	2,630,681,000	37,174,000	2,593,507,000	375,611,359	375,611,359	66,366,456
FLORIDA	59.72	213,294,091	216,706,796	22,430,097,000	362,102,000	22,067,995,000	3,314,083,809	3,314,083,809	216,706,796
GEORGIA	66.94	286,613,936	291,199,759	9,915,707,000	434,725,000	9,480,982,000	1,386,218,278	1,386,218,278	291,199,759
ILLINOIS	50.76	229,291,148	232,959,806	19,753,482,000	456,614,000	19,296,868,000	3,032,535,665	3,032,535,665	232,959,806
INDIANA	66.52	227,958,061	231,605,390	10,719,730,000	474,987,000	10,244,743,000	1,499,956,649	1,499,956,649	231,605,390
KANSAS	56.63	43,991,907	44,695,778	3,161,490,000	74,228,000	3,087,262,000	470,082,851	470,082,851	44,695,778
KENTUCKY	69.94	154,638,217	157,112,428	8,903,447,000	241,000,000	8,662,447,000	1,254,784,004	1,254,784,004	157,112,428
LOUISIANA [1]	62.05	731,960,000	743,671,360	7,995,712,000	551,048,000	7,444,664,000	1,107,551,811	1,107,551,811	743,671,360
MAINE	61.88	111,979,398	113,771,068	2,565,931,000	38,566,000	2,527,365,000	376,247,024	376,247,024	113,771,068
MARYLAND	50.00	81,318,372	82,619,466	11,133,665,000	92,859,000	11,040,806,000	1,743,285,158	1,743,285,158	82,619,466
MASSACHUSETTS	50.00	325,273,489	330,477,865	16,287,567,000	0	16,287,567,000	2,571,721,105	2,571,721,105	330,477,865
MICHIGAN	65.54	282,614,672	287,136,507	16,050,268,000	322,351,000	15,727,917,000	2,310,364,618	2,310,364,618	287,136,507
MISSISSIPPI	73.58	162,636,745	165,238,933	5,362,441,000	228,204,000	5,134,237,000	736,168,545	736,168,545	165,238,933
MISSOURI	63.45	505,240,380	513,324,226	9,641,725,000	713,722,000	8,928,003,000	1,321,240,327	1,321,240,327	513,324,226
NEVADA	64.36	49,324,258	50,113,446	2,848,030,000	78,128,000	2,769,902,000	408,565,835	408,565,835	50,113,446
NEW HAMPSHIRE	50.00	170,740,344	173,472,190	1,816,048,000	76,097,000	1,739,951,000	274,729,105	274,729,105	173,472,190
NEW JERSEY	50.00	686,540,358	697,525,004	14,214,233,000	1,213,776,000	13,000,457,000	2,052,703,737	2,052,703,737	697,525,004
NEW YORK	50.00	1,713,018,172	1,740,426,463	68,512,267,000	5,326,800,000	63,185,467,000	9,976,652,684	9,976,652,684	1,740,426,463
NORTH CAROLINA	65.88	314,608,785	319,642,526	12,482,232,000	411,389,000	12,070,843,000	1,771,107,209	1,771,107,209	319,642,526
OHIO	62.64	433,253,624	440,185,682	21,305,059,000	0	21,305,059,000	3,162,438,142	3,162,438,142	440,185,682
PENNSYLVANIA	51.82	598,556,544	608,133,449	24,679,963,000	787,072,000	23,892,891,000	3,731,179,141	3,731,179,141	608,133,449
RHODE ISLAND	50.00	69,320,580	70,429,709	3,117,756,000	142,487,000	2,975,269,000	469,779,316	469,779,316	70,429,709
SOUTH CAROLINA	70.64	349,269,075	354,857,380	5,636,583,000	494,437,000	5,142,146,000	743,331,228	743,331,228	354,857,380
TENNESSEE [2]	na	na	na	na	na	na	na	na	53,100,000
TEXAS	58.05	1,019,812,376	1,036,129,374	35,894,535,000	2,630,047,000	33,264,488,000	5,031,931,019	5,031,931,019	1,036,129,374
VERMONT [5]	56.21	23,995,586	24,379,515	1,577,599,000	37,449,000	1,540,150,000	234,983,483	234,983,483	24,379,515
VIRGINIA	50.00	93,430,890	94,925,784	8,689,637,000	193,862,000	8,495,775,000	1,341,438,158	1,341,438,158	94,925,784
WASHINGTON	50.03	197,297,035	200,453,788	12,536,442,000	405,243,000	12,131,199,000	1,915,089,832	1,915,089,832	200,453,788
WEST VIRGINIA	71.35	71,986,756	73,138,544	3,631,855,000	71,987,000	3,559,868,000	513,556,694	513,556,694	73,138,544
Total		11,130,266,762	11,308,351,030	490,537,457,000	17,499,048,000	473,038,409,000	72,723,757,629	72,723,757,629	11,361,451,030
LOW DSH STATES									
ALASKA	50.00	21,723,676	22,071,255	1,661,590,000	21,894,000	1,639,696,000	258,899,368.42	258,899,368	22,071,255
ARKANSAS	70.88	46,005,171	46,741,254	6,070,657,000	65,820,000	6,004,837,000	867,437,867	867,437,867	46,741,254
DELAWARE	53.63	9,654,966	9,809,445	1,549,168,000	24,248,000	1,524,920,000	235,738,053	235,738,053	9,809,445
HAWAII [3]	52.23	10,393,600	10,559,898	1,951,834,000	0	1,951,834,000	304,084,384.25	304,084,384	10,559,898
IDAHO	71.75	17,530,110	17,810,592	2,009,716,000	24,470,000	1,985,246,000	286,074,779.25	286,074,779	17,810,592
IOWA	55.54	41,998,821	42,670,802	4,714,183,000	34,688,000	4,679,495,000	716,304,508	716,304,508	42,670,802
MINNESOTA	50.00	79,653,479	80,927,935	11,849,443,000	154,792,000	11,694,651,000	1,846,523,842	1,846,523,842	80,927,935
MONTANA	65.90	12,105,267	12,298,951	1,030,146,000	1,896,000	1,028,250,000	150,860,872	150,860,872	12,298,951
NEBRASKA	53.27	30,179,217	30,662,084	2,053,612,000	42,720,000	2,010,892,000	311,471,433	311,471,433	30,662,084
NEW MEXICO	69.65	21,723,676	22,071,255	4,758,998,000	31,196,000	4,727,802,000	685,428,779	685,428,779	22,071,255
NORTH DAKOTA	50.00	10,186,905	10,349,895	1,155,141,000	1,735,000	1,153,406,000	182,116,737	182,116,737	10,349,895
OKLAHOMA	62.30	38,619,866	39,237,784	5,404,554,000	58,140,000	5,346,414,000	794,628,053	794,628,053	39,237,784
OREGON	64.06	48,274,835	49,047,232	8,294,293,000	81,136,000	8,213,157,000	1,212,757,981	1,212,757,981	49,047,232
SOUTH DAKOTA	51.64	11,778,790	11,967,251	857,827,000	1,613,000	856,214,000	133,849,317	133,849,317	11,967,251
UTAH	70.56	20,922,000	21,256,752	2,276,646,000	31,390,000	2,245,256,000	324,641,933	324,641,933	21,256,752
WISCONSIN	58.27	100,816,461	102,429,524	8,016,231,000	166,265,000	7,849,966,000	1,186,300,027	1,186,300,027	102,429,524
WYOMING	50.00	241,374	245,236	596,915,000	476,000	596,439,000	94,174,579	94,174,579	245,236

ADDENDUM 2—PRELIMINARY DSH ALLOTMENTS FOR FY 2015—Continued

State	FY 2015 FMAPs (percent)	Prior FY (2014) DSH allotments	Prior FY (2014) DSH Allotment (Col C) × 100% + Pct increase in CPIU: 101.6%	FY 2015 TC MAP Exp. Including DSH [4]	FY 2015 TC DSH Expenditures [4]	FY 2015 TC MAP EXP. Net Of DSH Col E–F	"12% Amount" = Col G × .12/(1–.12/Col B)* (in FS)	Greater of Col H or Col C (12% Limit, FY 2014 allotment)	FY 2015 DSH Allotment Min Col I, Col D
A	B	C	D	E	F	G	H	I	J
Total Low DSH States	.....	521,808,214	530,157,145	64,250,954,000	742,479,000	63,508,475,000	9,591,292,512	9,591,292,512	530,157,145
Total	.....	11,652,074,976	11,838,508,176	554,788,411,000	18,241,527,000	536,546,884,000	82,315,050,141	82,315,050,141	11,891,608,175

[1] Louisiana's FY 2015 DSH allotment is determined under the provisions of section 1923(f)(3)(C) and (D) of the Act.
[2] Tennessee's DSH allotment for FY 2015 determined under section 1923(f)(6)(A)(vi) of the Act
[3] Beginning FY 2013, under section 1923(f)(6)(B)(II) of the Act, Hawaii's DSH allotment for a fiscal year is determined as for low-DSH states. This means Hawaii's DSH allotment for a fiscal year is determined as for all States, by increasing the previous fiscal year allotment by the percentage increase in the CPIU for the previous fiscal year.
[4] Expenditures based on the amounts reported by States on the Form CMS–37.
[5] FMAP for Vermont for FY 2015 determined in accordance with section 1905(z)(1)(A) of the Act.

KEY TO ADDENDUM 3—FINAL IMD DSH LIMITS FOR FY 2013

[The final FY 2013 IMD DSH Limits for the Non-Low DSH States are presented in the top section of this addendum and the preliminary FY 2013 IMD DSH Limits for the Low-DSH States are presented in the bottom section of the addendum]

Column	Description
Column A	State.
Column B	Inpatient Hospital Services FY 95 DSH Total Computable This column contains the States' total computable FY 1995 inpatient hospital DSH expenditures as reported on the Form CMS–64.
Column C	IMD and Mental Health Services FY 95 DSH Total Computable. This column contains the total computable FY 1995 mental health facility DSH expenditures as reported on the Form CMS–64 as of January 1, 1997.
Column D	Total Inpatient Hospital & IMD & Mental Health FY 95 DSH Total Computable, Col. B + C. This column contains the total computation of all inpatient hospital DSH expenditures and mental health facility DSH expenditures for FY 1995 as reported on the Form CMS–64 as of January 1, 1997 (representing the sum of Column B and Column C).
Column E	Applicable Percentage, Col. C/D. This column contains the ''applicable percentage'' representing the total Computable FY 1995 mental health facility DSH expenditures divided by total computable all inpatient hospital and mental health facility DSH expenditures for FY 1995 (the amount in Column C divided by the amount in Column D) Per section 1923(h)(2)(A)(ii)(III) of the Act, for FYs after FY 2002, the applicable percentage can be no greater than 33 percent.
Column F	FY 2013 Federal Share DSH Allotment This column contains the states' FY 2013 DSH allotments from Column J Addendum 1.
Column G	FY 2013 FMAP.
Column H	FY 2013 DSH Allotments in Total Computable, Col. F/G. This column contains states' FY 2013 total computable DSH allotment (determined as Column F/Column G).
Column I	Applicable Percentage Applied to FY 2013 Allotments in TC, Col E × Col H. This column contains the applicable percentage of FY 2012 total computable DSH allotment (calculated as the percentage in Column E multiplied by the amount in Column H).
Column J	FY 2013 TC IMD DSH Limit. Lesser of Col. I or C. This column contains the total computable FY 2013 TC IMD DSH Limit equal to the lesser of the amount in Column I or Column C.
Column K	FY 2013 IMD DSH Limit in Federal Share, Col. G × J. This column contains the FY 2013 Federal Share IMD DSH limit determined by converting the total computable FY 2013 IMD DSH Limit from Column J into a federal share amount by multiplying it by the FY 2013 FMAP in Column G.

ADDENDUM 3—FINAL IMD DSH LIMITS FOR FY 2013

State	Inpatient Hospital services FY 95 DSH Total computable	IMD And mental health services FY 95 DSH Total computable	Total inpatient & IMD & mental health FY 95 DSH total computable Col B + C	Applicable percent Col C/D (percent)	FY 2013 Allotment In FS	FY 2013 FMAPs (percent)	FY 2013 Allotments in TC Col F/G	Applicable percentage applied to FY 2013 allotments in TC Col E × Col H	FY 2013 TC IMD Limit (Lesser Of Col I or Col C)	FY 2013 IMD Limit In FS Col G × J	MMA LOW DSH Status
A	B	C	D	E	F	G	H	I	J	K	L
ALABAMA	$413,006,229	$4,451,770	$417,457,999	1.07	$323,093,267	68.53	471,462,523	$5,027,674	$4,451,770	$3,050,798	N/A
ARIZONA	93,916,100	28,474,900	122,391,000	23.27	106,384,369	65.68	161,973,765	37,684,035	28,474,900	18,702,314	N/A
CALIFORNIA	2,189,879,543	1,555,919	2,191,435,462	0.07	1,151,840,630	50.00	2,303,681,260	1,635,614	1,555,919	777,960	N/A
COLORADO	173,900,441	594,776	174,495,217	0.34	97,190,657	50.00	194,381,314	662,559	594,776	297,388	N/A
CONNECTICUT	303,359,275	105,573,725	408,933,000	25.82	210,141,962	50.00	420,283,924	108,504,179	105,573,725	52,786,863	N/A
DISTRICT OF COLUMBIA	39,532,234	6,545,136	46,077,370	14.20	64,355,975	70.00	91,937,107	13,059,358	6,545,136	4,581,595	N/A
FLORIDA	184,468,014	149,714,986	334,183,000	33.00	210,141,962	58.08	361,814,673	119,398,842	119,398,842	69,346,847	N/A
GEORGIA	407,343,557	0	407,343,557	0.00	282,378,262	65.56	430,717,300	0	0	0	N/A
ILLINOIS	315,868,508	89,408,276	405,276,784	22.06	225,902,609	50.00	451,805,218	99,672,933	89,408,276	44,704,138	N/A
INDIANA	79,960,783	153,566,302	233,527,085	33.00	224,589,223	67.16	334,409,206	110,355,038	110,355,038	74,114,444	N/A
KANSAS	11,587,208	76,663,508	88,250,716	33.00	43,341,780	56.51	76,697,540	25,310,188	25,310,188	14,302,787	N/A
KENTUCKY	158,804,908	37,443,073	196,247,981	19.08	152,352,923	70.55	215,950,281	41,202,167	37,443,073	26,416,088	N/A
LOUISIANA	1,078,512,169	132,917,149	1,211,429,318	10.97	731,960,000	65.51	1,117,325,599	122,592,157	122,592,157	80,310,122	N/A
MAINE	99,957,958	60,958,342	160,916,300	33.00	110,324,530	62.57	176,321,768	58,186,183	58,186,183	36,407,095	N/A
MARYLAND	22,226,467	120,873,531	143,099,998	33.00	80,116,623	50.00	160,233,246	52,876,971	52,876,971	26,438,486	N/A
MASSACHUSETTS	469,653,946	105,635,054	575,289,000	18.36	320,466,492	50.00	640,932,984	117,688,658	105,635,054	52,817,527	N/A
MICHIGAN	133,258,800	304,765,552	438,024,352	33.00	278,438,100	66.39	419,397,650	138,401,225	138,401,225	91,884,573	N/A
MISSISSIPPI	182,608,033	0	182,608,033	0.00	160,233,246	73.43	218,212,238	0	0	0	N/A
MISSOURI	521,946,524	207,234,618	729,181,142	28.42	497,773,773	61.37	811,102,775	230,516,896	207,234,618	127,179,885	N/A
NEVADA	73,560,000	0	73,560,000	0.00	48,595,328	59.74	81,344,707	0	0	0	N/A
NEW HAMPSHIRE	92,675,916	94,753,948	187,429,864	33.00	168,217,088	50.00	336,434,176	111,023,278	94,753,948	47,376,974	N/A
NEW JERSEY	736,742,539	357,370,461	1,094,113,000	32.66	676,394,441	50.00	1,352,788,882	441,861,843	357,370,461	178,685,231	N/A
NEW YORK	2,418,869,368	605,000,000	3,023,869,368	20.01	1,687,702,633	50.00	3,375,405,266	675,333,468	605,000,000	302,500,000	N/A
NORTH CAROLINA	193,201,966	236,072,627	429,274,593	33.00	309,959,394	65.51	473,148,212	156,138,910	156,138,910	102,286,600	N/A
OHIO	535,731,956	93,432,758	629,164,714	14.85	426,850,861	63.58	671,360,272	99,698,919	93,432,758	59,404,548	N/A
PENNSYLVANIA	388,207,319	579,199,682	967,407,001	33.00	589,710,881	54.28	1,086,423,878	358,519,880	358,519,880	194,604,591	N/A
RHODE ISLAND	108,503,167	2,397,833	110,901,000	2.16	68,296,138	51.26	133,234,760	2,880,720	2,397,833	1,229,129	N/A
SOUTH CAROLINA	366,681,364	72,076,341	438,757,705	16.43	344,107,463	70.43	488,580,808	80,260,965	72,076,341	50,763,367	N/A
TENNESSEE	0	0	0	0.00	53,100,000	66.13	80,296,386	0	0	0	N/A
TEXAS	1,220,515,401	292,513,592	1,513,028,993	19.33	1,004,741,257	59.30	1,694,336,015	327,565,642	292,513,592	173,460,560	N/A
VERMONT	19,979,252	9,071,297	29,050,549	31.23	23,640,971	56.04	42,185,887	13,172,925	9,071,297	5,083,555	N/A
VIRGINIA	129,313,480	7,770,268	137,083,748	5.67	92,050,138	50.00	184,100,276	10,435,289	7,770,268	3,885,134	N/A
WASHINGTON	171,725,815	163,836,435	335,562,250	33.00	194,381,315	50.00	388,762,630	128,291,668	128,291,668	64,145,834	N/A
WEST VIRGINIA	66,962,606	18,887,045	85,849,651	22.00	70,922,912	72.04	98,449,350	21,658,997	18,887,045	13,606,227	N/A
Total	13,402,460,846	4,118,758,904	17,521,219,750	.....	11,029,697,203	.....	19,545,491,877	3,709,617,180	3,410,261,852	1,921,150,660	
LOW DSH STATES											
ALASKA	$2,506,827	$17,611,765	$20,118,592	33.00	$21,402,636	50.00	$42,805,272	$14,125,740	$14,125,740	$7,062,870	LOW DSH
ARKANSAS	2,422,649	819,351	3,242,000	25.27	45,325,292	70.17	64,593,547	16,324,734	819,351	574,939	LOW DSH
DELAWARE	0	7,069,000	7,069,000	33.00	9,512,282	55.67	17,086,909	5,638,680	5,638,680	3,139,053	LOW DSH
HAWAII	0	0	0	0.00	10,240,000	51.86	19,745,469	0	0	0	LOW DSH
IDAHO	2,081,429	0	2,081,429	0.00	17,271,044	71.00	24,325,414	0	0	0	LOW DSH
IOWA	12,011,250	0	12,011,250	0.00	41,378,149	59.59	69,438,075	0	0	0	LOW DSH
MINNESOTA	24,240,000	5,257,214	29,497,214	17.82	78,476,334	50.00	156,952,668	27,973,278	5,257,214	2,628,607	LOW DSH
MONTANA	237,048	0	237,048	0.00	11,926,371	66.00	18,070,259	0	0	0	LOW DSH
NEBRASKA	6,449,102	1,811,337	8,260,439	21.93	29,733,219	55.76	53,323,563	11,692,713	1,811,337	1,010,002	LOW DSH
NEW MEXICO	6,490,015	254,786	6,744,801	3.78	21,402,636	69.07	30,986,877	1,170,535	254,786	175,981	LOW DSH
NORTH DAKOTA	214,523	988,478	1,203,001	33.00	10,036,360	52.27	19,200,995	6,336,328	988,478	516,677	LOW DSH
OKLAHOMA	20,019,969	3,273,248	23,293,217	14.05	38,049,129	64.00	59,451,764	8,354,379	3,273,248	2,094,879	LOW DSH

OREGON	11,437,908	19,975,092	31,413,000	33.00	47,561,414	62.44	76,171,387	25,136,558	19,975,092	12,472,447	LOW DSH
SOUTH DAKOTA	321,120	751,299	1,072,419	33.00	11,604,719	56.19	20,652,641	6,815,372	751,299	422,155	LOW DSH
UTAH	3,621,116	934,586	4,555,702	20.51	20,612,808	69.61	29,611,849	6,074,765	934,586	650,565	LOW DSH
WISCONSIN	6,609,524	4,492,011	11,101,535	33.00	99,326,563	59.74	166,264,752	54,867,368	4,492,011	2,683,527	LOW DSH
WYOMING	0	0	0	0.00	237,807	50.00	475,614	0	0	0	LOW DSH
Total Low DSH States	98,662,480	63,238,167	161,900,647		514,096,763		869,157,055	184,510,449	58,321,822	33,431,702	
Total	13,501,123,326	4,181,997,071	17,683,120,397		11,543,793,966		20,414,648,932	3,894,127,630	3,468,583,674	1,954,582,362	

KEY TO ADDENDUM 4—PRELIMINARY IMD DSH LIMITS FOR FY 2015

[The preliminary FY 2015 IMD DSH Limits for the Non-Low DSH States are presented in the top section of this addendum and the preliminary FY 2015 IMD DSH Limits for the Low-DSH States are presented in the bottom section of the addendum]

Column	Description
Column A	State.
Column B	Inpatient Hospital Services FY 95 DSH Total Computable. This column contains the States' total computable FY 1995 inpatient hospital DSH expenditures as reported on the Form CMS–64.
Column C	IMD and Mental Health Services FY 95 DSH Total Computable. This column contains the total computable FY 1995 mental health facility DSH expenditures as reported on the Form CMS–64 as of January 1, 1997.
Column D	Total Inpatient Hospital & IMD & Mental Health FY 95 DSH Total Computable, Col. B + C. This column contains the total computation of all inpatient hospital DSH expenditures and mental health facility DSH expenditures for FY 1995 as reported on the Form CMS–64 as of January 1, 1997 (representing the sum of Column B and Column C).
Column E	Applicable Percentage, Col. C/D. This column contains the ''applicable percentage'' representing the total Computable FY 1995 mental health facility DSH expenditures divided by total computable all inpatient hospital and mental health facility DSH expenditures for FY 1995 (the amount in Column C divided by the amount in Column D) Per section 1923(h)(2)(A)(ii)(III) of the Act, for FYs after FY 2002, the applicable percentage can be no greater than 33 percent.
Column F	FY 2015 Federal Share DSH Allotment. This column contains the states' preliminary FY 2015 DSH allotments from Column J Addendum 1.
Column G	FY 2015 FMAP.
Column H	FY 2015 DSH Allotments in Total Computable, Col. F/G. This column contains states' FY 2015 total computable DSH allotment (determined as Column F/Column G).
Column I	Applicable Percentage Applied to FY 2015 Allotments in TC, Col E x Col H. This column contains the applicable percentage of FY 2014 total computable DSH allotment (calculated as the percentage in Column E multiplied by the amount in Column H).
Column J	FY 2015 TC IMD DSH Limit. Lesser of Col. I or C. This column contains the total computable FY 2015 TC IMD DSH Limit equal to the lesser of the amount in Column I or Column C.
Column K	FY 2015 IMD DSH Limit in Federal Share, Col. G × J. This column contains the FY 2015 Federal Share IMD DSH limit determined by converting the total computable FY 2015 IMD DSH Limit from Column J into a federal share amount by multiplying it by the FY 2015 FMAP in Column G.

ADDENDUM 4—PRELIMINARY IMD DSH LIMITS FOR FY 2015

State	Inpatient hospital services FY 95 DSH total computable	IMD and mental health services FY 95 DSH total computable	Total inpatient & IMD & mental health FY 95 DSH total computable Col B + C	Applicable percent Col C/D	FY 2015 allotment in FS	FY 2015 FMAPs (percent)	FY 2015 allotments in TC Col. F/G	Applicable percentage applied to FY 2015 allotments in TC Col E × Col H	FY 2015 TC IMD Limit (Lesser Of Col I or Col C)	FY 2015 TC IMD limit in FS Col G × J	MMA LOW DSH Status
A	B	C	D	E	F	G	H	I	J	K	L
ALABAMA	$413,006,229	$4,451,770	$417,457,999	1.07	$333,186,701	68.99	$482,949,269	$5,150,169	$4,451,770	$3,071,276	N/A
ARIZONA	93,916,100	28,474,900	122,391,000	23.27	109,707,817	68.46	160,250,974	37,283,219	28,474,900	19,493,917	N/A
CALIFORNIA	2,189,879,543	1,555,919	2,191,435,462	0.07	1,187,824,131	50.00	2,375,648,262	1,686,710	1,555,919	777,960	N/A
COLORADO	173,900,441	594,776	174,495,217	0.34	100,226,893	51.01	196,484,793	669,729	594,776	303,395	N/A
CONNECTICUT	303,359,275	105,573,725	408,933,000	25.82	216,706,796	50.00	433,413,592	111,893,849	105,573,725	52,786,863	N/A
DISTRICT OF COLUMBIA	39,532,234	6,545,136	46,077,370	14.20	66,366,456	70.00	94,809,223	13,467,332	6,545,136	4,581,595	N/A
FLORIDA	184,468,014	149,714,986	334,183,000	33.00	216,706,796	59.72	362,871,393	119,747,560	119,747,560	71,513,243	N/A
GEORGIA	407,343,557	0	407,343,557	0.00	291,199,759	66.94	435,016,073	0	0	0	N/A
ILLINOIS	315,868,508	89,408,276	405,276,784	22.06	232,959,806	50.76	458,943,668	101,247,749	89,408,276	45,383,641	N/A
INDIANA	79,960,783	153,566,302	233,527,085	33.00	231,605,390	66.52	348,174,068	114,897,442	114,897,442	76,429,779	N/A
KANSAS	11,587,208	76,663,508	88,250,716	33.00	44,695,778	56.63	78,925,972	26,045,571	26,045,571	14,749,607	N/A
KENTUCKY	158,804,908	37,443,073	196,247,981	19.08	157,112,428	69.94	224,638,873	42,859,905	37,443,073	26,187,685	N/A
LOUISIANA	1,078,512,169	132,917,149	1,211,429,318	10.97	743,671,360	62.05	1,198,503,400	131,498,927	131,498,927	81,595,084	N/A
MAINE	99,957,958	60,958,342	160,916,300	33.00	113,771,068	61.88	183,857,576	60,673,000	60,673,000	37,544,452	N/A
MARYLAND	22,226,467	120,873,531	143,099,998	33.00	82,619,466	50.00	165,238,932	54,528,848	54,528,848	27,264,424	N/A
MASSACHUSETTS	469,653,946	105,635,054	575,289,000	18.36	330,477,865	50.00	660,955,730	121,365,252	105,635,054	52,817,527	N/A
MICHIGAN	133,258,800	304,765,552	438,024,352	33.00	287,136,507	65.54	438,108,799	144,575,904	144,575,904	94,755,047	N/A
MISSISSIPPI	182,608,033	0	182,608,033	0.00	165,238,933	73.58	224,570,444	0	0	0	N/A
MISSOURI	521,946,524	207,234,618	729,181,142	28.42	513,324,226	63.45	809,021,633	229,925,432	207,234,618	131,490,365	N/A
NEVADA	73,560,000	0	73,560,000	0.00	50,113,446	64.36	77,864,273	0	0	0	N/A
NEW HAMPSHIRE	92,675,916	94,753,948	187,429,864	33.00	173,472,190	50.00	346,944,380	114,491,645	94,753,948	47,376,974	N/A
NEW JERSEY	736,742,539	357,370,461	1,094,113,000	32.66	697,525,004	50.00	1,395,050,008	455,665,607	357,370,461	178,685,231	N/A
NEW YORK	2,418,869,368	605,000,000	3,023,869,368	20.01	1,740,426,463	50.00	3,480,852,926	696,430,885	605,000,000	302,500,000	N/A
NORTH CAROLINA	193,201,966	236,072,627	429,274,593	33.00	319,642,526	65.88	485,189,019	160,112,376	160,112,376	105,482,034	N/A
OHIO	535,731,956	93,432,758	629,164,714	14.85	440,185,682	62.64	702,722,992	104,356,372	93,432,758	58,526,280	N/A
PENNSYLVANIA	388,207,319	579,199,682	967,407,001	33.00	608,133,449	51.82	1,173,549,689	387,271,397	387,271,397	200,684,038	N/A
RHODE ISLAND	108,503,167	2,397,833	110,901,000	2.16	70,429,709	50.00	140,859,418	3,045,575	2,397,833	1,198,917	N/A
SOUTH CAROLINA	366,681,364	72,076,341	438,757,705	16.43	354,857,380	70.64	502,346,234	82,522,262	72,076,341	50,914,727	N/A
TENNESSEE*	0	0	0	0.00	53,100,000	64.99	81,704,878	0	0	0	N/A
TEXAS	1,220,515,401	292,513,592	1,513,028,993	19.33	1,036,129,374	58.05	1,784,891,256	345,072,669	292,513,592	169,804,140	N/A
VERMONT**	19,979,252	9,071,297	29,050,549	31.23	24,379,515	56.21	43,372,202	13,543,363	9,071,297	5,098,976	N/A
VIRGINIA	129,313,480	7,770,268	137,083,748	5.67	94,925,784	50.00	189,851,568	10,761,287	7,770,268	3,885,134	N/A
WASHINGTON	171,725,815	163,836,435	335,562,250	33.00	200,453,788	50.03	400,667,176	132,220,168	132,220,168	66,149,750	N/A
WEST VIRGINIA	66,962,606	18,887,045	85,849,651	22.00	73,138,544	71.35	102,506,719	22,551,624	18,887,045	13,475,907	N/A
Total	13,402,460,846	4,118,758,904	17,521,219,750	.....	11,361,451,030	.....	20,240,755,414	3,845,561,828	3,471,761,983	1,944,527,968	.....
LOW DSH STATES											
ALASKA	2,506,827	17,611,765	20,118,592	33.00	22,071,255	50.00	44,142,510	14,567,028	14,567,028	7,283,514	LOW DSH
ARKANSAS	2,422,649	819,351	3,242,000	25.27	46,741,254	70.88	65,944,207	16,666,086	819,351	580,756	LOW DSH
DELAWARE	0	7,069,000	7,069,000	33.00	9,809,445	53.63	18,290,966	6,036,019	6,036,019	3,237,117	LOW DSH
HAWAII	0	0	0	0.00	10,559,898	52.23	20,218,070	0	0	0	LOW DSH
IDAHO	2,081,429	0	2,081,429	0.00	17,810,592	71.75	24,823,125	0	0	0	LOW DSH
IOWA	12,011,250	0	12,011,250	0.00	42,670,802	55.54	76,828,956	0	0	0	LOW DSH
MINNESOTA	24,240,000	5,257,214	29,497,214	17.82	80,927,935	50.00	161,855,870	28,847,163	5,257,214	2,628,607	LOW DSH
MONTANA	237,048	0	237,048	0.00	12,298,951	65.90	18,663,052	0	0	0	LOW DSH

ADDENDUM 4—PRELIMINARY IMD DSH LIMITS FOR FY 2015—Continued

State	Inpatient hospital services FY 95 DSH total computable	IMD and mental health services FY 95 DSH total computable	Total inpatient & IMD & mental health FY 95 DSH total computable Col B + C	Applicable percent Col C/D	FY 2015 allotment in FS	FY 2015 FMAPs (percent)	FY 2015 allotments in TC Col. F/G	Applicable percentage applied to FY 2015 allotments in TC Col E × Col H	FY 2015 TC IMD Limit (Lesser Of Col I or Col C)	FY 2015 TC IMD limit in FS Col G × J	MMA LOW DSH Status
A	B	C	D	E	F	G	H	I	J	K	L
NEBRASKA	6,449,102	1,811,337	8,260,439	21.93	30,662,084	53.27	57,559,760	12,621,620	1,811,337	964,899	LOW DSH
NEW MEXICO	6,490,015	254,786	6,744,801	3.78	22,071,255	69.65	31,688,808	1,197,050	254,786	177,458	LOW DSH
NORTH DAKOTA	214,523	988,478	1,203,001	33.00	10,349,895	50.00	20,699,790	6,830,931	988,478	494,239	LOW DSH
OKLAHOMA	20,019,969	3,273,248	23,293,217	14.05	39,237,784	62.30	62,981,997	8,850,460	3,273,248	2,039,234	LOW DSH
OREGON	11,437,908	19,975,092	31,413,000	33.00	49,047,232	64.06	76,564,521	25,266,292	19,975,092	12,796,044	LOW DSH
SOUTH DAKOTA	321,120	751,299	1,072,419	33.00	11,967,251	51.64	23,174,382	7,647,546	751,299	387,971	LOW DSH
UTAH	3,621,116	934,586	4,555,702	20.51	21,256,752	70.56	30,125,782	6,180,197	934,586	659,444	LOW DSH
WISCONSIN	6,609,524	4,492,011	11,101,535	33.00	102,429,524	58.27	175,784,321	58,008,826	4,492,011	2,617,495	LOW DSH
WYOMING	0	0	0	0.00	245,236	50.00	490,472	0	0	0	LOW DSH
Total Low DSH States	98,662,480	63,238,167	161,900,647	.....	530,157,145	.....	909,836,589	192,719,219	59,160,449	33,866,778	.....
Total	13,501,123,326	4,181,997,071	17,683,120,397	.....	11,891,608,175	.....	21,150,592,003	4,038,281,047	3,530,922,432	1,978,394,746	.....

*Tennessee's DSH allotment for FY 2015 determined under section 1923(f)(6)(A)(vi) of the Act.
** Vermont's FMAP for FY 2015 determined in accordance with section 1905(z)(1)(A) of the Act

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1661–NC]

Medicare Program; Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

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

ACTION: Notice with request for comment.

SUMMARY: The Social Security Act (the Act) prohibits a physician-owned hospital from expanding its facility capacity, unless the Secretary of the Department of Health and Human Services (the Secretary) grants the hospital's request for an exception to that prohibition after considering input on the hospital's request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services (CMS) has received a request from a physician-owned hospital for an exception to the prohibition against expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the physician-owned hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition against expansion of facility capacity.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 3, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1661–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1661–NC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1661–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: *POH-ExceptionRequests@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

We will allow stakeholders 30 days from the date of this notice to submit written comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1–800–743–3951.

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law—(1) prohibits a physician from making referrals for certain ''designated health services'' (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Section 1877(d)(2) of the Act provides an exception for physician ownership or investment interests in rural providers (the ''rural provider exception''). In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 1877(d)(3) of the Act provides an exception, known as the hospital ownership exception, for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to together as ''the Affordable Care Act'') amended the rural provider and hospital ownership exceptions to the physician self-referral prohibition to impose additional restrictions on physician ownership and investment in hospitals and rural providers. Since March 23, 2010, a physician-owned hospital that seeks to

avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an ''applicable hospital'' or ''high Medicaid facility'' (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the prohibition by the Secretary of the Department of Health and Human Services (the Secretary). Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider's application for the exception. For further information, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.*

II. Exception Request Process

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized § 411.362(c), which specified the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We published a subsequent final rule in the **Federal Register** on November 10, 2014 (79 FR 66770) that made certain revisions. These revisions include, among other things, permitting the use of data from an external data source or data from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

As stated in regulations at § 411.362(c)(5), we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an ''applicable hospital'' or ''high Medicaid facility,'' as such terms are defined in § 411.362(c)(2) and (3). In the November 30, 2011 final rule (76 FR 74522), we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs; however, we noted that these were examples only and that we will not restrict the type of community input that may be submitted. If we receive timely comments from the community, we will notify the hospital, and the hospital will have 30 days after such notice to submit a rebuttal statement (§ 411.362(c)(5)(ii)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only HCRIS data: (1) The end of the 30-day comment period if CMS receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(i)).
- If the request, any written comments, or any rebuttal statement include data from an external data source, no later than: (1) 180 days after the end of the 30-day comment period if CMS receives no written comments from the community; and (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

If we grant the request for an exception to the prohibition on expansion of facility capacity, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§ 411.362(c)(6)). The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

III. Hospital Exception Request

As permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Rockwall Regional Hospital, LLC, d/b/a Texas Health Presbyterian Hospital Rockwall.

Location: 3150 Horizon Road, Rockwall County, Texas 75032–7805.

Basis for Exception Request: Applicable Hospital.

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.* We especially welcome comments regarding whether the hospital qualifies as an applicable hospital. Under § 411.362(c)(2), an applicable hospital is a hospital that satisfies all of the following criteria:

- The hospital is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request.
- The hospital has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. The most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital located in the same county as the requesting hospital.
- The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.
- The hospital is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity.
- The hospital has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate.

Individuals and entities wishing to submit comments on the hospital's request should review the **DATES** and

ADDRESSES sections above and state whether or not they are in the community in which the hospital is located.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: January 6, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–01830 Filed 2–1–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0662]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Valid or Will Not Be Infringed

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 reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit either electronic or written comments on the collection of information by April 4, 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–0662 for ''Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications.'' 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed—OMB Control Number 0910–0513—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, ''the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'' Section 505(c)(2) of the FD&C Act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under § 505(b)(1) of the FD&C Act, we publish patent information after approval of an NDA application in the list entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book). If patent information is submitted after NDA approval, § 505(c)(2) of the FD&C Act directs us to publish the information upon its submission.

FDA regulations at §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement, and require persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Form FDA 3542a and Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or supplement in accordance with § 314.50 (a) through (f), and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained below, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Forms 3542 and 3542a, the required patent information described in this section.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, an amendment, or a supplement (collectively referred to as ''application'') the required patent declaration(s) on Form 3542a for each ''patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product'' (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method of use. If a patent is issued after the application is filed with FDA, but before the application is approved, the applicant must submit the required patent information on Form 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use for listing in the Orange Book. In addition, for patents issued after the date of approval of an application, Form 3542 must be submitted within 30 days of the date of issuance of the patent.

FDA requests OMB approval for the following information collection:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Form FDA 3542a	241	3.4	819	20	16,380
Form FDA 3542	200	3.4	680	5	3,400
Total					19,780

[1] There are no capital costs, operating and maintenance costs associated with this collection of information.

The numbers of patents submitted to FDA for listing in the Orange Book in 2012, 2013, and 2014 were 458, 509, and 617, respectively, for an annual average of 528 (458 patents + 509 patents + 617 patents)/3 years = 528 patents/year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our previous review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 74 (528 patents × 14 percent) patents will be multiple listings, and there will be a total of 602 patents (528 patents + 74 patents = 602 patents) declared on Form FDA 3542. We approved 86, 94, and 107 NDAs in calendar years 2012, 2013, and 2014, respectively, of which we estimate based on our previous review that approximately 71 percent submitted patent information for listing in the Orange Book. The remaining NDAs submitted Form FDA 3542 as required and declared that there were no relevant patents. We also approved approximately 101, 101, and 110 NDA supplements in FYs 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 200 instances (based on an average of 96 NDA approvals and 104 supplement approvals per year) where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 3.4 declarations (602 patent declarations + 74 no relevant patent declarations)/200 instances = 3.4 declarations per instance) on Form FDA 3542. We filed 112, 116, and 113 NDAs in 2012, 2013, and 2014, respectively, and 112, 112, 156 NDA supplements in 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 241 instances (based on an average of 114 NDAs filed and 127 NDA supplements filed per year) where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 819 declarations (241 instances × 3.4 declarations per instance = 819 declarations) on Form FDA 3542a submitted with these applications. Based upon information provided by regulated entities and other information, we previously estimated that the information collection burden associated with § 314.50(h) (citing § 314.53) and Forms FDA 3542 and 3542a will be approximately 5 hours and 20 hours per response, respectively.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01782 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0129]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Licensing Provisions; Section 351(k) Biosimilar Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''General Licensing Provisions; Section 351(k) Biosimilar Applications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 8, 2015, the Agency submitted a proposed collection of information entitled ''General Licensing Provisions; Section 351(k) Biosimilar Applications'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0719. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01783 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

The Arthritis Foundation—Food and Drug Administration Accelerating Osteoarthritis Clinical Trials Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: Osteoarthritis is the most common form of arthritis, and occurs when the cartilage that cushions the bones of the joint break down and the bones begin to rub together. This can cause pain, swelling, and loss of motion of the joint. The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in co-sponsorship with the Arthritis Foundation is announcing a workshop entitled, ''Accelerating OA Clinical Trials Workshop''. The purpose of the workshop is to discuss recommendations from the international Arthritis Foundation Accelerating Osteoarthritis Clinical Trial workgroup and identify next steps in forging new approaches to osteoarthritis clinical trials that may improve the likelihood of successful conduct and outcomes of these trials and lead to the development of safe and effective treatments for osteoarthritis.

DATES: The workshop will be held on February 24, 2016, from 8 a.m. to 5:30 p.m., and February 25, 2016, from 8 a.m. to 2 p.m.

ADDRESSES: The workshop will be held at the Atlanta Airport Hilton, 1031 Virginia Ave., Atlanta, GA 30354.

FOR FURTHER INFORMATION CONTACT: Sarah Yim, Office of New Drugs, Center for Drug Evaluation and Research, email: *sarah.yim@fda.hhs.gov;* Amanda Niskar, Arthritis Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404–964–7545, FAX: 404–965–7807, email: *aniskar@arthritis.org;* or Becky Bosworth, Arthritis Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404–965–7673, email: *bbosworth@arthritis.org.*

SUPPLEMENTARY INFORMATION:

I. Background

The osteoarthritis (OA) community of clinicians, physicians and scientists have been challenged to get new treatments to market so that people with OA can benefit at the point of care. The Arthritis Foundation and FDA are convening experts to discuss alternative approaches to clinical trials in OA.

Workshop objectives will include discussion and identification of promising innovations that could facilitate successful trials in OA, new approaches to recruitment for clinical trials, feasible and clinically meaningful trial endpoints, and approaches for reducing the time and cost of OA trials while maximizing the likelihood of success.

Registration: There is no fee to attend the workshop, but attendees must register in advance. Space is very limited. Persons interested in attending this workshop may request to register by sending their resume and inquiry to *AFScience@arthritis.org.* The registration deadline is February 2, 2016.

II. Accommodations

An online registration link and a meeting code will be provided through the registration process giving participants a reduced group rate for hotel accomodations, not including applicable taxes. No additional reservations are required. Industry and government attendees are responsible for the cost of their own accomodations. If you need special accommodations due to a disability, please contact Becky Bosworth at *bbosworth@arthritis.org* at least 7 days in advance.

III. Transcripts

No transcripts will be available from the event, however, the event will be video taped for the purposes of the Arthritis Foundation. Speaker presentation materials, if permitted by the presenter, will be available on the Arthritis Foundation Web site following the workshop.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01789 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 30, 2015, the Agency submitted a proposed collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0726. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy

[FR Doc. 2016–01785 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0275]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by March 3, 2016. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT: Cynthia Whitmarsh, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 240–402–8010, FAX: 301–595–1243, email: *Industry.Biologics@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005. Through these annual

notices, CBER is requesting that those firms that have previously applied and are still interested in participating reaffirm their interest. CBER is also requesting that new interested parties apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history. If you are a firm with multiple sites, please submit no more than three specific locations for consideration.

III. Requests for Participation

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01780 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0908]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 22, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0581. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01781 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 21, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0806. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01784 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0075]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 9, 2015, the Agency submitted a proposed collection of information entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0807. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01786 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1855]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 3, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products OMB Control Number 0910–NEW

FDA's Center for Tobacco Products proposes to conduct experimental studies to develop generalizable scientific knowledge to help inform its implementation of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k), wherein FDA will be evaluating information submitted to the Agency about how consumers understand and perceive tobacco products marketed as modified risk tobacco products (MRTPs). Section 911 of the FD&C Act authorizes FDA to grant orders to persons to allow the marketing of MRTPs. The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. FDA must issue an order authorizing the marketing of an MRTP if the Agency determines that the product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(1) of the FD&C Act).

FDA may also issue an order authorizing the marketing of an MRTP that reduces or eliminates exposure to a harmful substance if, among other requirements, the Agency determines that the order would be appropriate to promote the public health, the issuance of the order is expected to benefit the population as a whole taking into account both users and nonusers of tobacco products, and the existing evidence demonstrates that a measurable and substantial reduction in morbidity and mortality among individual tobacco users is reasonably likely to be shown in subsequent studies (section 911(g)(2) of the FD&C Act). In addition, section 911 requires that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health related conditions associated with the use of tobacco products (section 911(h)(1) of the FD&C Act). The proposed research will inform the Agency's efforts to implement the provisions of the FD&C Act related to MRTPs.

FDA proposes to conduct experimental studies in order to develop generalizable scientific information to better understand how consumers perceive and understand these products, how exposure to claims about modified risk or exposure influence intentions to try or purchase the product, and how individual characteristics such as current tobacco use and/or brand loyalty might influence these outcomes. Moreover, information from the experimental studies may assist FDA to determine the appropriate methods and

measures for gathering such information from consumers.

The impact of different claims pertaining to modified risk or exposure on understanding, perceptions, and use intentions will be evaluated by conducting a series of three studies that, in turn, will examine: The impact of claims about cigarette (Study 1) or smokeless tobacco products (Study 2) among young adult and adult current, former, or never users of tobacco; and the impact of claims on adolescents currently using, or susceptible to using, tobacco (Study 3). All three studies will assess individual-level factors that might influence the impact of claims on consumer responses, including: Brand loyalty, tobacco use history and behavior, concerns about health risks, and openness to new products.

Across all studies, participants will be randomized to either see modified risk claims or not (control condition). In Studies 1 and 2, modified risk claims will be displayed on mock tobacco product packages and ads. For ethical reasons, adolescents (Study 3) will see modified risk claims displayed as statements alone, not attached to product packaging or ads. Consumer reactions to claims will be evaluated by measuring constructs such as: Understanding of the modified risk information in the claims, perceptions of harm and risk, beliefs about the product, quit intentions, and intention to try or purchase the product.

In the **Federal Register** of November 19, 2014 (79 FR 68888), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, however only two were PRA related.

(Comment) One commenter critiqued the inclusion of items assessing brand loyalty, asserting such constructs have ''no practical utility'' for MRTPA review and is beyond the FDA's statutory authority because it is not mentioned in the FD&C Act.

(Response) FDA does not agree. Although concepts such as ''brand loyalty'' are not specifically mentioned in the FD&C Act, FDA seeks understanding of how attitudes toward one's preferred brand(s) may affect perceptions and understanding of modified risk information (section 911(h)(1)). The goal of the present experiments is to understand how consumers react to RM and EM claims, in order to inform FDA's ability to evaluate MRTPAs. Brand loyalty is widely regarded as an important driver of consumer behavior (Ref. 1). Moreover, psychological theory and evidence suggests that the source of information can affect how that information is processed—including whether or not it is perceived as believable and is persuasive (Ref. 2). Thus, consumers' brand attitudes are highly relevant to understanding how they interpret and respond to claims made by that brand. To omit this possible influence from our analyses would, in our assessment, limit our ability to fully understand consumer perceptions of MRTPs.

(Comment) One commenter suggested that to assess the variable ''purchase interest,'' FDA should assign a hypothetical price to the product being studied.

(Response) FDA acknowledges that price plays an important role in consumers' purchasing decisions. However, examination of the role of price is beyond the scope of the present studies. The experimental design of this study will enable comparisons between experimental conditions on intentions to use the product; thus, rather than evaluating absolute levels of interest, results will examine relative levels of interest across experimental conditions. Thus, the measure of intentions to use the product will assess consumer interest in the product without regard to cost.

(Comment) One commenter noted that Study 1 proposes to focus on conventional cigarettes and asks how FDA proposes to address the issue of novel devices/products when considering consumer perceptions?

(Response) FDA agrees that the current studies are not designed to assess interest in novel devices/products. Addressing questions related to consumer perceptions of novel devices/products, and reactions to claims about those products, is beyond the scope of the current set of studies.

(Comment) One commenter asked for specificity regarding how FDA will define susceptibility to tobacco use among the adolescents in Study 3.

(Response) FDA plans to use items from Pierce and colleagues (1996) to identify adolescents who are susceptible to using tobacco. These items are: (1) Do you think that you will smoke a cigarette soon? (2) Do you think you will smoke a cigarette at any time in the next year? and (3) If one of your best friends were to offer you a cigarette, would you smoke it? Response options are: (1) Definitely yes; (2) Probably yes; (3) Probably not; and (4) Definitely not. A respondent who selects a response of 1, 2, or 3 to any of these items is classified as susceptible.

(Comment) One commenter sought clarification regarding which health warnings will be used (on the study stimuli) alongside the claims and how FDA intends to address the balance between MRTP claims and warnings.

(Response) Study stimuli-images of tobacco product packages and ads-will display the warning labels currently mandated for each product category. The warnings will be rotated (between participants) so that all mandated warnings are used. Because the current studies are not intended to examine the relationship between warnings and claims (including potential interactions between the two), warning label assignment will not be an experimental factor in the study design. Instead, the warnings will be rotated throughout all conditions to control for any differences between them (alone or in combination with a particular claim).

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
Adult Screener	24,000	1	24,000	0.03 (2 minutes)	720
Study 1 (Adults)	1,800	1	1,800	0.333 (20 minutes)	599
Study 2 (Adults)	600	1	600	0.333 (20 minutes)	200
Total Adult Hours					1,519
Youth Screener	6,000	1	6,000	0.03 (2 minutes)	180
Study 3 (Youth)	600	1	600	0.333 (20 minutes)	200

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total Youth Hours					380
Total Hours					1,899

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 30,000 respondents will complete a screener to determine eligibility for participation in a study, estimated to take approximately 2 minutes (0.03 hours), for a total of 900 hours for screening activities. Three thousand respondents will complete a full study, estimated to last 20 minutes (0.333 hours), for a total of 999 hours for completion of both adult studies and 1 youth study. The estimated total hour burden of the collection of information is 1,899 hours.

References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.*

1. Keller, Kevin L. and Donald R. Lehman, ''Brands and Branding: Research Findings and Future Priorities,'' *Marketing Science,* vol. 25, no. 6, pp. 740–759, 2006.
2. Eagly, Alice H. and Shelly Chaiken, ''Process Theories of Attitude Formation and Change: Reception and Cognitive Responding,'' *The Psychology of Attitudes,* Chapter 6, Harcourt Brace Jovanovich College Publishers, 1993.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01788 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–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: Medical Imaging Investigations.
Date: February 18, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484; *mohsenim@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Diseases and Pathophysiology of the Visual System Study Section.
Date: February 25–26, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.
Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301–435–1265; *gordiyenkon@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group, Cancer Immunopathology and Immunotherapy Study Section.
Date: February 25–26, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.
Contact Person: Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198; *shawdeni@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group, Tumor Progression and Metastasis Study Section.
Date: March 2–3, 2016.
Time: 8:00 a.m. to 5:00 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: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718; *jakobir@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Alcohol, Drugs and Neurotoxicology.
Date: March 2–3, 2016.
Time: 8:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119; *selmanom@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–13–327: Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care.
Date: March 2, 2016.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414; *huzhuang@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: January 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–01818 Filed 2–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Patient-Oriented Research Review Committee.

Date: February 25–26, 2016.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Stephanie Johnson Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, *stephanie.webb@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–01816 Filed 2–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; PPG Review for Transfusion.

Date: February 23, 2016.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Methods for Measuring Tissue Oxygenation.

Date: February 25, 2016.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, *Pintuccig@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–01817 Filed 2–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N03A, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified

laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare ,* 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW., Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370 (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

Summer King,

Statistician.

[FR Doc. 2016–01819 Filed 2–1–16; 8:45 am]

BILLING CODE 4160–20–P

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0087

Agency Information Collection Activities: Application for Citizenship and Issuance of Certificate Under Section 322, Form N–600K; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until April 4, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0087 in the subject box, the agency name and Docket ID USCIS–2007–0019. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at

http://www.regulations.gov under e-Docket ID number USCIS–2007–0019;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0019 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Citizenship and Issuance of Certificate under Section 322.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–600K; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This form provides an organized framework for establishing the authenticity of an applicant's eligibility and is essential for providing prompt, consistent and correct processing of such applications for citizenship under section 322 of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–600K is 4,272 and the estimated hour burden per response is 2.0833 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 8,900 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $523,320.

Dated: January 27, 2016.

Elizabeth Zemlan,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–01794 Filed 2–1–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0082]

Agency Information Collection Activities: Application to Replace Permanent Resident Card, Form I–90; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on November 9, 2015 at 80 FR 69243, allowing for a 60-day public comment period. USCIS did receive eight comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 3, 2016. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* Comments may also be submitted via fax at (202) 395–5806 (This is not a toll-free number). All submissions received must include the agency name and the OMB Control Number 1615–0082.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact

information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0002 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Replace Permanent Resident Card.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–90; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–90 is used by USCIS to determine eligibility to replace a Lawful Permanent Resident Card.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

485,298 respondents responding via the paper Form I–90 at an estimated1 hour and 45 minutes (1.75 hours) per response.

326,532 respondents responding via the Electronic Immigration System (ELIS) requiring an estimated 1 hour and 25 minutes (1.42 hours) per response. This estimated time was previously reported as .50 hours per response.

808,830 respondents requiring Biometric Processing at an estimated 1 hour and 10 minutes (1.17 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,259,277 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $206,656,065.

Dated: January 20, 2016.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–01861 Filed 2–1–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0057]

Agency Information Collection Activities: Application of Certificate of Citizenship, Form N–600, Form N–600; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until April 4, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0057 in the subject box, the agency name and Docket ID USCIS–2006–0023. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2006–0023;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0023 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact

the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application of Certificate of Citizenship, Form N–600.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–600; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS uses the information on Form N–600 to make a determination that the citizenship eligibility requirements and conditions are met by the applicant so that a certificate of citizenship can be generated.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–600 is 61,279 and the estimated hour burden per response is 1.6 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 98,046 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $6,982,500.

Dated: January 27, 2016.

Elizabeth Zemlan,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–01793 Filed 2–1–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0100]

Agency Information Collection Activities: Request for the Return of Original Documents (Form G–884); Revision of an Existing Information Collection; Comment Request

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on November 9, 2015, at 80 FR 69244, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 3, 2016. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* Comments may also be submitted via fax at (202) 395–5806 (This is not a toll-free number). All submissions received must include the agency name and the OMB Control Number [1615–0100].

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0010 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Request for the Return of Original Documents.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–884; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information will be used by USCIS to determine whether a person is eligible to obtain original documents(s) contained in an alien file.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection G–884 is 7,500 and the estimated hour burden per response is 0.5 hours (30 minutes).

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $3,750.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

Dated: January 20, 2016.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–01860 Filed 2–1–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5909–N–05]

30-Day Notice of Proposed Information Collection: Disaster Management

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: Comments Due Date: March 3, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on November 9, 2015 at 80 FR 69245.

A. Overview of Information Collection

Title of Information Collection: Disaster Management.

OMB Approval Number: 2502–0582.

Type of Request: Extension of currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: To provide an orderly and continuing means of assistance by the Federal Government to State and local governments in carrying out their responsibilities to alleviate the suffering and damage resulting from such disasters.

Respondents: HUD staff and multifamily housing project owners who are subject to HUD regulations.

Estimated Number of Respondents: 11,736.

Estimated Number of Responses: 8.

Frequency of Response: Upon Presidentially declared disasters involving individual assistance.

Average Hours per Response: 1.75 hours.

Total Estimated Burdens: 14.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Date: January 21, 2016.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2016–01791 Filed 2–1–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2016–N009; FXES11130300000–167–FF03E00000]

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (Act) prohibits activities with endangered or threatened species unless a Federal permit allows such activity. The Act requires that we invite public comment before issuing these permits.

DATES: We must receive any written comments on or before March 3, 2016.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; or by electronic mail to *permitsR3ES@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, (612) 713–5343.

SUPPLEMENTARY INFORMATION:

Background

We invite public comment on the following permit applications for certain

activities with endangered species authorized by section 10(a)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) and our regulations governing the taking of endangered species in the Code of Federal Regulations (CFR) at 50 CFR part 17. Submit your written data, comments, or request for a copy of the complete application to the mailing address or email address shown in **ADDRESSES**.

Permit Applications

Permit Application Number: TE35517B

Applicant: Bryan Arnold, Illinois College, Jacksonville, IL

The applicant requests a permit renewal, with amendments to the existing permit to take (capture and release, conduct nonlethal sampling, and radio-tag) Florida bonneted bat (*Eumops floridanus*) and add the State of Florida. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: 81974B

Applicant: Eastern Illinois University, Charleston, IL

The applicant requests a permit to take (conduct phylogeny studies) pallid sturgeon (*Scaphirhynchus albus*) and shovelnose sturgeon (*S. platorynchus*) in Illinois. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: 81973B

Applicant: Chequamegon-Nicolet National Forest and Northern Research Station, Washburn, WI

The applicant requests a permit to take (capture and release, conduct nonlethal sampling, band, and radio-tag) Indiana bat (*Myotis sodalis*) and northern long-eared bat (*M. septentrionalis*) in the States of Illinois, Iowa, Maine, Michigan, Minnesota, New Hampshire, New York, Pennsylvania, Vermont, and Wisconsin. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: 81968B

Applicant: Curtis Hart, Hudson, MI

The applicant requests a permit to take (capture and release, harass, conduct nonlethal sampling, band, trap, radio-tag, and salvage) Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*C. t. ingens*) in the States of Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE697830

Applicant: Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, Bloomington, MN

The applicant requests a permit renewal to take listed species that occur within the States of Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin for activities to recover the species and enhance the survival of the species in the wild.

Request for Public Comments

We seek public review and comments on these permit applications. Please refer to the permit number when you submit comments. Comments and materials we receive are available for public inspection, by appointment, during normal business hours at the address shown in the **ADDRESSES** section. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 27, 2016.

Lynn M. Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2016–01840 Filed 2–1–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2015–N246]; [FXES11130600000–167–FF06E00000]

Endangered and Threatened Wildlife and Plants; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct activities intended to enhance the survival of endangered or threatened species.

DATES: To ensure consideration, please send your written comments by March 3, 2016.

ADDRESSES: You may submit comments or requests for copies or more information by any of the following methods. Alternatively, you may use one of the following methods to request hard copies or a CD–ROM of the documents. Please specify the permit you are interested in by number (*e.g.,* Permit No. TE–XXXXXX).

- *Email: permitsR6ES@fws.gov.* Please refer to the respective permit number (*e.g.,* Permit No. TE–XXXXXX) in the subject line of the message.
- *U.S. Mail:* Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 25486–DFC, Denver, CO 80225.
- *In-Person Drop-off, Viewing, or Pickup:* Call (719) 628–2670 to make an appointment during regular business hours at 134 Union Blvd., Suite 645, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Recovery Permits Coordinator, Ecological Services, (719) 628–2670 (phone); *permitsR6ES@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. Along with our implementing regulations at 50 CFR 17, the Act provides for permits and requires that we invite public comment before issuing these permits for endangered species.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittees to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following applications. Documents and other information the applicants have submitted with their applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Application Number TE85057B

Applicant: George Cunningham, Omaha, NE.

The applicant requests a permit to conduct presence/absence surveys for Topeka shiner (*Notropis topeka*) in Nebraska, Kansas, and South Dakota to conduct presence/absence surveys for the purpose of enhancing the species' survival.

Permit Application Number TE047288

Applicant: National Park Service, Heartland Network, Republic, MO.

The applicant requests a renewal to an existing permit to continue presence/absence surveys for Topeka shiner (*Notropis topeka*) in Kansas and Minnesota for the purpose of enhancing the species' survival.

Permit Application Number TE85664B

Applicant: Wingate Biological Solutions, LLC, Durango, CO.

The applicant requests a permit to conduct survey and monitoring activities for the southwestern willow flycatcher (*Empidonax traillii extimus*) in Colorado, Utah, New Mexico, and Arizona for the purpose of enhancing the species' survival.

Permit Application Number TE056001

Applicant: East Dakota Water Development District, Brookings, SD.

The applicant requests a renewal to an existing permit to continue presence/absence surveys for Topeka shiner (*Notropis topeka*) in Kansas and Minnesota for the purpose of enhancing the species' survival.

National Environmental Policy Act

In compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in these permits are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM 6 Appendix 1, 1.4C(1)).

Public Availability of Comments

All comments and materials we receive in response to these requests will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

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.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Michael G. Thabault,

Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2016–01834 Filed 2–1–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON00000 L10200000 DF0000.LXSS080C0000]

Notice of Public Meetings, Northwest Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Northwest Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Northwest RAC has scheduled meetings August 18 and December 8, 2016, from 8 a.m. to 3 p.m. with public comment periods regarding matters on the agenda at 10 a.m. and 2 p.m. A specific agenda for each meeting will be available prior to the meetings at *http://www.blm.gov/co/st/en/BLM_Resources/racs/nwrac.html.*

ADDRESSES: The August 18 meeting will be held in Craig, Colorado, at the Craig Memorial Hospital on 750 Hospital Loop, Craig, CO 81625. The December 8 meeting will be held at the Courtyard by Marriott, 765 Horizon Drive, Grand Junction, CO 81506.

FOR FURTHER INFORMATION CONTACT: Chris Joyner, Public Affairs Specialist, Grand Junction Field Office, 2815 H Road, Grand Junction, CO 81506, or by telephone at (970) 244–3097. 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: The Northwest RAC advises the Secretary of the Interior, through the BLM, on a variety of public land issues in northwestern Colorado.

Topics of discussion during Northwest RAC meetings may include management of Greater Sage-Grouse, working group reports, recreation, fire management, land use planning, invasive species management, energy and minerals management, travel management, wilderness, wild horse herd management, land exchange proposals, cultural resource management, and other issues as appropriate.

These meetings are open to the public. Subcommittees under this RAC may meet this year regarding travel management in the White River Field Office. Active subcommittees report to the NW RAC at each council meeting. Subcommittee meetings are open to the public. More information is available at *http://www.blm.gov/co/st/en/BLM_Resources/racs/nwrac.html.* The public may present written comments to the RACs. Each formal RAC meeting will also have time, as identified above, allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016–01740 Filed 2–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORS00100.L63340000.PH0000.LXSSH 1020000.16XL1116AF.HAG 16–0064]

Notice of Meeting of the Northwest Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory

Committee Act, the Bureau of Land Management's (BLM) Northwest Oregon Resource Advisory Council (RAC) will meet as indicated below.

DATES: The RAC will meet on Wednesday through Friday, March 9–11, 2016, from 9:00 a.m.–5:00 p.m. The RAC members will review and select Secure Rural Schools Title II project proposals for the counties in Northwest Oregon. The Wednesday and Thursday meetings will be held at the Willamette Heritage Center (Mission Mill), 1313 Mill Street SE., Salem, OR 97301. On Wednesday, March 9, the public comment period will occur from 10:00–10:30 a.m. On Thursday, March 10, the public comment period will occur from 9:00–9:30 a.m. On Friday, March 11, 2016, the RAC will meet at the Eugene BLM Office at 3106 Pierce Parkway, Suite E, Springfield, OR 97477.

On Friday, March 11, the public comment period will occur from 1:00–1:30 p.m.

FOR FURTHER INFORMATION CONTACT: Trish Hogervorst, Co-Coordinator for the Northwest Oregon RAC, 1717 Fabry Road SE., Salem, OR 97306, (503) 375–5657, *phogervo@blm.gov* or Jennifer Velez, 3106 Pierce Parkway SE., Springfield, OR 97477, (541) 222–9241, *jvelez@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 individuals during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The fifteen-member Northwest Oregon RAC was chartered to serve in an advisory capacity concerning the planning and management of the public land resources located within the BLM's Salem and Eugene Districts. Members represent an array of stakeholder interests in the land and resources from within the local area and statewide. Planned agenda items include reviewing and voting on Secure Rural Schools project submissions for each county in Northwest Oregon. On each day of the three day meeting, members of the public will have the opportunity to make comments to the RAC during a public comment period. All advisory committee meetings are open to the public. Persons wishing to make comments during the public comment period should register in person with the BLM, at the meeting location, preceding that meeting day's comment period. Depending on the number of persons wishing to comment, the length of comments may be limited. The public may send written comments to the RAC at the Salem District office, 1717 Fabry Road SE., Salem, OR 97306. The BLM appreciates all comments.

Kim Titus,

Salem District Manager.

[FR Doc. 2016–01839 Filed 2–1–16; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–RTCA–20119; PPMPSPD1T.Y00000;PPSESERO10]

Wekiva River System Advisory Management Committee 2016 Meeting Schedule

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, (5 U.S.C. Appendix 1–16), of the 2016 meeting schedule for the Wekiva River System Advisory Management Committee.

DATES: The meetings are scheduled for: March 9, 2016; June 1, 2016; September 7, 2016; and November 9, 2016. (Eastern) All meetings will begin at 3:00 p.m. and will end by 5:00 p.m.

ADDRESSES: All scheduled meetings will be held at the Wekiwa Springs State Park, 1800 Wekiwa Circle, Apopka, FL 32712. Call (407) 884–2006 or visit online at *floridastateparks.org/wekiwasprings/* for additional information on this facility.

FOR FURTHER INFORMATION CONTACT: Jaime Doubek-Racine, Community Planner and Designated Federal Official, Rivers, Trails, and Conservation Assistance Program, Florida Field Office, Southeast Region, 5342 Clark Road, PMB #123, Sarasota, Florida 34233, or via telephone (941) 685–5912.

SUPPLEMENTARY INFORMATION: The Wekiva River System Advisory Management Committee was established by Public Law 106–299 to assist in the development of the comprehensive management plan for the Wekiva River System and provide advice to the Secretary of the Interior in carrying out management responsibilities of the Secretary under the Wild and Scenic Rivers Act (16 U.S.C. 1274). Efforts have been made locally to ensure that the interested public is aware of the meeting dates.

The scheduled meetings will be open to the public. Each scheduled meeting will result in decisions and steps that advance the Wekiva River System Advisory Management Committee towards its objective of managing and implementing projects developed from the Comprehensive Management Plan for the Wekiva Wild and Scenic River.

Any member of the public may file with the Committee a written statement concerning any issues relating to the development of the Comprehensive Management Plan for the Wekiva Wild and Scenic River. The statement should be addressed to the Wekiva River System Advisory Management Committee, National Park Service, 5342 Clark Road, PMB #123, Sarasota, Florida 34233.

Before including your address, telephone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you 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.

Dated: January 19, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–01814 Filed 2–1–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–20046; PPWOCRADN0–PCU00RP16.R50000]

Native American Graves Protection and Repatriation Review Committee; Meetings

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, (5 U.S.C. Appendix 1–16), of four meetings of the Native American Graves Protection and Repatriation Review Committee (Review Committee). All meetings will be open to the public.

DATES: The Review Committee will meet on April 19, 2016, from 2 p.m. until approximately 6 p.m. (Eastern); July 13–14, 2016, from 8:30 a.m. to 5:00 p.m. (Mountain) and July 15, 2016, from 8:30 a.m. to 12:00 p.m. (Mountain); September 13, 2016, from 2:00 p.m. until approximately 6:00 p.m. (Eastern); and, if necessary, December 6, 2016, from 2:00 p.m. until approximately 6:00 p.m. (Eastern). Related deadlines for participating in each meeting are detailed in this notice.

ADDRESSES: The Review Committee will meet on July 13–July 15, 2016, at the Holiday Inn Missoula Downtown, 200 S. Pattee Street, Missoula, MT 59802. Electronic submissions of materials or requests are to be sent to *nagpra_dfo@nps.gov.* Those who desire to participate via telephone should register at *http://www.nps.gov/nagpra,* to be provided the telephone access number for the meeting.

SUPPLEMENTARY INFORMATION: The Review Committee was established in Section 8 of the Native American Graves Protection and Repatriation Act of 1990 (NAGPRA), 25 U.S.C. 3006.

April 19, 2016

The Review Committee will meet via teleconference on April 19, 2016, from 2:00 p.m. until approximately 6:00 p.m. (Eastern). This meeting will be open to the public. The agenda for this meeting will include a report from the National NAGPRA Program; the discussion of the Review Committee Report to Congress for 2016; subcommittee reports and discussion; and other topics related to the Review Committee's responsibilities under Section 8 of NAGPRA. In addition, the agenda may include requests to the Review Committee for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be culturally unidentifiable proceed; presentations by Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals; and public comment. The agenda and materials for this meeting will be posted on or before March 22, 2016, at *http://www.nps.gov/nagpra.*

The Review Committee is soliciting presentations from Indian tribes, Native Hawaiian organizations, museums, and Federal agencies on the following two topics: (1) The progress made, and any barriers encountered, in implementing NAGPRA and (2) the outcomes of disputes reviewed by the Review Committee pursuant to 25 U.S.C. 3006(c)(4). The Review Committee also will consider other presentations from Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals. A presentation request must, at minimum, include an abstract of the presentation and contact information for the presenter(s). Presentation requests and materials must be received by March 15, 2016. Written comments will be accepted from any party and provided to the Review Committee. Written comments received by March 15, 2016, will be provided to the Review Committee before the meeting.

The Review Committee will consider requests for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be culturally unidentifiable (CUI) proceed. A CUI disposition request must include the appropriate, completed form posted on the National NAGPRA Program Web site and, as applicable, the ancillary materials noted on the form. To access and download the appropriate form—either the form for CUI with a ''tribal land'' or ''aboriginal land'' provenience or the form for CUI without a ''tribal land'' or ''aboriginal land'' provenience—go to *http://www.nps.gov/nagpra,* and then click on ''Request for CUI Disposition Forms.'' CUI disposition requests must be received by March 8, 2016.

Submissions and requests should be sent to *nagpra_dfo@nps.gov.* Such items are subject to posting on the National NAGPRA Program Web site prior to the meeting. Those who desire to attend the meeting should register at *http://www.nps.gov/nagpra* to be provided the telephone access number for the meeting. A transcript and minutes of the meeting will also appear on the Web site.

July 13–July 15, 2016

The Review Committee will meet on July 13–14, 2016, from 8:30 a.m. to 5:00 p.m. (Mountain) and July 15, 2016, from 8:30 a.m. to 12:00 p.m. (Mountain), at the Holiday Inn Missoula Downtown, Missoula, MT. This meeting will be open to the public. The agenda for this meeting will include a report from the National NAGPRA Program; the discussion of the Review Committee Report to Congress for 2016; subcommittee reports and discussion; and other topics related to the Review Committee's responsibilities under Section 8 of NAGPRA. In addition, the agenda may include requests to the Review Committee for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be culturally unidentifiable proceed; presentations by Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals; public comment; requests to the Review Committee, pursuant to 25 U.S.C. 3006(c)(3), for review and findings of fact related to the identity or cultural affiliation of human remains or other cultural items, or the return of such items; and facilitation of the resolution of disputes among parties convened by the Review Committee pursuant to 25 U.S.C. 3006 (c)(4). Presentation to the Review Committee by telephone may be requested but is not guaranteed. The agenda and materials for this meeting will be posted on or before June 15, 2016, at *http://www.nps.gov/nagpra.*

The Review Committee is soliciting presentations from Indian tribes, Native Hawaiian organizations, museums, and Federal agencies on the following two topics: (1) The progress made, and any barriers encountered, in implementing NAGPRA and (2) the outcomes of disputes reviewed by the Review Committee pursuant to 25 U.S.C. 3006(c)(4). The Review Committee also will consider other presentations from Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals. A presentation request must, at minimum, include an abstract of the presentation and contact information for the presenter(s). Presentation requests and materials must be received by June 1, 2016. Written comments will be accepted from any party and provided to the Review Committee. Written comments received by June 8, 2016, will be provided to the Review Committee before the meeting.

The Review Committee will consider requests for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be CUI proceed. A CUI disposition request must include the appropriate, completed form posted on the National NAGPRA Program Web site and, as applicable, the ancillary materials noted on the form. To access and download the appropriate form—either the form for CUI with a ''tribal land'' or ''aboriginal land'' provenience or the form for CUI without a ''tribal land'' or ''aboriginal land'' provenience—go to *http://www.nps.gov/nagpra,* and then click on ''Request for CUI Disposition Forms.'' CUI disposition requests must be received by May 4, 2016.

The Review Committee will consider requests, pursuant to 25 U.S.C. 3006(c)(3), for review and findings of fact related to the identity or cultural affiliation of human remains or other cultural items, or the return of such items, where consensus among affected parties is unclear or uncertain. A request for findings of fact must be accompanied by a statement of the fact(s) at issue and supporting materials, including those exchanged by the parties to consultation concerning the Native American human remains and/or other cultural items. To access procedures for presenting findings of fact, go to *http://www.nps.gov/nagpra/*

REVIEW/Procedures.htm. Requests for findings of fact must be received by March 2, 2016.

The Review Committee will consider requests, pursuant to 25 U.S.C. 3006(c)(4), to convene parties and facilitate the resolution of a dispute, where consensus clearly has not been reached among affected parties regarding the identity or cultural affiliation of human remains or other cultural items, or the return of such items. A request to convene parties and facilitate the resolution of a dispute must be accompanied by a statement of the decision of the museum or Federal agency subject to the dispute resolution request, a statement of the issue, and the materials exchanged by the parties concerning the Native American human remains and/or other cultural items. To access procedures for presenting disputes, go to *http://www.nps.gov/nagpra/REVIEW/Procedures.htm.* Requests to convene parties and facilitate resolution of a dispute must be received by March 2, 2016.

Submissions and requests should be sent to *nagpra_dfo@nps.gov.* Such items are subject to posting on the National NAGPRA Program Web site prior to the meeting.

September 13, 2016

The Review Committee will meet via teleconference on September 13, 2016, from 2:00 p.m. until approximately 6:00 p.m. (Eastern). This meeting will be open to the public. The agenda for this meeting will include a report from the National NAGPRA Program; the discussion of the Review Committee Report to Congress for 2016; subcommittee reports and discussion; and other topics related to the Review Committee's responsibilities under Section 8 of NAGPRA. In addition, the agenda may include requests to the Review Committee for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be culturally unidentifiable proceed; presentations by Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals; and public comment. The agenda and materials for this meeting will be posted on or before August 16, 2016, at *http://www.nps.gov/nagpra.*

The Review Committee is soliciting presentations from Indian tribes, Native Hawaiian organizations, museums, and Federal agencies on the following two topics: (1) The progress made, and any barriers encountered, in implementing NAGPRA and (2) the outcomes of disputes reviewed by the Review Committee pursuant to 25 U.S.C. 3006(c)(4). The Review Committee also will consider other presentations from Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals. A presentation request must, at minimum, include an abstract of the presentation and contact information for the presenter(s). Presentation requests and materials must be received by August 2, 2016. Written comments will be accepted from any party and provided to the Review Committee. Written comments received by August 9, 2016, will be provided to the Review Committee before the meeting.

The Review Committee will consider requests for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be CUI proceed. A CUI disposition request must include the appropriate, completed form posted on the National NAGPRA Program Web site and, as applicable, the ancillary materials noted on the form. To access and download the appropriate form—either the form for CUI with a ''tribal land'' or ''aboriginal land'' provenience or the form for CUI without a ''tribal land'' or ''aboriginal land'' provenience—go to *http://www.nps.gov/nagpra,* and then click on ''Request for CUI Disposition Forms.'' CUI disposition requests must be received by July 5, 2016.

Submissions and requests should be sent to *nagpra_dfo@nps.gov.* Such items are subject to posting on the National NAGPRA Program Web site prior to the meeting. Those who desire to attend the meeting should register at *http://www.nps.gov/nagpra* to be provided the telephone access number for the meeting. A transcript and minutes of the meeting will also appear on the Web site.

December 6, 2016

The Review Committee will meet, if necessary, via teleconference on December 6, 2016, from 2:00 p.m. until approximately 6:00 p.m. (Eastern). This meeting will be open to the public. The agenda for this meeting will include a report from the National NAGPRA Program; the finalization of the Review Committee Report to Congress for 2016; subcommittee reports and discussion; and other topics related to the Review Committee's responsibilities under Section 8 of NAGPRA. In addition, the agenda may include requests to the Review Committee for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be culturally unidentifiable proceed; presentations by Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals; and public comment. The agenda and materials for this meeting will be posted on or before November 8, 2016, at *http://www.nps.gov/nagpra.*

The Review Committee is soliciting presentations from Indian tribes, Native Hawaiian organizations, museums, and Federal agencies on the following two topics: (1) The progress made, and any barriers encountered, in implementing NAGPRA and (2) the outcomes of disputes reviewed by the Review Committee pursuant to 25 U.S.C. 3006 (c)(4). The Review Committee also will consider other presentations from Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals. A presentation request must, at minimum, include an abstract of the presentation and contact information for the presenter(s). Presentation requests and materials must be received by October 25, 2016. Written comments will be accepted from any party and provided to the Review Committee. Written comments received by November 1, 2016, will be provided to the Review Committee before the meeting.

The Review Committee will consider requests for a recommendation to the Secretary of the Interior that an agreed-upon disposition of Native American human remains determined to be CUI proceed. A CUI disposition request must include the appropriate, completed form posted on the National NAGPRA Program Web site and, as applicable, the ancillary materials noted on the form. To access and download the appropriate form—either the form for CUI with a ''tribal land'' or ''aboriginal land'' provenience or the form for CUI without a ''tribal land'' or ''aboriginal land'' provenience—go to *http://www.nps.gov/nagpra,* and then click on ''Request for CUI Disposition Forms.'' CUI disposition requests must be received by September 27, 2016.

Submissions and requests should be sent to *nagpra_dfo@nps.gov.* Such items are subject to posting on the National NAGPRA Program Web site prior to the meeting. Those who desire to attend the meeting should register at *http://www.nps.gov/nagpra* to be provided the telephone access number for the meeting. A transcript and minutes of the meeting will also appear on the Web site.

General Information

Information about NAGPRA, the Review Committee, and Review

Committee meetings is available on the National NAGPRA Program Web site at *http://www.nps.gov/nagpra.* For the Review Committee's meeting procedures, click on ''Review Committee,'' then click on ''Procedures.'' Meeting minutes may be accessed by going to the Web site, then clicking on ''Review Committee,'' and then clicking on ''Meeting Minutes.'' Approximately fourteen weeks after each Review Committee meeting, the meeting transcript is posted on the National NAGPRA Program Web site.

Review Committee members are appointed by the Secretary of the Interior. The Review Committee is responsible for monitoring the NAGPRA inventory and identification process; reviewing and making findings related to the identity or cultural affiliation of cultural items, or the return of such items; facilitating the resolution of disputes; compiling an inventory of culturally unidentifiable human remains that are in the possession or control of each Federal agency and museum, and recommending specific actions for developing a process for disposition of such human remains; consulting with Indian tribes and Native Hawaiian organizations and museums on matters affecting such tribes or organizations lying within the scope of work of the Review Committee; consulting with the Secretary of the Interior on the development of regulations to carry out NAGPRA; and making recommendations regarding future care of repatriated cultural items. The Review Committee's work is carried out during the course of meetings that are open to the public.

Before including your address, telephone number, email address, or other personal identifying information in your submission, you should be aware that your entire submission—including your personal identifying information—may be made publicly available at any time. While you may ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 19, 2016.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–01815 Filed 2–1–16; 8:45 am]

BILLING CODE 4310–EE–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Review)]

Certain Magnesia Carbon Bricks From China and Mexico

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930, that revocation of the countervailing duty order on certain magnesia carbon bricks from China and the antidumping duty orders on certain magnesia carbon bricks from China and Mexico would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), instituted these reviews on August 3, 2015 (80 FR 46050) and determined on November 6, 2015 that it would conduct expedited reviews (80 FR 74799, November 30, 2015).

The Commission made these determinations pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on January 15, 2016. The views of the Commission are contained in USITC Publication 4589 (January 2016), entitled *Certain Magnesia Carbon Bricks from China and Mexico: Investigation Nos. 701–TA–468 and 731–TA–1166–1167 (Review).*

Issued: January 27, 2016.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–01792 Filed 2–1–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on CHEDE–VII

Notice is hereby given that, on January 6, 2016, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute: Cooperative Research Group on CHEDE–VII (''CHEDE–VII'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the parties to the venture are: Borgwarner, Inc., Auburn Hills, MI; Caterpillar Inc., Peoria, IL; Cummins, Columbus, IN; Federal-Mogul Corporation, Plymouth, MI; Honeywell International, Inc., Torrance, CA; Hyundai Motor Group, Seoul, REPUBLIC OF KOREA; Isuzu, Shanghai, PEOPLE'S REPUBLIC OF CHINA; Jacobs Vehicle Systems, Bloomfield, CT; Lubrizol Corporation, Wickliffe, OH Vandyne Superburbo, Inc., Loveland, CO; and Weichai Power Co. Ltd., Weifang, PEOPLE'S REPUBLIC OF CHINA. The general areas of CHEDE–VII's planned activities are: research activity for diesel combustion system improvements; research activity for dual fuel combustion system improvements; improved fuel efficiency for future diesel and alternative fueled heavy-duty engines; and improved emissions for future diesel and alternative fueled engines.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–01870 Filed 2–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1122—NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection: Campus Program Grantee Needs and Progress Assessment Tool

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DATES: Comments are encouraged and will be accepted for 60 days until April 4, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Campus Program Grantee Needs and Progress Assessment Tool.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122—NEW. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes current grantees under the Grants to Reduce Sexual Assault, Domestic Violence, Dating Violence, and Stalking on Campus Program. The Campus Program strengthens the response of institutions of higher education to the crimes of sexual assault, domestic violence, dating violence and stalking on campuses and enhances collaboration among campuses, local law enforcement, and victim advocacy organizations. Eligible applicants are institutions of higher education. The affected public includes the approximately 100 institutions of higher education currently funded through the Campus program.

The Grantee Needs and Progress Assessment Tool will be used to determine the training and technical assistance needs of Campus Program grantees—both new and continuation grantees—throughout the life of the grant award as well measure the development of the capacity of grantees to respond and prevent violence against women on their campuses. In addition, the tool will help campuses and OVW document the impact of their grant-funded work, promote sustainability of important intervention and prevention activities, and provide outcome-based information throughout the life of the grant to help OVW-funded technical assistance providers and grantees make changes to the goals and objectives necessary to achieve the statutory intent when Congress authorized the Campus Program.

There is a need for a more effective assessment tool that better achieves the following purposes: (1) Assess grantee needs and resources related to achieving the program's core competencies that are central to the goals of the Campus Program; (2) assess capacity building by the grantees over the three year grant period which will help campuses and OVW document the impact of their work and promote sustainability, (3) provide information throughout the grant cycle to help technical assistance providers and campuses work together to achieve key goals of the Campus Program. This data collection tool will promote matching the specific technical assistance needs of each campus and also reflection by the grantees on their goals for the grant. The questions will be given in an online survey platform. The questions are mainly multiple choice. The few narrative questions used are brief and require one or two sentence answers.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 100 respondents (Campus Program grantees) approximately 2 hours to complete an online assessment tool.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 200 hours, that is 100 grantees completing a tool once a year with an estimated completion time for the form being 2 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: January 27, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–01772 Filed 2–1–16; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

Employment and Training Administration

Change of Address for the National Prevailing Wage Center: Prevailing Wage Determination Requests for Use in the E–3, H–1B, H–1B1, H–2B, and Permanent/''Green Card'' Visa Programs

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department) is providing notice that the Office of Foreign Labor Certification's National Prevailing Wage Center, responsible for the processing of prevailing wage determination requests for use in the E–3 (Australia), H–1B, H–1B1 (Chile/Singapore), H–2B, and the permanent/''green card'' visa programs is relocating within Washington, DC effective on January 11, 2016.

DATES: Effective Date: This notice is effective on January 11, 2016.

FOR FURTHER INFORMATION CONTACT: William W. Thompson, II, Acting Administrator, Office of Foreign Labor Certification, U.S. Department of Labor, 200 Constitution Avenue NW., Box 12–200, Washington, DC 20210–0001; Telephone: (202) 513–7350 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Immigration and Nationality Act (INA) assigns specific responsibilities to the U.S. Secretary of Labor for the administration of certain employment-based immigration programs that require a labor certification, a labor condition application, or a labor attestation (LCA). In the case of a labor

certification, these statutory responsibilities include, determining that there are not able, willing, qualified and available U.S. workers for a position and location for which certification is being requested, and that the employment of the foreign worker(s) will not have an adverse impact on similarly employed U.S. workers.

Employers seeking to hire foreign workers in the D–1, E–3, H–1B, H–1B1, H–2A, H–2B, or the permanent/''green card'' visa programs must first apply to the Secretary of Labor to obtain a labor certification or for the approval of a labor condition application, or a labor attestation. The Secretary has delegated the responsibilities for the administration of these programs to the Employment and Training Administration's (ETA) Office of Foreign Labor Certification (OFLC).

Before obtaining a certification from the Department, most employers must first obtain a Prevailing Wage Determination (PWD) for the appropriate occupation and area of intended employment from OFLC. Since January 1, 2010, the receipt and processing of PWD requests for use in the E–3, H–1B, H–1B1, H–2B, and the permanent/''green card'' programs has been centralized in OFLC's National Prevailing Wage Center (NPWC) in Washington, DC.

The purpose of this Notice is to inform the public that the NPWC is relocating within Washington, DC and provide a new mailing address.

II. NPWC Address

Old Address: U.S. Department of Labor, Employment and Training Administration, Office of Foreign Labor Certification, National Prevailing Wage Center, 1341 G Street, Suite 201, NW., Washington, DC 20005–3105; Telephone: (202) 693–8200; Facsimile (202) 693–8260.

New Address: U.S. Department of Labor, Employment and Training Administration, Office of Foreign Labor Certification, National Prevailing Wage Center, 200 Constitution Avenue NW.; Room N–5311, Washington, DC 20210; Telephone: (202) 693–8200; Facsimile (202) 693–8260.

The NPWC is fully operational at the new address on January 11, 2016. Affected stakeholders should direct any mailed correspondence addressed to the NPWC at the new address on and after January 11, 2015. Currently, the vast majority of PWD requests and related correspondence are submitted electronically to the NPWC. However, to ensure a smooth transition to the new address, the NPWC will rely on the standard United States Postal Service for mail forwarding from the old to the new address after the effective date of this Notice.

III. NPWC Email Help Desk

The change in the physical address for the NPWC will not affect the NPWC Email Help Desk. Members of the public who require technical assistance with PWD requests and/or related matters may continue to direct their inquiries to the National Prevailing Wage Center Help Desk at *FLC.PWD@dol.gov.*

Portia Wu,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2016–01848 Filed 2–1–16; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for the Trade Activity Participant Report (TAPR), Extension Without Revisions

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506(c)(2)(A)]. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, ETA is soliciting comments concerning the collection of data about the Trade Activity Participant Report (OMB No. 1205–0392), which provides information on participant activities and performance outcomes for those served under the Trade Adjustment Assistance Program, as authorized under the Trade Act of 1974, as amended.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before April 4, 2016.

ADDRESSES: Submit written comments to Susan Worden, Office of Trade Adjustment Assistance Room N–5428, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202–693–3517 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–693–3585 Email: *worden.susan@dol.gov.* A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above.

SUPPLEMENTARY INFORMATION:

I. Background

The Department uses information from the Trade Activity Participant Report Form completed by the states to establish state funding needs and evaluate the effectiveness of state administration of the Trade Adjustment Assistance Program under the Trade Act. The Department is requesting a three year extension of the currently approved collection in order to continue to meet reporting requirements in sections 239 and 249B of the Trade Act, as amended.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

Type of Review: extension without changes.

Title: Trade Activity Participant Report.

OMB Number: 1205–0392.

Affected Public: State, Local or Tribal Governments.

Form(s): Trade Activity Participant Report.

Total Annual Respondents: 50.

Annual Frequency: Quarterly.

Total Annual Responses: 200.

Average Time per Response: 47.5 hours.

Estimated Total Annual Burden Hours: 9,500.

Total Annual Burden Cost for Respondents: $0.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the ICR; they will also become a matter of public record.

Portia Wu,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2016–01849 Filed 2–1–16; 8:45 am]

BILLING CODE 4510–FN–P

LEGAL SERVICES CORPORATION

Assessing the Goals in the Strategic Plan 2012–2016; Request for Comments; Correction

AGENCY: Legal Services Corporation.

ACTION: Correction notice.

SUMMARY: On January 22, 2016, the Legal Services Corporation (LSC) published a notice in the **Federal Register** (81 FR 3836) titled ''Assessing the Goals in the Strategic Plan 2012–2016; Request for Comments.'' The contact information listed in the Supplementary Information section of the previous notice has an incorrect link to LSC's Strategic Plan. This document corrects the notice by correcting the link to LSC's Strategic Plan with the correct web link.

DATES: This correction is effective January 22, 2016.

FOR FURTHER INFORMATION CONTACT: Rebecca Fertig Cohen, Chief of Staff, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007; (202) 295–1576; *cohenr@lsc.gov.*

SUPPLEMENTARY INFORMATION: The correct link to LSC's Strategic Plan is available at *http://www.lsc.gov/about-lsc/who-we-are/strategic-plan.*

Dated: January 28, 2016.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2016–01845 Filed 2–1–16; 8:45 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Discount Rates for Cost-Effectiveness Analysis of Federal Programs

AGENCY: Office of Management and Budget.

ACTION: Revisions to Appendix C of OMB Circular A–94.

SUMMARY: The Office of Management and Budget revised Circular A–94 in 1992. The revised Circular specified certain discount rates to be updated annually when the interest rate and inflation assumptions used to prepare the Budget of the United States Government were changed. These discount rates are found in Appendix C of the revised Circular. The updated discount rates are shown below. The discount rates in Appendix C are to be used for cost-effectiveness analysis, including lease-purchase analysis, as specified in the revised Circular. They do not apply to regulatory analysis.

DATES: The revised discount rates will be in effect through December 2016.

FOR FURTHER INFORMATION CONTACT: Gideon Lukens, Office of Economic Policy, Office of Management and Budget, (202) 395–3316.

Devin O'Connor,

Associate Director for Economic Policy, Office of Management and Budget.

OMB Circular No. A–94

APPENDIX C

(Revised November 2015)

DISCOUNT RATES FOR COST-EFFECTIVENESS, LEASE PURCHASE, AND RELATED ANALYSES

Effective Dates. This appendix is updated annually. This version of the appendix is valid for calendar year 2016. A copy of the updated appendix can be obtained in electronic form through the OMB home page at *http://www.whitehouse.gov/omb/circulars_a094/a94_appx-c/.* The text of the Circular is found at *http://www.whitehouse.gov/omb/circulars_a094/,* and a table of past years' rates is located at *http://www.whitehouse.gov/sites/default/files/omb/assets/a94/dischist.pdf.* Updates of the appendix are also available upon request from OMB's Office of Economic Policy (202–395–3316).

Nominal Discount Rates. A forecast of nominal or market interest rates for calendar year 2016 based on the economic assumptions for the 2017 Budget is presented below. These nominal rates are to be used for discounting nominal flows, which are often encountered in lease-purchase analysis.

NOMINAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[in percent]

3-year	5-year	7-year	10-year	20-year	30-year
2.0	2.4	2.7	2.9	3.2	3.5

Real Discount Rates. A forecast of real interest rates from which the inflation premium has been removed and based on the economic assumptions from the 2017 Budget is presented below. These real rates are to be used for discounting constant-dollar flows, as is often required in cost-effectiveness analysis.

REAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[in percent]

3-year	5-year	7-year	10-year	20-year	30-year
0.3	0.6	0.8	1.0	1.2	1.5

Analyses of programs with terms different from those presented above may use a linear interpolation. For example, a four-year project can be evaluated with a rate equal to the average of the three-year and five-year rates. Programs with durations longer

than 30 years may use the 30-year interest rate.

[FR Doc. 2016–01604 Filed 2–1–16; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 16–004]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Public Law 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: Consideration will be given to all comments received within 30 days from the date of this publication.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington, DC 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instruments and instructions should be directed to Ms. Frances Teel, NASA PRA Clearance Officer, NASA Headquarters, 300 E Street SW., Mail Code JF0000, Washington, DC 20546 or *frances.c.teel@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request to reinstate OMB control number 2700–0092, with changes. This collection is required to ensure proper accounting of Federal funds and property provided under finanical assistance awards (grants and cooperative agreements). Reporting and recordkeeping are prescribed at 2 CFR 1800 for awards issued to non-profits, institutions of higher education, government, and commercial firms when cost sharing is not required and at 14 CFR part 1274 for awards issued to commercial firms when cost sharing is required. This information collection was formerly titled Cooperative Agreements with Commercial Firms. Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record. The basis for calculating the estimated burden remain the same as reported in the November 30, 2015 **Federal Register** Notice (80 FR 74812); however, corrections were made to the total estimated hours and costs.

II. Method of Collection

NASA collects approximately 90% of this information via electronic media, which is the preferred manner. However, certain information may also be collected via mail or fax.

III. Data

Title: Financial Assistance Awards/ Grants and Cooperative Agreements.

OMB Control Number: 2700–0092.

Type of Review: Reinstatement with Change of a Previously Approved Information Collection.

Affected Public: Non-profits, institutions of higher educations, government, and commercial firms.

Estimated Number of Respondents: 13,600.

Estimated Total Annual Burden Hours: 717,281.

Estimated Total Annual Cost: $23,950,013.

IV. Request for Comments

Comments are invited on (1) whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2016–01853 Filed 2–1–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Request for Comment Regarding National Credit Union Administration Draft 2017–2021 Strategic Plan

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and Request for comment.

SUMMARY: On January 27, 2016 the **Federal Register** published a Notice and Request for Comment for the NCUA Draft 2017–2021 Strategic Plan (Citation 81 FR 4679). This **Federal Register** Notice repairs a hyperlink within the notice. The NCUA Board (Board) is requesting comment on its 2017–2021 Draft Strategic Plan. The *NCUA Draft Strategic Plan 2017–2021* summarizes our analysis of the internal and external environment impacting NCUA; evaluates NCUA programs and risks; and provides goals and objectives for the next five years. While the Board welcomes all comments from the public and stakeholders, it specifically invites comments and input on the proposed goals and objectives of the strategic plan.

DATES: Comments must be received on or before April 4, 2016 to be assured of consideration.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *NCUA Web site: https://www.ncua.gov/about/pages/board-comments.aspx.* Follow the instructions for submitting comments.
- *Email:* Address to *boardcomments@ncua.gov.* Include ''[Your name]—Comments on NCUA 2017–2021 Draft Strategic Plan'' in the email subject line.
- *Fax:* (703) 518–6319. Include your name and the following subject line: ''Comments on NCUA 2017–2021 Draft Strategic Plan.''
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You can view all public comments on NCUA's Web site at *https://www.ncua.gov/about/pages/board-comments.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments at NCUA's headquarters at 1775 Duke Street, Alexandria, Virginia 22314, by

appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6570 or send an email to *boardcomments@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Lowden, Performance Analyst, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428 or telephone: (703) 518–1182.

Authority: 5 U.S.C. 306.

SUPPLEMENTARY INFORMATION: The Government Performance and Results Act of 1993 (GPRA) requires agencies to prepare strategic plans, annual performance plans and annual performance reports with measurable performance indicators to address the policy, budgeting and oversight needs of both Congress and agency leaders, partners/stakeholders, and program managers. In 2010, Congress passed the GPRA Modernization Act of 2010, which further requires a leadership-driven governance model with emphasis on quarterly reviews and transparency. The GPRA Modernization Act requires agencies to set priority goals linked to longer-term Agency strategic goals. Part 6 of Office of Management and Budget (OMB) Circular A–11 provides additional guidance and requirements for federal agencies to implement these laws.

The *NCUA Draft Strategic Plan 2017–2021* is issued pursuant to the GPRA, the GPRA Modernization Act, and OMB Circular A–11.

It highlights the agency's three strategic goals and supporting strategic objectives, which reflect the outcome or greater impact of the broader strategic goals. The three strategic goals for 2017–2021 are to:

- Ensure a Safe and Sound Credit Union System.
- Promote Consumer Protection and Financial Literacy.
- Cultivate an Inclusive, Collaborative Workplace at NCUA that Maximizes Productivity and Enhances Impact.

On January 27, 2016 the **Federal Register** published a Notice and Request for Comment for the NCUA Draft 2017–2021 Strategic Plan (Citation 81 FR 4679). This **Federal Register** Notice repairs a hyperlink within the notice.

The draft *NCUA Draft Strategic Plan 2017–2021* is available at the following Web address: *https://www.ncua.gov/About/Documents/Agenda%20Items/AG20160121Item2b.pdf.*

By the National Credit Union Administration Board on January 21, 2016.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2016–01777 Filed 2–1–16; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board (NSB), pursuant to National Science Foundation (NSF) regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of a cancellation of one session and the addition of an agenda item in a plenary session during the National Science Board meetings on February 2–3, 2016, as shown below. The original notice appeared in the **Federal Register** on January 29, 2016 at 81 FR 70259.

CANCELLED SESSION:

Plenary Board Meeting

Open Session: 11:30–11:45 a.m.

NSB Chair's remarks
Guest speaker—Senator Gary Peters
NSB Chair's closing remarks

AMENDED AGENDA:

Plenary Board Meeting

Open Session: 1:00–1:30 p.m.

NSB Chair's remarks
NSF Director's remarks
Approval of open plenary minutes for November 2015
NEON update from the Chair of the ad hoc task force on NEON Performance and Plans
Open committee reports
Possible Board Vote on SEI's Recommendations, including draft Companion Brief and sense of the Board Statement on the Value of Higher Education [ADDED]
NSB Chair's closing remarks

UPDATES: Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp.*

AGENCY CONTACT: Ron Campbell, *jrcampbe@nsf.gov,* 703–292–7000.

Kyscha Slater-Williams,

Program Specialist, National Science Board.

[FR Doc. 2016–02015 Filed 1–29–16; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0010]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of one amendment request. The amendment request is for Shearon Harris Nuclear Power Plant, Unit 1; and H. B. Robinson Steam Electric Plant, Unit No. 2. The NRC proposes to determine that the amendment request involves no significant hazards consideration. In addition, the amendment request contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Comments must be filed by March 3, 2016. A request for a hearing must be filed by April 4, 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 February 12, 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–2016–0010. 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: Paula Blechman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–2242, email: *Paula.Blechman@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0010 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–2016–0010.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0010, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC 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. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes a notice of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of

the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the basis for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing 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 amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

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 April 4, 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 April 4, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the

participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format 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 amendment action, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1 (SHNPP), Wake and Chatham Counties, North Carolina

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2 (HBRSEP), Darlington County, South Carolina

Date of amendment request: August 19, 2015. A publicly-available version is in ADAMS under Accession No. ML15236A044.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The licensee requested plant-specific review and approval of a new reactor core design methodology report, DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' for adoption into the SHNPP and HBRSEP Technical Specifications.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The CASMO–5 and SIMULATE–3 codes are not used in the operation of any plant equipment. The benchmark calculations performed confirm the accuracy of the codes and develop a methodology for calculating power distribution uncertainties for use in reload design calculations. The use of power distribution uncertainties in conjunction with predicted peaking factors ensures that thermal accident acceptance criteria are satisfied. The proposed use of this methodology does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). It does not change any system functions or maintenance activities. The change does not involve physical alteration of the plant, that is, no new or different type of equipment will be installed. The software is not installed in any plant equipment, and therefore the software is incapable of initiating an equipment malfunction that would result in a new or different type of accident from any previously evaluated. The change does not alter assumptions made in the safety analyses but ensures that the core will operate within safe limits. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The proposed change requests review and approval of DPC–NE–1008–P, Revision 0, ''Nuclear Design Methodology Using CASMO–5/SIMULATE–3 for Westinghouse Reactors,'' to be applied to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). As with the existing methodology, the qualification of the methods therein and the use of power distribution uncertainties ensure the acceptability of analytical limits under normal, transient, and accident conditions. The use of the proposed methodology revision once it has been approved by the NRC will ensure that all applicable design and safety limits are satisfied such that the fission product barriers will continue to perform their design functions.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, North Carolina 28202.

NRC Branch Chief: Benjamin G. Beasley.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina; and

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must

[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.

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 19th day of January, 2016.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[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.

[FR Doc. 2016–01373 Filed 2–1–16; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0019]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from January 5, 2016, to January 15, 2016. The last biweekly notice was published on January 19, 2016.

DATES: Comments must be filed by March 3, 2016. A request for a hearing must be filed by April 4, 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–2016–0019. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- 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: Janet Burkhardt, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1384, email: *Janet.Burkhardt@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0019 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–2016–0019.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section of this document.
- 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–2016–0019, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov,* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing 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 amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

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 April 4, 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 April 4, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not

submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Exelon Generation Company, LLC, Docket Nos. 50–373 and 50–374, LaSalle County Station (LSCS), Units 1 and 2, LaSalle County, Illinois

Date of amendment request: November 19, 2015. A publicly available version is in ADAMS under Accession No. ML15324A309.

Description of amendment request: The proposed amendments would revise LSCS Technical Specifications

(TS) Section 2.1.1, ''Reactor Core SLs,'' to reflect a lower reactor steam dome pressure stated for Reactor Core Safety Limits (SLs) 2.1.1.1 and 2.1.1.2. Specifically, the proposed amendment will reduce the reactor steam dome pressure in TS SLs 2.1.1.1 and 2.1.1.2 from 785 psig [pound per square inch gage] to 685 psig. This change to TS Section 2.1.1 was identified as a result of General Electric Part 21 report SC05–03, ''Potential to Exceed Low Pressure Technical Specification Safety Limit.'' This change is valid for the NRC-approved pressure range pertinent to the critical power correlations applied to the fuel types in use at LSCS.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the reactor steam dome pressure in the LSCS Reactor Core Safety Limits TS 2.1.1.1 and 2.1.1.2 does not alter the use of the analytical methods used to determine the safety limits that have been previously reviewed and approved by the NRC. The proposed change is in accordance with an NRC approved critical power correlation methodology, and as such, maintains required safety margins. The proposed change does not adversely affect accident initiators or precursors, nor does it alter the design assumptions, conditions, or configuration of the facility or the manner in which the plant is operated and maintained.

The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change does not require any physical change to any plant SSCs nor does it require any change in systems or plant operations. The proposed change is consistent with the safety analysis assumptions and resultant consequences.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed reduction in the reactor dome pressure safety limit from 785 psig to 685 psig is a change based upon previously approved documents and does not involve changes to the plant hardware or its operating characteristics. As a result, no new failure modes are being introduced.

There are no hardware changes nor are there any changes in the method by which any plant systems perform a safety function. No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed change.

The proposed change does not introduce any new accident precursors, nor does it involve any physical plant alterations or changes in the methods governing normal plant operation. Also, the change does not impose any new or different requirements or eliminate any existing requirements. The change does not alter assumptions made in the safety analysis.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The margin of safety is established through the design of the plant structures, systems, and components, and through the parameters for safe operation and setpoints for the actuation of equipment relied upon to respond to transients and design basis accidents.

Evaluation of the 10 CFR part 21 condition by General Electric determined that since the Minimum Critical Power Ratio improves during the PRFO [Pressure Regulator Failure Maximum Demand (Open)] transient, there is no decrease in the safety margin and therefore there is not a threat to fuel cladding integrity.

The proposed change in reactor dome pressure supports the current safety margin, which protects the fuel cladding integrity during a depressurization transient, but does not change the requirements governing operation or availability of safety equipment assumed to operate to preserve the margin of safety. The change does not alter the behavior of plant equipment, which remains unchanged.

The proposed change to Reactor Core Safety Limits 2.1.1.1 and 2.1.1.2 is consistent with and within the capabilities of the applicable NRC approved critical power correlation for the fuel designs in use at LSCS, Units 1 and 2. No setpoints at which protective actions are initiated are altered by the proposed change.

The proposed change does not alter the manner in which the safety limits are determined. This change is consistent with plant design and does not change the TS operability requirements; thus, previously evaluated accidents are not affected by this proposed change.

Therefore, the proposed changes do 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 requested amendments involve no significant hazards consideration.

Attorney for licensee: Bradley J. Fewell, Associate General Counsel, Exelon Nuclear, 4300 Winfield Road, Warrenville, IL 60555.

NRC Acting Branch Chief: Justin C. Poole.

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania

Date of amendment request: December 3, 2015. A publicly-available version is in ADAMS under Accession No. ML15337A413.

Description of amendment request: The amendments would revise the technical specification (TS) surveillance requirements (SRs) associated with the emergency diesel generator (EDG) fuel oil transfer system. Specifically, the amendments would allow for the crediting of manual actions, in lieu of automatic actions, without having to declare the EDGs inoperable.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change will revise SR 3.8.1.6 by adding a note to allow for procedurally controlled simple manual actions associated with the fuel oil transfer system without having to declare the EDG inoperable [under] administrative control. The fuel oil transfer system is required to support continuous operation of standby power sources. The surveillance provides assurance that the fuel oil transfer system is OPERABLE. The fuel oil transfer system is not an initiator of any event previously evaluated. Therefore, the probability of any accident previously evaluated is not increased.

In the event of an accident, if simple manual actions were necessary to restore the automatic feature of the EDG day tank fill, analysis shows that significant margin exists to ensure that EDG operability would not be adversely affected. Although the proposed change to allow simple manual actions could introduce additional potential malfunctions, such that human error could result in the potential to improperly realign the fuel oil transfer system during a DBA [design-basis accident], the improper realignment would be detected when the transfer of fuel oil from the storage tank to the day tank did not occur as expected and the error would be corrected prior to having a significant impact.

The proposed change does not involve any physical changes to the structures, systems, or components (SSCs) in the plant. Further the proposed change does not alter or prevent the ability of SSCs from performing their intended function to mitigate the consequences of an event.

The proposed change is consistent with NRC regulatory requirements regarding the content of plant TS as identified in 10 CFR 50.36. Additionally, the proposed change is consistent with NUREG–1433, ''Standard Technical Specifications General Electric BWR/4 Plants,'' in that the word 'automatically' is bracketed (*i.e.,* optional or as required by plant design).

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant. Accordingly, the change does not introduce any new accident initiators, nor does it reduce or adversely affect the capabilities of any plant structure, system, or component to perform their safety function. Consequently, there are no new initiators that could result in a new or different kind of accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change conforms to NRC regulatory guidance regarding the content of plant Technical Specifications. The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant. The proposed change has no adverse impact on current Safety Limits, Limiting Safety System Settings, Limiting Control Settings, Limiting Conditions for Operation, Surveillance Requirements, Design Features, or Administrative Controls.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Rd., Warrenville, IL 60555.

NRC Branch Chief: Douglas A. Broaddus.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: December 17, 2015, and supplemented by letter dated January 11, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15351A452 and ML16011A500, respectively.

Description of amendment request: The proposed changes, if approved, would amend Combined License Nos. NPF–93 and NPR–94 for VCSNS, Units 2 and 3, respectively. The requested amendment proposes to change the design of the auxiliary building Wall 11 and other changes to the licensing basis for the use of Category II structures, such as Wall 11.2 in the turbine building. The changes in the proposed amendment are located primarily in the VCSNS Updated Final Safety Analysis Report (UFSAR) Tier 2* and Tier 2 information, and also require conforming changes to a license condition.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes do not adversely affect the operation of any systems or equipment inside or outside the auxiliary building that could initiate or mitigate abnormal events, *e.g.,* accidents, anticipated operational occurrences, earthquakes, floods, tornado missiles, and turbine missiles, or their safety or design analyses, evaluated in the UFSAR. The changes do not adversely affect any design function of the auxiliary building or the systems and equipment contained therein. The ability of the affected auxiliary building [main steam isolation valve] MSIV compartments to withstand the pressurization effects from the design basis pipe rupture is not adversely affected by the removal of the Wall 11 upper vent openings, because vents at these locations are not credited in the subcompartment pressurization analysis. MSIV compartment temperatures following the limiting one square foot pipe rupture with the vent openings removed remain acceptably within the envelope for environmental qualification of equipment in the compartments. The credit of seismic Category II Wall 11.2 as a [high energy line break] HELB barrier and the seismic Category II turbine building first bay and associated missile barriers to protect Wall 11 openings from tornado missiles continues to provide adequate protection of structures, systems, and components (SSCs) required to safely shut down the plant, as these structures are designed to the same requirements as seismic Category I structures, and with the additional HELB loadings assumed, remain well within the applicable acceptance criteria.

Therefore, the proposed activity 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 changes do not change the design function of the auxiliary building or of any of the systems or equipment in the auxiliary building or elsewhere within the Nuclear Island structure. These proposed changes do not introduce any new equipment or components that would result in a new failure mode, malfunction or sequence of events that could affect safety-related or nonsafety-related equipment. This activity will not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that would result in significant fuel cladding failures.

Therefore, this activity does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The margin of safety for the design of the auxiliary building is maintained through continued use of the current codes and standards as stated in the UFSAR and adherence to the assumptions used in the analyses of this structure and the events associated with this structure. The auxiliary building will continue to maintain a seismic Category I rating which preserves the current structural safety margins. The 3-hour fire rating requirements for the impacted auxiliary building walls are maintained. The Wall 11 upper vents are not credited in the subcompartment pressurization analysis and the remaining vents and pressure relief devices provide sufficient venting to maintain the MSIV compartment pressures below the design limit and design basis. The credit of turbine building Wall 11.2 as a HELB barrier provides protection of Wall 11 from selected dynamic effects, which in turn provides that essential SSCs remain protected from the effects of postulated HELB events. The credit of the seismic Category II turbine building first bay and associated missile barriers to provide protection of Wall 11 openings from tornado missiles provides sufficient protection for the essential SSCs located in the auxiliary building in the vicinity of Wall 11 from the effects of external missiles. Thus the requested changes will not adversely affect any safety-related equipment, design code, function, design analysis, safety analysis input or result, or design/safety margin. No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the requested change, thus, no margin of safety is reduced.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are

satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Acting Branch Chief: John McKirgan.

Southern Nuclear Operating Company, Inc., Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: November 16, 2015. A publicly-available version is in ADAMS under Accession No. ML15320A464.

Description of amendment request: The requested amendment proposes to depart from Tier 2* information in the Updated Final Safety Analysis Report related to the construction methods used for the composite floors and roof of the auxiliary building.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The design functions of the nuclear island structures are to provide support, protection, and separation for the seismic Category I mechanical and electrical equipment located in the nuclear island. The nuclear island structures are structurally designed to meet seismic Category I requirements as defined in Regulatory Guide 1.29.

The use of [American Concrete Institute (ACI)] 349 and [American Institute of Steel Construction (AISC)] N690 provides criteria for the design, qualification, fabrication, and inspection of composite steel beam floors and roof in the auxiliary building. These structures continue to meet the applicable portions of ACI 349 and AISC N690. The proposed change does not have an adverse impact on the response of the nuclear island structures to safe shutdown earthquake ground motions or loads due to anticipated transients or postulated accident conditions. The change does not impact the support, design, or operation of mechanical and fluid systems. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor does the change described create any new accident precursors.

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 change revises the description of the construction of composite steel beam floors and roof in the auxiliary building. The proposed change does not change the design function, support, design, or operation of mechanical and fluid systems. The proposed change does not result in a new failure mechanism for the pertinent structures or new accident precursors. As a result, the design function of the structures is not adversely affected by the proposed change.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change is consistent with ACI 349 and AISC N690. The design and construction of the auxiliary building floors and roof remain in conformance with the requirements in ACI 349 and AISC N690.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North Birmingham, AL 35203–2015.

NRC Acting Branch Chief: John McKirgan.

Susquehanna Nuclear, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES), Luzerne County, Pennsylvania

Date of amendment request: March 19, 2015, as supplemented by letters dated October 15, 2015, October 16, 2015, and January 8, 2016. Publicly-available versions are in ADAMS under Package Accession Nos. ML15091A657, ML15296A048, and ML15296A057, and Accession No. ML16011A103, respectively.

Description of amendment request: The NRC staff previously made a proposed determination that the amendment request dated March 19, 2015, involved no significant hazards consideration (80 FR 38762; July 7, 2015). Subsequently, the supplemental letter dated October 15, 2015, provided additional information that expanded the scope of the application as originally noticed. Accordingly, this notice supersedes the previous notice in its entirety. The amendments would revise the Emergency Plan for SSES to adopt the Nuclear Energy Institute's (NEI's) revised emergency action level (EAL) scheme described in NEI 99–01, Revision 6, ''Development of Emergency Action Levels for Non-Passive Reactors'' (ADAMS Accession No. ML12326A805), which was endorsed by the NRC as documented in NRC letter dated March 28, 2013 (ADAMS Accession No. ML12346A463). Supplemental changes in these amendments were discussed in a September 23, 2015, public meeting held with Susquehanna Nuclear, LLC. The public meeting summary was issued October 9, 2015, and is available in ADAMS under Accession No. ML15278A492. The additional information, and the changes discussed at the public meeting, are included in the two Susquehanna Nuclear, LLC letters dated October 15, 2015, and October 16, 2015. The revised Emergency Plan includes the appropriate plant-specific changes as a result of an emergency operating procedure upgrade project and corrective action in response to an NRC Emergency Preparedness White Finding, documented in NRC Inspection Report No. 05000387/2015504 and 05000388/2015504, dated June 22, 2015 (ADAMS Accession Nos. ML15173A297 and ML15181A332).

On June 1, 2015, the NRC staff issued an amendment changing the name on the SSES license from PPL Susquehanna, LLC to Susquehanna Nuclear, LLC. This amendment was issued subsequent to an order issued on April 10, 2015, to SSES, approving an indirect license transfer.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, along with NRC edits in square brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed changes to the EAL scheme to adopt the NRC-endorsed guidance in NEI 99–01, Revision 6, ''Development of Emergency Action Levels for Non-Passive Reactors,'' [and the additional plant-specific Emergency Plan changes] do not reduce the capability to meet the emergency planning requirements established in 10 CFR 50.47 and 10 CFR 50, Appendix E. The proposed changes do not reduce the functionality, performance, or capability of the ERO [Emergency Response Organization] to

respond in mitigating the consequences of any design basis accident.

The probability of a reactor accident requiring implementation of Emergency Plan EALs has no relevance in determining whether the proposed changes to the EALs reduce the effectiveness of the Emergency Plan. As discussed in Section I.D, ''Planning Basis,'' of NUREG–0654, Revision 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'';

. . . The overall objective of emergency response plans is to provide dose savings (and in some cases immediate life saving) for a spectrum of accidents that could produce offsite doses in excess of Protective Action Guides (PAGs). No single specific accident sequence should be isolated as the one for which to plan because each accident could have different consequences, both in nature and degree. Further, the range of possible selection for a planning basis is very large, starting with a zero point of requiring no planning at all because significant offsite radiological accident consequences are unlikely to occur, to planning for the worst possible accident, regardless of its extremely low likelihood. . . .

Therefore, risk insights are not considered for any specific accident initiation or progression in evaluating the proposed changes.

The proposed changes do not involve any physical changes to plant equipment or systems, nor do they alter the assumptions of any accident analyses. The proposed changes do not adversely affect accident initiators or precursors nor do they alter the design assumptions, conditions, and configuration or the manner in which the plants are operated and maintained. The proposed changes do not adversely affect the ability of Structures, Systems, or Components (SSCs) to perform their intended safety functions in mitigating the consequences of an initiating event within the assumed acceptance limits.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the EAL scheme to adopt the NRC-endorsed guidance in NEI 99–01, Revision 6, [and the additional plant-specific Emergency Plan changes] do not involve any physical changes to plant systems or equipment. The proposed changes do not involve the addition of any new plant equipment. The proposed changes will not alter the design configuration, or method of operation of plant equipment beyond its normal functional capabilities. All ERO functions will continue to be performed as required. The proposed changes do not create any new credible failure mechanisms, malfunctions, or accident initiators.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from those that have been previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes to the EAL scheme to adopt the NRC-endorsed guidance in NEI 99–01, Revision 6, [and the additional plant-specific Emergency Plan changes] do not alter or exceed a design basis or safety limit. There is no change being made to safety analysis assumptions, safety limit, or limiting safety system settings that would adversely affect plant safety as a result of the proposed changes. There are no changes to setpoints or environmental conditions of any SSC or the manner in which any SSC is operated. Margins of safety are unaffected by the proposed changes to adopt the NEI 99–01, Revision 6 EAL scheme guidance. The applicable requirements of 10 CFR 50.47 and 10 CFR 50, Appendix E will continue to be met.

Therefore, the proposed changes do not involve any reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Damon D. Obie, Associate General Counsel, Talen Energy Supply, LLC, 835 Hamilton St., Suite 150, Allentown, PA 18101.

NRC Branch Chief: Douglas A. Broaddus.

Tennessee Valley Authority, Docket No. 50–391, Watts Bar Nuclear Plant (WBN), Unit 2, Rhea County, Tennessee

Date of amendment request: December 15, 2015. A publicly-available version is in ADAMS under Accession No. ML15350A250.

Brief description of amendment request: The amendment would revise the technical specification (TS) surveillance requirements (SRs) for the WBN, Unit 2, ice condenser lower inlet doors.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequence of an accident previously evaluated?

Response: No.

The ice condenser is a passive heat removal plant feature. The proposed amendment to the TS 3.6.12 does not change the design, physical features or the function of the ice condenser or the ice condenser doors. The ice condenser is not an accident initiator, thus the proposed amendment does not increase the probability of an accident previously evaluated.

The ice condenser is credited in mitigating the consequences of postulated Design Basis Accidents (DBAs) and remains capable of performing its design basis functions. The proposed amendment to the SRs during the first cycle of WBN Unit 2 operation does not change the ice condenser configuration or how it behaves in the event of a DBA. Thus it is concluded that a significant increase in the consequences of an accident previously evaluated will not occur as a result of the proposed amendment.

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 does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed amendment does not introduce any new modes of plant operation, change the design function of the ice condenser or any other Structure System or Component (SSC), or change the mode of operation of the ice condenser or any other SSC. There are no new equipment failure modes or malfunctions created as the ice condenser and ice condenser lower inlet doors continue to operate in the same manner assumed in the accident analysis. The ice condenser is a passive post-accident heat removal feature that is not an accident initiator.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Ice condensers have been in-service at nine nuclear units in the United States for many years. Operating experience has shown that an 18-month surveillance frequency for evaluating operability is appropriate for the lower inlet doors. The proposed amendment to perform a revised schedule of lower inlet door surveillances in the first cycle before transitioning to the standard 18-month surveillance frequency does not result in a significant reduction in the margin of safety.

Therefore, since there is no adverse impact of this amendment on the WBN Unit 2 safety analysis, there is no significant reduction in the margin of safety of the plant.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Scott A. Vance, Associate General Counsel, Nuclear, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 6A–K, Knoxville, TN 37902.

NRC Branch Chief: Benjamin G. Beasley.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Duke Energy Progress, Inc., Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of amendment request: January 30, 2015, as supplemented by letter dated November 23, 2015.

Brief description of amendments: The amendments authorized the upgrade of the emergency action level scheme for each unit based on the Nuclear Energy Institute (NEI) document NEI 99–01, Revision 6, ''Development of Emergency Action Levels for Non-Passive Reactors,'' dated November 2012. NEI 99–01, Revision 6, was endorsed by the NRC by letter dated March 28, 2013.

Date of issuance: January 8, 2016.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment Nos.: 268 (Unit 1) and 296 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML15344A153; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–71 and DPR–62: Amendments revised the Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register****:* April 28, 2015 (80 FR 23602). The supplemental letter dated November 23, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 8, 2016.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket Nos. 50–003, 50–247, and 50–286, Indian Point Nuclear Generating Station (IP), Unit Nos. 1, 2, and 3, and Docket No. 72–51 for IP Independent Spent Fuel Storage Installation (ISFSI), Westchester County, New York

Date of application for amendments: August 20, 2013, as supplemented by letters dated November 21, 2013, and May 13 and July 24, 2014.

Brief description of amendments: The amendments modified the licenses to reflect a grant of Section 161A of the Atomic Energy Act, to authorize the licensee the authority to possess and use certain firearms, ammunition, and other devices such as large-capacity ammunition feeding devices, and to implement the NRC-approved security plan for IP including the general-licensed ISFSI.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment Nos.: Unit 1—58, Unit 2—282, and Unit 3—259. A publicly-available version is in ADAMS under Package Accession No. ML14259A209; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License Nos. DPR–5, DPR–26, and DPR–64 and Special Nuclear Materials General-License: The amendments revised the Facility Operating Licenses including the general-licensed ISFSI.

Date of initial notice in ***Federal Register****:* February 27, 2014 (79 FR 11147).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–333, James A. Fitzpatrick Nuclear Power Plant (Fitzpatrick), and Docket No. 72–12 for Fitzpatrick Independent Spent Fuel Storage Installation (ISFSI), Oswego County, New York

Date of application for amendment: August 30, 2013, as supplemented by letters dated November 12, 2013, May 14, and July 11, 2014, and January 15, 2015.

Brief description of amendment: The amendment modified the licenses to reflect a grant of Section 161A of the Atomic Energy Act, to authorize the licensee the authority to possess and use certain firearms, ammunition, and other devices such as large-capacity ammunition feeding devices, and to implement the NRC-approved security plan for Fitzpatrick including the general-licensed ISFSI.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment No.: 310. A publicly-available version is in ADAMS under package Accession No. v; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–59 and Special Nuclear Materials General-License: The amendment revised the Renewed Facility Operating License including the general-licensed ISFSI.

Date of initial notice in ***Federal Register****:* May 6, 2014 (79 FR 25900).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket No. 50–410, Nine Mile Point Nuclear Station (NMP), Unit 2, Oswego County, New York

Date of amendment request: September 3, 2015.

Brief description of amendment: The amendment changed Technical Specification (TS) Section 2.1.1.2, ''Reactor Core SLs [Safety Limits],'' to revise the cycle-specific safety limit

minimum critical power ratio for Cycle 16 for NMP, Unit 2.

Date of issuance: January 5, 2016.

Effective date: As of the date of issuance and shall be implemented prior to startup from the refueling outage where Global Nuclear Fuel 2 is loaded.

Amendment No.: 153. A publicly-available version is in ADAMS under Accession No. ML15341A336; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–69: Amendment revised the Renewed Facility Operating License and TSs.

Date of initial notice in ***Federal Register:*** November 3, 2015 (80 FR 67801).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–220 and 50–410, Nine Mile Point Nuclear Station, Units 1 and 2 (NMP), and Docket No. 72–1036 for NMP Independent Spent Fuel Storage Installation (ISFSI), Oswego County, New York

Date of application for amendments: August 14, 2013, as supplemented by letters dated September 10, 2013, and May 14, 2014.

Brief description of amendments: The amendments modified the licenses to reflect a grant of Section 161A of the Atomic Energy Act, to authorize the licensee the authority to possess and use certain firearms, ammunition, and other devices such as large-capacity ammunition feeding devices, and to implement the NRC-approved security plan for NMP including the general-licensed ISFSI.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment Nos.: Unit 1—220; Unit 2—154. A publicly-available version is in ADAMS under Package Accession No. ML14254A450; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–63 and NPF–69, and Special Nuclear Materials General-License: The amendments revised the Renewed Facility Operating Licenses including the general-licensed ISFSI.

Date of initial notice in ***Federal Register:*** October 27, 2014 (79 FR 63956).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket No. 50–244, R.E. Ginna Nuclear Power Plant (Ginna), and Docket No. 72–67 for Ginna Independent Spent Fuel Storage Installation (ISFSI), Wayne County, New York

Date of application for amendment: August 14, 2013, as supplemented by letters dated November 4, 2013, and May 14, 2014.

Brief description of amendment: The amendment modified the licenses to reflect a grant of Section 161A of the Atomic Energy Act, to authorize the licensee the authority to possess and use certain firearms, ammunition, and other devices such as large-capacity ammunition feeding devices, and to implement the NRC-approved security plan for Ginna including the general-licensed ISFSI.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment No.: 120. A publicly-available version is in ADAMS under Package Accession No. ML14260A140; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–18 and Special Nuclear Materials General-License: The amendment revised the Renewed Facility Operating License including the general-licensed ISFSI.

Date of initial notice in ***Federal Register:*** October 27, 2014 (79 FR 63951).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

Luminant Generation Company LLC, Docket Nos. 50–445 and 50–446, Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 (CPNPP), Somervell County, Texas

Date of amendment request: January 28, 2015, as supplemented by letter dated July 29, 2015.

Brief description of amendments: The amendments revised Technical Specification (TS) 5.5.16, ''Containment Leakage Rate Testing Program,'' for CPNPP, to allow an increase in the 10 CFR part 50, Appendix J, ''Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors,'' Type A Integrated Leak Rate Test (ILRT) interval from a 10-year frequency to a maximum of 15 years and the extension of the containment isolation valves leakage Type C tests from its current 60-month frequency to 75 months in accordance with Nuclear Energy Institute (NEI) 94–01, Revision 3–A, ''Industry Guidance for Implementing Performance-Based Option of 10 CFR 50, Appendix J,'' July 2012, and conditions and limitations specified in NEI 94–01, Revision 2–A, ''Industry Guidance for Implementing Performance-Based Option of 10 CFR 50, Appendix J,'' October 2008, in addition to limitations and conditions of NEI 94–01, Revision 3–A. The amendments also deleted the listing of one-time exceptions previously granted to ILRT frequencies.

Date of issuance: December 30, 2015.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1—165; Unit 2—165. A publicly-available version is in ADAMS under Accession No. ML15309A073; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** March 31, 2015 (80 FR 17092). The supplemental letter dated July 29, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 30, 2015.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, and Docket No. 72–26 for Diablo Canyon Independent Spent Fuel Storage Installation (ISFSI), San Luis Obispo County, California

Date of application for amendments: September 24, 2013, as supplemented by letters dated December 18, 2013, and May 15, 2014.

Brief description of amendments: The amendments modified the licenses to reflect a grant of Section 161A of the Atomic Energy Act, to authorize the

licensee the authority to possess and use certain firearms, ammunition, and other devices such as large-capacity ammunition feeding devices, and to implement the NRC-approved security plan for Diablo Canyon Power Plant and Diablo Canyon ISFSI.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment Nos.: Unit 1—222; Unit 2—224, ISFSI–4. A publicly-available version is in ADAMS under package Accession No. ML15029A249; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–80 and DPR–82 and Special Nuclear Materials License No. SNM–2511: The amendments revised the Facility Operating Licenses and Special Nuclear Materials License.

Date of initial notice in ***Federal Register:*** February 18, 2015 (80 FR 8706).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: No.

South Carolina Electric & Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: September 18, 2014, and supplemented by letter dated May 28, 2015.

Description of amendment: The amendment authorizes a departure from VCSNS, Units 2 and 3 plant-specific AP1000 Design Control Document (DCD) Tier 2* material contained within the VCSNS Units 2 and 3 Updated Final Safety Analysis Report by relocating fire area rated fire barriers due to changes to the layout of the switchgear rooms and office area in the turbine building.

Date of issuance: December 17, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 38. A publicly-available version is in ADAMS under Accession No. ML15313A052; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Combined Licenses No. NPF–93 and NPF–94: Amendment revised the Facility Combined Licenses.

Date of initial notice in ***Federal Register:*** January 6, 2015 (80 FR 526).

The Commission's related evaluation of the amendment is contained in the Safety Evaluation dated December 17, 2015. The supplemental letter dated May 28, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register.**

No significant hazards consideration comments received: No.

Southern California Edison Company, et al., Docket Nos. 50–361, 50–362, and 72–41, San Onofre Nuclear Generating Station, Units 2 and 3, and Independent Spent Fuel Storage Installation (ISFSI), San Diego County, California

Date of amendment request: August 28, 2013, as supplemented by letters dated December 31, 2013, May 15, 2014, and February 10, 2015.

Brief description of amendments: The conforming amendments would permit the security personnel at San Onofre Nuclear Generating Station to transfer, receive possess, transport, import, and use certain firearms and large capacity ammunition feeding devices not previously permitted to be owned or possessed under NRC authority, notwithstanding certain local, state, or federal firearms laws, including regulations that prohibit such actions.

Date of issuance: January 5, 2016.

Effective date: As of its date of issuance and shall be implemented within 20 days.

Amendment Nos.: Unit 2–232 and Unit 3–225: A publicly-available version is in ADAMS under Accession No. ML15027A221; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–10 and NPF–15: The amendments revised the Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** February 18, 2015 (80 FR 8701). The supplemental letter dated February 10, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register.**

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 5, 2016.

No significant hazards consideration comments received: Yes, addressed in Safety Evaluation.

Tennessee Valley Authority (TVA), Docket No. 50–296, Browns Ferry Nuclear Plant (BFN), Unit 3, Limestone County, Alabama

Date of amendment request: January 27, 2015, as supplemented by letters dated August 13 and October 23, 2015.

Brief description of amendment: The amendment revised the Technical Specifications (TSs) for Limiting Condition for Operation (LCO) 3.4.9, ''RCS [Reactor Coolant System] Pressure and Temperature (P/T) Limits.'' The amendment also revised Note 1 of TS Surveillance Requirement 3.4.9.1 to change the vessel pressure from less than 312 pounds per square inch gauge (psig) to less than 313 psig to conform to the modified P/T limit curves. The amendment satisfied TVA's commitment to submit revised BFN, Unit 3, P/T limits prior to the start of the period of extended operation, as discussed in NRCs Safety Evaluation Report dated April 2006 (ADAMS Accession No. ML061030032), related to the license renewal of BFN, Units 1, 2, and 3.

Specifically, the amendment revised the current sets of TS Figures 3.4.9–1, ''Pressure/Temperature Limits for Mechanical Heatup, Cooldown following Shutdown, and Reactor Critical Operations,'' and 3.4.9–2, ''Pressure/Temperature Limits for Reactor In-Service Leak and Hydrostatic Testing.'' The amendment replaced the current set valid up to 20 effective full-power years (EFPYs) with a new set valid up to 38 EFPYs, and replaced the current set valid up to 28 EFPYs with a new set valid up to 54 EFPYs.

Effective date: As of the date of issuance and shall be implemented 60 days from the date of issuance.

Amendment No.: 278. A publicly available version is in ADAMS under Accession No. ML15344A321; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–68: Amendment revised the Renewed Facility Operating License and TSs.

Date of initial notice in ***Federal Register:*** May 5, 2015 (80 FR 25720). The supplemental letters dated August 13 and October 23, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 7, 2016.

No significant hazards consideration comments received: Yes. The comment received on Amendment No. 278 is addressed in the Safety Evaluation dated January 7, 2016.

Dated at Rockville, Maryland, this 21st day of January 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–01771 Filed 2–1–16; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

[OPIC–162, OMB 3420–0019]

Submission for OMB Review; Comments Request

AGENCY: Overseas Private Investment Corporation (OPIC).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is modifying an existing information collection for OMB review and approval and requests public review and comment on the submission. Comments are being solicited on the need for the information; the accuracy of OPIC's burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collection techniques and uses of other forms of technology.

The proposed change to OPIC–162 clarifies existing questions, incorporates sector-specific development impact questions and eliminates ineffective questions in an effort to harmonize development impact indicators with other Development Finance Institutions (''DFIs''). OPIC is a signatory to a ''Memorandum of Understanding'' with 25 partnering DFIs to harmonize development impact metrics where possible. The goal of this effort is to reduce the reporting burden on clients that receive financing from multiple DFIs and to instill best practices in the collection and the reporting on OPIC's developmental impacts. To minimize the reporting burden on respondents, OPIC has designed OPIC–162 as an electronic form with questions populating only if they relate to a project.

DATES: Comments must be received within sixty (60) calendar days of publication of this Notice.

ADDRESSES: Mail all comments and requests for copies of the subject form to OPIC's Agency Submitting Officer: James Bobbitt, Overseas Private Investment Corporation, 1100 New York Avenue NW., Washington, DC 20527. See **SUPPLEMENTARY INFORMATION** for other information about filing.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: James Bobbitt, (202) 336–8558.

SUPPLEMENTARY INFORMATION: All mailed comments and requests for copies of the subject form should include form number OPIC–162 on both the envelope and in the subject line of the letter. Electronic comments and requests for copies of the subject form may be sent to *James.Bobbitt@opic.gov,* subject line OPIC–162.

SUMMARY FORM UNDER REVIEW

Type of Request: Revision of a currently approved information collection.

Title: Self-Monitoring Questionnaire.

Form Number: OPIC–162.

Frequency of Use: One per investor per project annually.

Type of Respondents: Business or other institutions and individuals.

Standard Industrial Classification Codes: All.

Description of Affected Public: U.S. companies or citizens investing overseas.

Reporting Hours: 2,186 (4.7 hours per form).

Number of Responses: 465 per year.

Federal Cost: $48,518.

Authority for Information Collection: Sections 231, 231A, 239(d), and 240A of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The Self-Monitoring Questionnaire is the principal document used by OPIC to monitor the developmental effects of OPIC's investment projects, monitor the economic effects on the U.S. economy, and collect information on compliance with environmental and labor policies.

Dated: January 27, 2016.

Nichole Skoyles,

Administrative Counsel, Department of Legal Affairs.

[FR Doc. 2016–01859 Filed 2–1–16; 8:45 am]

BILLING CODE 3210–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Nanotechnology Commercialization Success Stories

ACTION: Request for information.

SUMMARY: The purpose of this Request for Information (RFI) is to seek examples of commercialization success stories stemming from U.S. Government-funded nanotechnology research and development (R&D) since the inception of the National Nanotechnology Initiative (NNI) in 2001. The information gathered in response to this RFI may be used as examples to highlight the impact of the Initiative or to inform future activities to promote the commercialization of federally funded nanotechnology R&D. Depending on the nature of the feedback, responses may be used to shape the agenda for a workshop to share best practices and showcase commercial nanotechnology-enabled products and services. Commercial entities, academic institutions, government laboratories, and individuals who have participated in federally funded R&D; collaborated with Federal laboratories; utilized federally funded user facilities for nanoscale fabrication, characterization, and/or simulation; or have otherwise benefited from NNI agency resources are invited to respond.

DATES: Responses are requested by February 29, 2016.

ADDRESSES: You may submit responses by any of the following methods (email is preferred):

- *Email: NNISuccessStories@nnco.nano.gov.* Include [*NNI Success Story*] in the subject line of the message.
- *Mail:* Mike Kiley, National Nanotechnology Coordination Office, ATTN: RFI0116, 4201 Wilson Blvd., Stafford II, Suite 405, Arlington, VA 22230. If submitting a response by mail, allow sufficient time for mail processing.

Instructions: Submissions are limited to five pages, one of which we strongly recommend be an overview slide using the template provided at *www.nano.gov/NNISuccessStories.* Responses must be unclassified and should not contain any sensitive personally identifiable information (such as home address or social security number), or information that might be considered proprietary or confidential). Please include a contact name, email address, and/or phone number in case clarification of details in your submission is required.

Disclaimer: Federal agencies may or may not use any responses to this RFI

as a basis for subsequent projects, programs, or funding opportunities. Responses to this RFI will not be returned. The Office of Science and Technology Policy is under no obligation to acknowledge receipt of the information received, or to provide feedback to respondents with respect to any information submitted under this RFI. Respondents to this RFI will have no competitive advantage in receiving any future awards.

FOR FURTHER INFORMATION CONTACT: Mike Kiley, (703) 292–4399, *NNISuccessStories@nnco.nano.gov,* National Nanotechnology Coordination Office. Any requests for clarification must be received no later than seven (7) business days prior to the close of this RFI in order to receive a timely response.

SUPPLEMENTARY INFORMATION:

Background Information: The National Nanotechnology Initiative (NNI), established in 2001, is a U.S. Government research and development (R&D) initiative of 20 Federal departments, independent agencies, and independent commissions (hereafter referred to as ''agencies'') working together toward the common challenging vision of *a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society* (see *www.nano.gov*). Over the life of the NNI, participating agencies have invested a total of $22 billion in nanotechnology research, development, and commercialization; their combined, coordinated efforts have accelerated the discovery, development, and deployment of nanotechnology to address agency mission goals and broader national needs.

One of the four goals of the NNI is to *foster the transfer of new technologies into products for commercial and public benefit.* Recent external assessments of the NNI by the President's Council of Advisors for Science and Technology (PCAST) have highlighted the need to better assess and highlight the Initiative's progress towards this goal. While there are a number of excellent examples of nanotechnology-based commercial products, the purpose of this RFI is to collect more comprehensive information about the impact of NNI investments on nanotechnology commercialization. This RFI seeks to collect examples of commercial products or services attributable at least in part to the NNI, through direct funding of the developer and/or a collaborator, the use of federally funded facilities, or based at least in part on intellectual property or specific research results that arose from Federal investment in nanotechnology.

The feedback received may be used to inform strategic activities to further foster nanotechnology commercialization. Depending on the nature of the feedback, responses may also be used to shape the agenda for a workshop to share best practices and showcase examples of successful transfer of nanotechnology from lab to market, and respondents may be invited to this and other events related to nanotechnology commercialization. In addition, information gained from this RFI may be used to update commercialization activities and goals in the 2016 NNI Strategic Plan, and may be incorporated into future NNI reports, publications, public remarks, and other materials.

Information Requested: The National Nanotechnology Coordination Office seeks examples of nanotechnology commercialization success stories enabled by Federal investments under the auspices of the NNI. Examples should include a description of the nanotechnology-enabled product or service, key things that led to commercialization success, the role nanotechnology plays in the product, and how the Federal Government helped make success possible, including the following details:

- Description of the nanotechnology-enabled product or service.
- Success story details, which may include but are not limited to: Companies formed; jobs created; collaborations with larger companies or research institutions; revenues; patent applications or patents granted; and/or awards.
- Role of the U.S. Government in commercial success. The Government role could include direct funding of research and development; collaboration with Federal laboratories; use of federally funded user facilities for nanoscale fabrication, characterization, and/or simulation; or other benefits from NNI agency resources.

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2016–01521 Filed 2–1–16; 8:45 am]

BILLING CODE 3270–F6–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, February 4, 2016 at 12 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(7), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Piwowar, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Adjudicatory matters;

Opinion; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: January 28, 2016.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–01942 Filed 1–29–16; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Military Reservist Economic Injury Disaster Loans Interest Rate for Second Quarter FY 2016

In accordance with the Code of Federal Regulations 13—Business Credit and Assistance § 123.512, the following interest rate is effective for Military Reservist Economic Injury Disaster Loans approved on or after January 22, 2016.

Military Reservist Loan Program 4.000%.

Dated: January 21, 2016.

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–01880 Filed 2–1–16; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before March 3, 2016.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: Small Business Administration Surety Bond Guarantee Program was created to encourage surety companies to issue bonds for small contractors. The information collected on these forms from Small Business contractors or surety companies/agents is used to evaluate the eligibility of program application. One form is used by surety companies to request claims payments or report recoveries related to defaulted contractors.

Solicitation of Public Comments

Title: Surety Bond Guarantees Assistance.

Description of Respondents: Surety Companies.

Form Number: SBA Forms 990, 991, 994, 994B, 994F, 994H.

Estimated Annual Responses: 1,026.

Estimated Annual Hour Burden: 3,065.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2016–01886 Filed 2–1–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14599 and #14600]

Connecticut Disaster #CT–00037

AGENCY: U.S. Small Business Administration.

ACTION: Notice

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Connecticut dated 01/21/2016.

Incident: Condominium Complex Fire.

Incident Period: 12/31/2015.

Effective Date: 01/21/2016.

Physical Loan Application Deadline Date: 03/21/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 10/21/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Fairfield.

Contiguous Counties:

Connecticut: Litchfield, New Haven.

New York: Dutchess, Putnam, Westchester.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.625
Homeowners Without Credit Available Elsewhere	1.813
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14599 5 and for economic injury is 14600 0.

The States which received an EIDL Declaration # are Connecticut, New York.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 21, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–01881 Filed 2–1–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Region III—Charleston, WV; Regulatory Fairness Hearing

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Hearing of Region III Small Business Owners in Charleston, WV.

SUMMARY: The SBA, Office of the National Ombudsman is issuing this notice to announce the location, date and time of the Charleston, WV Regulatory Fairness Hearing. This hearing is open to the public.

DATES: The hearing will be held on Friday, February 19, 2016, from 9:30 a.m. to 12:30 p.m. (EST).

ADDRESSES: The hearing will be at the Charleston Area Alliance, 1116 Smith Street, Charleston, WV 25301.

FOR FURTHER INFORMATION CONTACT: The hearing is open to the public; however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation at the Charleston, WV hearing must contact Yolanda Swift by February 15th in writing or by fax or email in order to be placed on the agenda. For further information, please contact Yolanda Swift, Deputy National Ombudsman, Office of the National Ombudsman, 409 3rd Street SW., Suite 3316, Washington, DC 20416, by phone (202) 205–6918 and

fax (202) 481–6128. Additionally, if you need accommodations because of a disability, translation services, or require additional information, please contact Yolanda Swift as well.

For more information on the Office of the National Ombudsman, see our Web site at *www.sba.gov/ombudsman.*

SUPPLEMENTARY INFORMATION: Pursuant to the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), Sec. 222, SBA announces the hearing for Small Business Owners, Business Organizations, Trade Associations, Chambers of Commerce and related organizations serving small business concerns to report experiences regarding unfair or excessive Federal regulatory enforcement issues affecting their members.

Dated: January 20, 2016.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2016–01878 Filed 2–1–16; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Small Business Investment Companies—Early Stage SBICs

AGENCY: U.S. Small Business Administration.

ACTION: Call for early stage fund managers.

SUMMARY: This call for proposals (''Call'') invites experienced early stage fund managers to submit the preliminary materials discussed in Section II below, in the form of the Small Business Investment Company (''SBIC'') Management Assessment Questionnaire (''MAQ''), for consideration by the Small Business Administration (''SBA'') to be licensed as Early Stage Small Business Investment Companies. Licensed Early Stage SBICs may receive SBA-guaranteed debenture leverage of up to 100 percent of their Regulatory Capital, up to a maximum of $50 million. However, Early Stage SBICs may, and most existing Early Stage SBICs do, request less than 100 percent of their Regulatory Capital. Importantly, Early Stage SBICs must invest at least 50% of their investment dollars in early stage small businesses. For the purposes of this initiative, an ''early stage'' business is one that has never achieved positive cash flow from operations in any fiscal year. By licensing and providing SBA guaranteed leverage to Early Stage SBICs, SBA seeks to expand entrepreneurs' access to capital and encourage innovation as part of President Obama's Start-Up America Initiative launched on January 31, 2011. More information on the Early Stage SBIC Initiative and the regulations governing these SBICs may be found at *www.sba.gov/inv/earlystage.*

DATES: The following table provides the key milestones for the Early Stage SBIC Initiative.

Milestones	Dates/Times
MAQ Submission Period/Initial Review	
Management Assessment Questionnaires (''MAQs'') may be submitted at any time between the following dates:.	5 p.m. EST—April 1, 2016–September 30, 2016.
	Applications considered as they are received.
Licensing	
Funds have 12 months from issuance of a Green Light to submit their license application	Applications considered as they are received.

ADDRESSES: Visit *www.sba.gov/inv/MAQ* to download a copy of the Management Assessment Questionnaire (the ''MAQ''). You must submit via express or next day delivery service (i) the relevant MAQ signature pages and (ii) the completed MAQ on a CD–ROM in *Word* and *Excel* format to the following: Scott Schaefer, Senior Investment Officer, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd St. SW., Suite #6300, Washington, DC 20416.

SBA will not accept MAQs in .pdf format or MAQs delivered via regular mail (due to irradiation requirements), or hand delivery or courier service.

SUPPLEMENTARY INFORMATION:

I. Background Information

SBA invites early stage fund managers to submit the preliminary materials, as discussed in Section II below, in the form of a Management Assessment Questionnaire (''MAQ'') for the formation and management of an Early Stage SBIC. In 2012, SBA introduced the Early Stage Initiative. Early Stage SBICs represent a new sub-category of SBICs that will focus on making investments in early stage small businesses. Go to *www.sba.gov/inv/earlystage* for information on the Early Stage Initiative and links to the Early Stage SBIC Final Rule (''Final Rule''). This initiative is part of President Obama's ''Start-Up America Initiative'' to promote American innovation and job creation by encouraging private sector investment in job-creating startups and small firms, accelerating research, and addressing barriers to success for entrepreneurs and small businesses. In the Final Rule, SBA stated that it intended to allocate $200 million per year ($1 billion total) of leverage commitments to Early Stage SBICs over the five year period from Fiscal Year (''FY'') 2012 through FY 2016. The Early Stage initiative is scheduled to terminate at the end of FY 2016. However, in FY 2016 SBA intends to make certain modifications to the Early Stage regulations and make clear SBA's intent to make the Early Stage program (including issuing new Early Stage licenses and leverage commitments) an ongoing part of the SBIC program.

II. Management Assessment Questionnaire/License Application Materials

The first required submission in the Early Stage Licensing process is SBA's MAQ. The MAQ consists of two forms that cover qualitative and quantitative information on the management team, the proposed strategy for the SBIC, the principals' investment track record, and the proposed fund structure and economics. The MAQ consists of SBA Form 2181 and Exhibits A–F of SBA Form 2182.

Should SBA issue you a ''Green Light letter,'' you must submit the SBIC License Application, consisting of SBA Forms 2181, 2182 and 2183 (each of SBA Forms 2181 and 2182 updated to reflect any changes), for the final licensing phase. Exhibit O in SBA Form 2183 includes the fund's limited partnership agreement (''LPA''). Applicants should review this notice for special instructions associated with the LPA for Early Stage SBICs.

III. Early Stage Licensing Process

There are four stages in SBA's Early Stage Licensing Process: (A) Call Period;

(B) Initial Review; (C) Applicant Fundraising and Document Preparation; and (D) Licensing. Each of these stages is discussed below.

A. *Call Period.* This notice signals the start of the FY 2016 Early Stage SBIC call period. Interested parties should download a MAQ from *https://www.sba.gov/content/application-forms.* You should also review the information at *www.sba.gov/inv/earlystage* which includes a list of frequently asked questions (''FAQs'') regarding the Early Stage Initiative. If you still have questions regarding the Early Stage process, please email your questions to *erikka.robinson@sba.gov.* SBA will endeavor to respond to your question within three business days, depending on volume. SBA may not be able to respond to fund-specific questions or questions that require a legal opinion.

B. *Initial Review.* After completing its Initial Review of a submitted MAQ, SBA will issue a Green Light letter to the applicant if it has preliminarily met the evaluation criteria for an Early Stage SBIC, including the vintage year and geographic diversification criteria. The process for SBA's Initial Review is as follows:

1. Submit MAQ. SBA must receive your completed MAQ no later than September 30, 2016. SBA will send a confirmation that it has received your MAQ within three (3) business days of your submission.

2. Due Diligence. SBA will review all MAQs against the evaluation criteria identified in this notice. SBA may engage a contractor to assist in evaluating MAQs received in response to this Call. The Investment Committee (composed of senior managers from the Office of Investment and Innovation) will consider each MAQ, and if the Investment Committee concludes that the management team may be qualified for an Early Stage SBIC license, the entire team will be invited to SBA Headquarters at 409 Third Street SW., Washington, DC for an interview. Those applicants not invited for interviews will be notified. SBA will provide feedback upon request to applicants not selected for an interview.

3. Interview. SBA's invitation for an interview will identify a 1-hour time block, along with the topics that the applicant should be prepared to address. SBA will conduct interviews at SBA Headquarters.

4. Green Light Letter. Following the interview, the SBA will issue a Green Light letter to an applicant that has met the criteria identified in this notice, as determined by the Investment Committee. Applicants approved by the Investment Committee can expect to receive the Green Light letter via email within a few days of the Investment Committee's decision. The Green Light letter formally invites an applicant to submit its application for an SBIC License. The Green Light letter is only an invitation to proceed to the next stage in the process, not a guarantee that a fund will be issued an Early Stage SBIC license. Those applicants that do not receive a Green Light letter will also be notified by email within a few days of the Investment Committee's decision.

C. *Fundraising and Document Preparation.* If you receive a Green Light letter, you will need to raise the minimum Regulatory Capital needed to execute your strategy (which can be no less than $20 million) and submit your completed license application within one year from the date of the letter.

1. Raise Regulatory Capital. An Early Stage SBIC applicant must have signed capital commitments for at least $20 million in Regulatory Capital prior to filing its license application.

2. SBIC Education. All principals of the Early Stage SBIC applicant must attend a one-day SBIC Regulations training class. This training is held quarterly in Washington, DC The purpose of this class is to familiarize principals with the SBIC rules, regulations and compliance procedures. Although an applicant may receive a license before all principals have completed the training, a majority of principals must do so before licensing and all must do so before a licensed Early Stage SBIC will be permitted to draw leverage. Information concerning registration for classes can be obtained at *www.sbia.org.* Certain non-principals such as members of a board of directors may also be required to take the class. In addition, any employees or consultants whom you have assigned to handle regulatory matters or to interact with the Office of Investment and Innovation should attend the class.

3. Finalize Documents & Perform Checklist. The following items must be completed and submitted in order to proceed to the Licensing phase:

Item
Updated SBA Form 2181.
SBA Forms 2182 & 2183.
At least $20 million in Regulatory Capital evidenced by signed Capital Certificate in Form 2183 (Exhibit K).
$25,000 Non-refundable licensing fee.

D. *Licensing.* During this last stage, SBA will review your completed application, perform further due diligence and analysis as needed, and make the final licensing decision. Applicants must apply within one year of the issuance of their Green Light letter. The process for Licensing is detailed below.

1. SBA acceptance of license application. Upon receipt of the application, SBA will acknowledge receipt by email. Within three business days, SBA will determine whether the application is complete, meets the minimum capital requirements and satisfies management ownership diversity requirements. If so, SBA will send the applicant an acceptance letter. If not, SBA will ask the applicant to resolve the issues identified.

2. Background and Documentation Review. Once the application has been accepted, SBA will forward the fingerprint cards and Statements of Personal History to SBA's Office of Inspector General for processing by the FBI. Following a review of the application and legal documents, SBA will provide the applicant with a ''comment letter.'' Applicants must respond in writing to the comment letter. Applicants should respond as quickly as possible, but in any event within 30 days. Failure to address all comments to SBA's satisfaction will slow down the licensing process. Please note that pre-licensing investments, which SBA must review and approve before they are closed, will also add to the licensing time.

3. Divisional Licensing Committee. After SBA's licensing staff and Office of General Counsel have completed their review, the license application is presented to the Divisional Licensing Committee. This committee is composed of the senior managers of the Office of Investment and Innovation. If approved by the Divisional Licensing Committee, the application is presented to the Agency Licensing Committee which consists of certain senior managers of SBA. Prior to consideration by the Agency Licensing Committee, an applicant must provide a signed, up-to-date capital certificate showing that it has at least $2.5 million in Leverageable Capital, consisting of cash on deposit, approved pre-licensing investments funded with partners' contributed capital, and/or approved organizational and operational expenses paid out of partners' contributed capital, and at least $20 million in Regulatory Capital. The applicant's bank must certify that the requisite funds are in the applicant's account and unencumbered.

4. Agency Licensing Committee and Administrator Approval. If the Agency Licensing Committee recommends approval of your license application, it will be forwarded to the SBA Administrator or her designee for final

action as soon as you submit fully executed copies of all legal documents. (Please note that your counsel must certify that the executed documents are identical to the ''final form'' of the documents approved by SBA.) If the Administrator or her designee approves your application, your Early Stage SBIC license is issued.

5. Leverage Commitments. As noted above, the Early Stage initiative is scheduled to terminate at the end of FY 2016, but during FY 2016 SBA intends make certain modifications to the Early Stage regulations and make clear SBA's intent to continue making Early Stage leverage commitments to current and newly licensed Early Stage SBICs.

IV. Early Stage SBIC LPA and Organizational Instructions

A. *Early Stage SBIC Model LPA.* In order to expedite the review of Early Stage SBIC license applications, SBA has adopted a Model Early Stage SBIC Limited Partnership Agreement (''Model LPA''). The Model LPA includes required provisions shown in Bold Arial type and optional provisions in a different font. Please email SBA at *erikka.robinson@sba.gov* for the appropriate version of the Model LPA. Applicants must use the Model LPA as a template and must follow the organizational structure of the Model LPA. Further, applicants must include in their limited partnership agreements all of the required provisions of the Model LPA that appear in Bold Arial type. SBA will not accept additions, deletions and other changes or modifications to any of those required provisions. Applicants are required to submit a copy of their limited partnership agreement blacklined against the Model LPA, as explained in the instructions provided at the beginning of the Model LPA. SBA provides the following further guidance on limited partnership agreements:

1. SBA encourages applicants to adhere to the Model LPA to the maximum extent possible. The entire agreement is subject to SBA's approval.

2. Conditions or restrictions on the ability of the general partner to call private capital commitments are limited to those permitted by the Model LPA.

3. Withdrawal rights are limited to those permitted by the Model LPA.

4. Applicants must adhere to SBA's management fee policies available at *http://www.sba.gov/sites/default/files/files/SBICTechnote07arev200804.pdf.* This policy sets a *maximum* allowable management fee only. The actual management fee will be set by negotiation between the management team and the limited partners and may be less than the maximum. Early Stage SBIC applicants should be aware that the calculation of an SBIC's capital impairment percentage is affected by all fund expenses, including management fees. SBA will consider the management fee in its licensing evaluation criteria as part of fund economics. SBA believes that the primary incentive for fund managers should be carried interest rather than fees.

5. The designation of fund expenses and expenses to be paid out of the management fee must be consistent with SBIC program regulations (see 13 CFR 107.520) and policies.

a. Organizational costs, expenses incurred in applying for a license and forming the SBIC and its entity general partner (but not its parent fund or any other affiliate), are considered a partnership expense. Organizational expenses typically include items such as the licensing fee, cost of legal and other professional and consulting services, travel and other fundraising expenses, costs of preparing, printing and distributing the private placement memorandum or other offering materials, and other related expenses such as telephone and supply costs. SBA strongly encourages, and may require, applicants to include in the LPA a reasonable cap on the total organizational costs to be paid by the applicant. Costs that SBA deems excessive can be paid by an affiliate of the applicant or deducted from the applicant's Regulatory Capital prior to licensing (Regulatory Capital must still be at least $20 million after the deduction).

b. Unreimbursed expenses on investments in small businesses that do not close may be designated as a partnership expense but must be capped at a reasonable level.

6. Right of limited partners to remove general partner—Provisions allowing removal of the general partner without cause (''no-fault divorce'' provisions) are permitted only after the Early Stage SBIC has repaid all outstanding leverage and any other amounts payable to SBA and has surrendered its SBIC license.

7. Any amendments to the limited partnership agreement required by SBA must be executed before licensing. Any amendments initiated by the applicant during the licensing process must be submitted to SBA in draft form as early as possible.

B. *Organization.* Early Stage SBIC applicants must adhere to the following rules regarding organizational structure:

1. Applicant cannot be a BDC or other public entity or a subsidiary of any such entity.

2. All provisions governing the operation of the SBIC must be included in the limited partnership agreement. While SBA does not encourage the use of side letters, SBA recognizes that side letters form the basis of the understanding of the investment in an SBIC for certain investors, and, in particular, certain investors subject to regulatory oversight. If an investor requests a side letter provision that is of general interest to all investors (*e.g.,* a provision regarding the fund's efforts to invest in certain geographic areas), that provision should be incorporated into the limited partnership agreement. Any provision of a side letter that purports to control, alter or supplement a section of the partnership agreement must expressly identify each such section. If a side letter fails to expressly identify any such section, SBA will consider the conflicting provision of the side letter to be without force or effect. All side letters require SBA's prior written approval.

3. Applicant must adopt SBA Model Valuation Guidelines.

4. Drop-down SBICs

a. The drop-down structure should be used only when it has a clear business purpose:

i. Example 1—Parent fund has already raised capital and begun operating and wants to commit a portion of its capital to an Early Stage SBIC.

ii. Example 2—Substantial capital will be retained for investment at the parent level (SBA suggests that managers consider the alternative of structuring a non-SBIC fund side by side with the SBIC).

b. Drop-down funds must have one parent fund only and the parent fund must be a U.S. entity.

c. Parent must qualify as a traditional investment company based on established SBA precedent.

d. Parent must disclose the identity of all of its investors.

e. All of the investors in the parent fund (the SBIC's ''Class A'' limited partner) must agree to be ''Class B'' limited partners of the SBIC with an obligation to fund the Early Stage SBIC capital calls if the Class A limited partner does not. The obligation of the Class B limited partners to the Early Stage SBIC is reduced dollar for dollar as the parent fund contributes capital to the SBIC. The Model LPA contains required provisions for drop-down funds.

f. The Class B limited partners' commitments to the SBIC applicant must be expressed as a specific dollar amount (not just as the ''proportionate share'' of parent fund's commitment).

g. The total dollar amount of Class B commitments must be equal to the Class A limited partner's unfunded commitment to the SBIC. SBA will not require Class B commitments if the SBIC's Regulatory Capital will not include any unfunded commitments from the Class A limited partner.

C. *Capitalization.* Applicants must raise the minimum $20 million in Regulatory Capital by the time the license application is submitted.

1. Capital commitments from limited partners must be made directly to the SBIC (and its parent fund, in the case of a drop-down) with no intermediaries involved.

2. The Early Stage SBIC applicant must have the unconditional ability to legally enforce collection of each capital commitment.

3. Capital Certificate. Capital commitments must be documented in the capital certificate (Exhibit K of SBA Form 2183) and comply with the following:

a. A signed Capital Certificate must be submitted with the license application.

b. SBA will permit only the sole following condition on private capital commitments: the receipt of an Early Stage SBIC license.

c. Individual investors must list primary residence address, not a business address.

d. Street addresses are required (no P.O. Box addresses).

4. A dual commitment may be obtained to back up the commitment of any direct investor in the SBIC who is not an Institutional Investor.

5. Capital commitments by the principals, general partner, or their affiliates must be payable in cash when called (cannot be satisfied with notes or management fee waivers).

D. *General Partner*

1. All principals must:

a. Hold direct ownership interests in and be the direct individual managers of the general partner, with no intervening entities.

b. Receive carried interest directly from the general partner; for drop-down SBICs, carried interest may be received from the parent fund's general partner.

2. A maximum of 25% of the carried interest may be allocated to non-principals.

3. Any provision to remove or terminate a principal must be spelled out within the general partner's organizational document and must not be tied to events occurring under other agreements (*e.g.,* a principal's employment agreement with the management company).

E. *Investment Advisor (''Management Company'').* Ownership of the Management Company that is highly disproportionate to the ownership of the general partner (*e.g.,* one principal is the 100% owner) is not viewed favorably by SBA, but may be acceptable if there are adequate checks and balances on the powers of the dominant owner. Areas that cannot be subject to unilateral decision-making include the following:

1. Power to remove or terminate other principals.

2. Power to change the composition of the Early Stage SBIC's investment committee.

V. Early Stage SBIC Licensing Evaluation Criteria

A. *General Criteria.* SBA will evaluate an Early Stage SBIC license applicant based on the submitted application materials, Investment Committee interviews with the applicant's management team, and the results of background investigations, public record searches, and other due diligence conducted by SBA and other Federal agencies. SBA will evaluate an Early Stage SBIC license applicant based on the same factors applicable to other license applicants, as set forth in 13 CFR 107.305, with particular emphasis on managers' skills and experience in evaluating and investing in early stage companies. As discussed in the Final Rule, evaluation criteria fall into four areas: (A) Management Team; (B) Track Record; (C) Proposed Investment Strategy; and (D) Organizational Structure and Fund Economics. You should review these regulations prior to completing your MAQ.

B. *Managing SBA Leverage.* SBA will pay particular attention to how a team's investment strategy works with proposed SBA leverage. Early Stage Debenture leverage either requires a 5 year interest and annual charge reserve from the date of issue or is structured with an original issue discount that covers the interest and annual charges for the first 5 years. In either case, Early Stage SBICs must identify how quarterly interest payments beginning in the 6th year from Debenture issue will be met. Sources of liquidity to make interest payments may include (a) private capital; (b) realizations; or (c) current income. As part of your plan of operations, you should carefully consider how your investment strategy will work with SBA leverage and make appropriate suggestions to manage risk. Risk mitigation strategies might include making some investments in current pay instruments, taking down less than a full tier of leverage (*i.e.,* leverage less than 100% of Regulatory Capital), taking leverage down later in the fund's life, lowering management expenses, and reserving more private capital. The strategies you choose to employ should be appropriate for your management team's track record and investment strategy.

C. *SBA Diversification Rights.* Per 13 CFR 107.320, SBA reserves the right to maintain diversification among Early Stage SBICs with respect to (i) the year in which they commence operations (''vintage year'') and (ii) geographic location.

1. Vintage Year Diversification. Vintage year has a major impact on the return expectations of a fund and excessive concentration in a single year could substantially increase program risk. Therefore, SBA reserves the right, when licensing Early Stage SBICs, to maintain diversification across vintage years. If SBA receives an extraordinary number of qualified applicants in FY 2016, it may not approve all such applicants in the same Fiscal Year.

2. Geographic Diversification. All Early Stage SBICs must first meet SBA's basic licensing criteria. After those criteria are met, SBA reserves the right to maintain diversification among Early Stage SBICs with respect to the geographic location in which the Early Stage SBIC expects to invest.

Michele Schimpp,

Deputy Associate Administrator Office of Investment and Innovation.

[FR Doc. 2016–01879 Filed 2–1–16; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0001]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel NN59; 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 March 3, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0001. 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 W23–465, 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 NN59 is:

Intended Commercial Use of Vessel: ''Teach sailing, take maritime heritage tourists, other user groups on the Sailboat's geographic region intended operation.''

Geographic Region: ''Washington State, Oregon, Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound]).''

The complete application is given in DOT docket MARAD–2016–0001 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: January 12, 2016.

Thomas M. Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–01874 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0006]

Inventory of U.S.-Flag Launch Barges

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Inventory of U.S.-flag launch barges.

SUMMARY: The Maritime Administration is updating its inventory of U.S.-flag launch barges. Additions, changes and comments to the list are requested. Launch barge information may be found at *http://www.marad.dot.gov/ships-and-shipping/domestic-shipping/launch-barge-program/.*

DATES: Any comments on this inventory should be submitted in writing to the contact person by March 3, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Hokana, Office of Cargo and Commercial Sealift, Maritime Administration, MAR–620, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone 202–366–0760; email: *Michael.Hokana@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 46 CFR part 389 (Docket No. MARAD–2008–0045) Determination of Availability of Coastwise-Qualified Vessels for the Transportation of Platform Jackets, the Final Rule requires that the Maritime Administration publish a notice in the **Federal Register** requesting that owners or operators (or potential owners or operators) of coastwise qualified launch barges notify us of: (1) Their interest in participating in the transportation and, if needed, the launching or installation of offshore platform jackets; (2) the contact information for their company; and, (3) the specifications of any currently owned or operated coastwise qualified launch barges or plans to construct same. In addition, we are also seeking information on non-coastwise qualified (U.S.-flag) launch barges as well.

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By Order of the Maritime Administrator.

Dated: January 12, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

REPORTED U.S.-FLAG LAUNCH BARGES

Vessel name	Owner	Built	Length (ft.)	Beam (ft.)	DWT (L. T.)	Approx launch capacity (L. T.)	Coaswise qualified
455 4	Crowley Marine Services.	2009	400	105	19,226	18,766	X
455 5	Crowley Marine Services.	2009	400	105	19,226	18,766	X
455 6	Crowley Marine Services.	2009	400	105	19,226	18,766	X
455 7	Crowley Marine Services.	2009	400	105	19,226	18,766	X
455 8	Crowley Marine Services.	2010	400	105	19,226	18,766	X
455 9	Crowley Marine Services.	2010	400	105	19,226	18,766	X

REPORTED U.S.-FLAG LAUNCH BARGES—Continued

Vessel name	Owner	Built	Length (ft.)	Beam (ft.)	DWT (L. T.)	Approx launch capacity (L. T.)	Coaswise qualified
Barge 400L	Crowley Marine Services.	1997	400	100	19,646	19,146	X
Barge 410	Crowley Marine Services.	1974	400	99.5	12,035	11,535	X
Barge 455–3	Crowley Marine Services.	2008	400	105	19,226	18,766	X
Barge 500–1	Crowley Marine Services.	1982	400	105	16,397	15,897	X
Julie B	Crowley Marine Services.	2008	400	130	23,600	23,100	X
Marty J	Crowley Marine Services.	2008	400	105	19,226	18,766	X
MWB 403	HMC Leasing, Inc	1979	400	105	16,322	6,800	X
INTERMAC 600	J. Ray McDermott, Inc.	1973	500	120	32,290	15,600	
McDermott Tidelands 020.	J. Ray McDermott, Inc.	1980	240	72	5,186	5,000	X
McDermott Tidelands 021.	J. Ray McDermott, Inc.	1980	240	72	4,700	2,200	X
McDermott Tidelands 021.	J. Ray McDermott, Inc.	1981	240	72	5,186	5,000	X
McDermott Tidelands No. 012.	J. Ray McDermott, Inc.	1973	240	72.2	4,217	4,000	X
McDermott Tidelands No. 014.	J. Ray McDermott, Inc.	1973	240	72.2	4,217	4,000	X
MARMAC 11	McDonough Marine Service.	1994	250	72	4,743	4,200	X
MARMAC 12	McDonough Marine Service.	1994	250	72	4,743	4,200	X
MARMAC 15	McDonough Marine Service.	1995	250	72	4,743	4,200	X
MARMAC 16	McDonough Marine Service.	1995	250	72	4,743	4,200	X
MARMAC 17	McDonough Marine Service.	1997	250	72	4,743	4,200	X
MARMAC 18	McDonough Marine Service.	1998	250	72	4,743	4,200	X
MARMAC 19	McDonough Marine Service.	1999	250	72	4,743	4,200	X
MARMAC 20	McDonough Marine Service.	1999	250	72	4,743	4,200	X
MARMAC 21	McDonough Marine Service.	2002	260	72	5,163	4,500	X
MARMAC 22	McDonough Marine Service.	2003	260	72	5,082	4,500	X
MARMAC 23	McDonough Marine Service.	2009	260	72	5,082	4,500	X
MARMAC 24	McDonough Marine Service.	2010	260	72	5,082	4,500	X
MARMAC 25	McDonough Marine Service.	2010	260	72	5,082	4,500	X
MARMAC 300	McDonough Marine Service.	1998	300	100	10,105	9,500	X
MARMAC 301	McDonough Marine Service.	1996	300	100	9,553	9,000	X
MARMAC 3018	McDonough Marine Service.	1996	318	95′–9″	10,046	9,500	
MARMAC 400	McDonough Marine Service.	2001	400	99′–9″	11,272	10,500	X
MARMAC 9	McDonough Marine Service.	1993	250	72	4,743	4,200	X
COLUMBIA NORFOLK.	Moran Towing	1982	329’ 3 1/2“	78	8,036	8,000	X
FAITHFUL SERVANT.	Puglia Engineering, Inc.	1979	492	131	23,174	23,000	
ATLANTA BRIDGE	Trailer Bridge, Inc	1998	402	100	6,017	6,017	X
BROOKLYN BRIDGE.	Trailer Bridge, Inc	1998	402	100	6,017	6,017	X
CHARLOTTE BRIDGE.	Trailer Bridge, Inc	1998	402	100	6,017	6,017	X

REPORTED U.S.-FLAG LAUNCH BARGES—Continued

Vessel name	Owner	Built	Length (ft.)	Beam (ft.)	DWT (L. T.)	Approx launch capacity (L. T.)	Coaswise qualified
CHICAGO BRIDGE	Trailer Bridge, Inc ...	1998	402	100	6,017	6,017	X
MEMPHIS BRIDGE	Trailer Bridge, Inc ...	1998	402	100	6,017	6,017	X

[FR Doc. 2016–01871 Filed 2–1–16; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0004]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HAWK; 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 March 3, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0004. 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: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HAWK is:

Intended Commercial Use of Vessel: ''6-pack charters and sightseeing trips.''

Geographic Region: ''California.''

The complete application is given in DOT docket MARAD–2016–0004 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

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By Order of the Maritime Administrator.
Dated: January 12, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–01876 Filed 2–1–16; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0003]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel Altitude Adjustment (Traveller); 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 March 3, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0003. 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: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended

service of the vessel Altitude Adjustment (Traveller) is:

Intended Commercial Use of Vessel: ''Charter sailing trips with 6 passengers or less''

Geographic Region: ''Puerto Rico, Florida''

The complete application is given in DOT docket MARAD–2016–0003 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: January 12, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–01862 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2016–0005]

Request for Comments of a Previously Approved Information Collection

AGENCY: Maritime Administration (MARAD), Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on October 15, 2015 (80 FR 62167, No.199).

DATES: Comments must be submitted on or before March 3, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Hokana, 202–366–0760, Office of Cargo and Commercial Sealift, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Jones Act Vessel Availability Determinations.

OMB Control Number: 2133–0545.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: The information is needed in order for the Maritime Administrator to make a timely and informed decision on the availability of coastwise qualified vessels in support of a request from the Department of Homeland Security prior to the final decision on granting a waiver request under 46 U.S.C. 501(b). The information will be specifically used to determine if there are coastwise qualified vessels available for a certain requirement.

Affected Public: Coastwise qualified vessel owners, operators, charterers, brokers and representatives.

Form(s): MA–1075, 1075A.

Estimated Number of Respondents: 85.

Estimated Number of Responses: 255.

Annual Estimated Total Annual Burden Hours: 383 hours.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; 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, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.93.

Dated: January 12, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–01863 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0002]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PAU HANA; 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 March 3, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2016–0002. 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 W23–465, 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 PAU HANA is:

Intended Commercial Use Of Vessel: ''Passenger Charter (term-average one week long)''

Geographic Region: ''Virginia, North Carolina, South Carolina, Georgia, Alabama, Puerto Rico, Hawaii, California''

The complete application is given in DOT docket MARAD–2016–0002 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.

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By Order of the Maritime Administrator.

Dated: January 12, 2016.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–01873 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Office of the Assistant Secretary for Research and Technology; University Transportation Centers Program Competition

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), DOT.

ACTION: Notice.

SUMMARY: The United States Department of Transportation (the Department) is publishing this notice to give eligible nonprofit institutions of higher learning advance notice that they will have an opportunity to submit grant applications for the University Transportation Centers (UTCs) program (Catalog of Federal Domestic Assistance number 20.701).

Funds for this grant program are authorized beginning on October 1, 2015. In the near future, the Department, via the Office of the Assistant Secretary for Research and Technology, will release a grant solicitation through Grants.gov, also posted on the UTC Program's Web site, *http://utc.dot.gov,* describing the competition and deadlines for applications. Proposals will be evaluated through a competitive process on the basis of demonstrated ability, research, technology transfer and education resources, leadership, multimodal research capability, commitment to transportation workforce development programs, dissemination of results, the use of peer review, cost effectiveness and partnerships to advance diversity.

FOR FURTHER INFORMATION CONTACT: Dr. Kevin Womack, Director, Office of Research, Development and Technology, mail code RDT–10, Office of the Assistant Secretary for Research and Technology (OST–R), 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone Number (405) 954–7312 or Email *Kevin.Womack@dot.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

The Fixing America's Surface Transportation Act (FAST Act; Pub. L. 114–94, Sec. 6002(a)(5); December 4, 2015) authorizes $72.5 million for Federal fiscal year 2016 (FY 2016), $75 million for fiscal years 2017 (FY 2017) and 2018 (FY 2018), and $77.5 million for fiscal years 2019 (FY 2019) and 2020 (FY 2020) for up to 35 competitive grants for UTCs. The FY 2016 through FY 2020 funds are subject to appropriations and to an annual obligation limitation. The amount of budget authority available in a given year may be less than the amount authorized for that fiscal year.

The FAST Act authorizes the Secretary of Transportation to make grants to eligible nonprofit institutions of higher education to establish and operate UTCs. Nonprofit institutions of higher education may include qualifying two-year institutions (20 U.S.C. 1001(a)). OST–R will manage the UTC Program for the Department. The Department will solicit competitive grant applications for National University Transportation Centers, Regional University Transportation Centers and Tier 1 University Transportation Centers as set forth in the FAST Act. UTCs will be selected by the Secretary, in consultation as appropriate with the Assistant Secretary for Research and Technology, and the Administrator of the Federal Highway Administration and other modal administrators as appropriate. (49 U.S.C. 5505(b)(4)(B) as amended by Pub. L 114–94, Sec. 6016).

The Department plans to competitively select five National UTCs with annual awards for five years of between $2 and $4 million each, ten Regional UTCs with annual awards of between $1.5 and $3 million each, and up to 20 Tier 1 UTCs with annual awards of between $1 and $2 million each.

The role of each UTC is to advance transportation expertise and technology in the varied disciplines that comprise the field of transportation through education, research, and technology transfer activities; to provide for a critical transportation knowledge base outside of the Department of Transportation; and to address critical workforce needs and educate the next generation of transportation leaders.

II. Eligibility

A UTC must be located in the United States or territories. A change in the UTC Program from prior authorizations is that each UTC must be a consortium of two or more nonprofit institutions of higher learning (49 U.S.C. 5505(b)(1) as amended by Pub. L. 114–94, § 6016).

A Regional UTC must be located in the region for which the grant is sought. (49 U.S.C. 5505(c)(3)(B)(ii) as amended by Pub. L. 114–94, § 6016). All members of a Regional UTC consortium must be located in the region for which the grant is sought.

Institutions may collaborate with state and local departments of transportation, Metropolitan Planning Organizations, the private sector, and non-governmental organizations; however, these organizations or others that are not U.S. nonprofit institutions of higher learning may not be considered members of a consortium. A change from previous UTC Program competitions is that two-year institutions may be members of a consortium if they meet the definition of ''institution of higher learning'' in 20 U.S.C. 1001(a). The grantee institution (lead institution of a consortium of institutions) will be the direct and primary recipient of UTC program

funds. The grantee institution must perform a substantive role in carrying out UTC activities, and not serve merely as a conduit for awards to other parties.

Applicants may apply for more than one type of grant, but the FAST Act limits the circumstances in which an institution may receive more than one grant. (49 U.S.C. 5505(b)(2)(A) as amended by Pub. L. 114–94, § 6016). The restriction is:

• A lead institution of a consortium of nonprofit institutions of higher education may only receive one grant per fiscal year for each type of Center. Thus, a lead institution may receive grants as a National Center, a Regional Center, and a Tier 1 Center, but not more than one grant in each category.

III. Matching Requirements

Each UTC is required to obtain matching funds from non-federal sources. The amount of matching funds required for a National or Regional UTC is 100 percent of the Federal award. The amount of matching funds required for a Tier 1 UTC is 50 percent of the Federal award. The matching amounts may include the amounts made available to a grant recipient under 23 U.S.C. 504(b) or 505.

IV. Application Process

Full and Open Competition. The Department will conduct the UTC program selection based on principles of full and open competition. Five National Centers, ten Regional Centers and up to 20 Tier 1 Centers will be selected from the pool of applicants for each type of UTC.

Subject Matter Focus. A change to the UTC Program in this competition is that applicants for a UTC must address research priorities identified in section 6503, Subtitle III of title 49 as amended by Public Law 114–94, § 6016:

A. Improving mobility of people and goods;

B. Reducing congestion;

C. Promoting safety;

D. Improving the durability and extending the life of transportation infrastructure;

E. Preserving the environment; and

F. Preserving the existing transportation system.

The Secretary will select nonexclusive candidate topic areas that will fall within these six priority areas. Each UTC will be awarded a grant based on its ability to address one of these six priorities and the topic areas that fall within the priority area selected.

National UTCs: The Department intends to select National UTCs to lead research in five of these priority areas.

Regional UTCs: One UTC will be selected in each of ten Standard Federal Regions. Regional UTCs are required to focus on transportation research and education (49 U.S.C. 5505(c)(3)(B) as amended by Public Law 114–94, § 6016). Regional UTCs must be able to conduct research in an area of focus from among nonexclusive candidate topic areas established by the Secretary that address the research priorities identified in section 6503, Subtitle III of title 49 as amended by Public Law 114–94, § 6016. One of the Regional Centers must focus on ''comprehensive transportation safety, safety, congestion, connected vehicles, connected infrastructure, and autonomous vehicles'' as its main research effort (49 U.S.C. 5505(c)(3)(E) as amended by Public Law 114–94, § 6016). An applicant for a Regional UTC must designate the region in which it is applying.

Tier 1 UTCs: Based on the statute's general selection criteria, the Tier 1 UTCs (no more than 20 UTCs) must focus on nonexclusive candidate topic areas that address the research priorities identified in section 6503, Subtitle III of title 49 as amended by Public Law 114–94, 6016. In making awards to Tier 1 UTCs, consideration will be given to minority institutions, as defined by section 365 of the Higher Education Act of 1965 (20 U.S.C. 1067k), or consortia that include such institutions that have demonstrated an ability in transportation-related research.

The Department seeks a balanced portfolio of UTCs across the 35 to be selected through this competition that supports the Department's Strategic Goals, contains different types and/or sizes of nonprofit institutions of higher education, and focuses on improving overall system performance using multiple transportation resources that address multimodal needs.

Letter of Intent. The solicitation will require that each applicant submit a non-binding letter of intent approximately one month after the solicitation is announced on Grants.gov, also posted on the UTC Program Web site *http://utc.dot.gov.* The letter of intent must identify the following items:

• The category of grant for which the applicant will apply (National, Regional, Tier I); and

• The chosen priority area in which to focus research, based on section 6503, Subtitle III of title 49 as amended by Public Law 114–94, § 6016.

Letters of intent will be required so that the Department's review panels, comprising relevant subject-matter experts drawn from inside and outside the Department, may be organized in advance of receipt of final proposals. If an institution intends to apply for more than one UTC grant, a separate letter of intent must be submitted for each intended application.

Selection criteria. The Department will evaluate and select UTC applicants based on the nine selection criteria outlined in the FAST Act:

''(i) the demonstrated ability of the recipient to address each specific topic area described in the research and strategic plans of the recipient;

''(ii) the demonstrated research, technology transfer, and education resources available to the recipient to carry out this section;

''(iii) the ability of the recipient to provide leadership in solving immediate and long-range national and regional transportation problems;

''(iv) the ability of the recipient to carry out research, education, and technology transfer activities that are multimodal and multidisciplinary in scope;

''(v) the demonstrated commitment of the recipient to carry out transportation workforce development programs through—

''(I) degree-granting programs or programs that provide other industry-recognized credentials; and

''(II) outreach activities to attract new entrants into the transportation field including women and underrepresented populations;

''(vi) the demonstrated ability of the recipient to disseminate results and spur the implementation of transportation research and education programs through national or statewide continuing education programs;

''(vii) the demonstrated commitment of the recipient to the use of peer review principles and other research best practices in the selection, management, and dissemination of research projects;

''(viii) the strategic plan submitted by the recipient describing the proposed research to be carried out by the recipient and the performance metrics to be used in assessing the performance of the recipient in meeting the stated research, technology transfer, education, and outreach goals; and

''(ix) the ability of the recipient to implement the proposed program in a cost-efficient manner, such as through cost sharing and overall reduced overhead, facilities, and administrative costs.''

(49 U.S.C. 5505(b)(4)(B) as amended by Pub. L. 114–94, § 6016).

These criteria apply to the evaluation and selection of all three categories of UTCs. The following additional selection criteria apply to Regional UTCs and Tier I UTCs:

Regional UTCs. The lead institution in a Regional consortium must have a

well-established, nationally recognized program in research and education, as shown by:

(i) recent expenditures by the institution in highway or public transportation research;

(ii) a historical track record of awarding graduate degrees in professional fields closely related to highways and public transportation; and

(iii) an experienced faculty who specialize in professional fields closely related to highways and public transportation.

(49 U.S.C. 5505(c)(3)(B) (iii) as amended by Pub. L. 114–94, § 6016).

Tier 1 UTCs. Consideration will be given to minority institutions, as defined by section 365 of the Higher Education Act of 1965 (20 U.S.C. 1067k), or consortia that include such institutions that have demonstrated an ability in transportation-related research.

Past Performance. The Department is required by 2 CFR 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,* Section 205, to review risk posed by applicants. This may be done through such publicly available information collections as the System for Award Management (SAM.gov) and/or through specifically collected information about the applicant's record in managing Federal awards.

External Stakeholders. The Department will consult with external stakeholders (including the Transportation Research Board of the National Academy of Sciences, among others), to the maximum extent practicable, to evaluate and review all proposals. (49 U.S.C. 5505(b)(6) as amended by Public Law 114–94, 6016).

V. Program Funding and Award

UTCs will be selected by the Secretary, in consultation as appropriate with the Assistant Secretary for Research and Technology, the Administrator of the Federal Highway Administration and other modal administrators as appropriate. Awards will be made no later than December 4, 2016, with Federal FY16 funds awarded at that time. Subsequent Federal FY17–FY20 funding will be awarded approximately annually after that date, subject to availability of funds and grantee compliance with grant terms and conditions.

VI. Use of Grant Funds

Grantees will have until September 30, 2022 to expend all funds, assuming availability of annual appropriations.

Issued in Washington, DC, on January 27, 2016.

Gregory D. Winfree,

Assistant Secretary.

[FR Doc. 2016–01838 Filed 2–1–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Proposed Collection; Comment Request; Bank Secrecy Act Currency Transaction Report (BCTR) Revised Layout and Proposed Additional Data Fields

AGENCY: Financial Crimes Enforcement Network (''FinCEN''), Treasury.

ACTION: Notice and request for comments.

SUMMARY: FinCEN published the revised Bank Secrecy Act Currency Transaction Report (''BCTR'') in March 2011. The BCTR was designed to facilitate financial institutions reporting the most frequently encountered transaction scenarios. Since that time, FinCEN has become aware that the current report is not configured to allow for alternative reporting models that have developed in the last few years, such as reports filed by a parent company on behalf of its subsidiary. To remedy some of the limitations of the current BCTR, FinCEN now proposes an amended report. This notice does not propose any new regulatory requirements or changes to the requirements related to currency transaction reporting, but rather seeks input on technical matters designed to improve the layout and reporting of the BCTR. This request for comments covers 31 CFR 1010.310. This request for comments is made pursuant to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

DATES: Written comments are welcome and must be received on or before April 4, 2016.

ADDRESSES: Written comments should be submitted to: Office of Regulatory Policy, Financial Crimes Enforcement Network, Department of the Treasury, P.O. Box 39, Vienna, Virginia 22183, ''Attention: PRA Comments—BCTR Revision.''

Comments also may be submitted by electronic mail to the following Internet address: *regcomments@fincen.gov,* with the caption, ''Attention: BCTR Revision'' in the body of the text. Please submit by one method only. All comments submitted by either method in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

Inspection of comments. Comments will be posted on the FinCEN public Web site. Persons wishing to review the comments submitted may access the posted comments by going to *https://www.fincen.gov/forms/bsa_forms/.*

FOR FURTHER INFORMATION CONTACT: FinCEN Resource Center at 1–800–767–2825 or 1–703–905–3591 (not a toll free number) and select option 3 for regulatory questions. Email inquiries can be sent to *FRC@fincen.gov.*

SUPPLEMENTARY INFORMATION:

Title: BSA Currency Transaction Report by Financial Institutions (See 31 CFR 1010.310).

Office of Management and Budget (''OMB'') Number: 1506–0064.[1]

Report Number: FinCEN 112.

Abstract: The statute generally referred to as the ''Bank Secrecy Act,'' (''BSA'') Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5332, authorizes the Secretary of the Treasury, *inter alia,* to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities, to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.[2] Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.

The Secretary of the Treasury was granted authority in 1970, with the enactment of 31 U.S.C. 5313, to require financial institutions to report currency transactions exceeding $10,000. The information collected on the ''report'' is required to be provided pursuant to 31 U.S.C. 5313 as implemented by FinCEN regulations found at 31 CFR 1010.310. The information collected under this requirement is made available to appropriate agencies and organizations as disclosed in FinCEN's Privacy Act

[1] The BCTR reporting requirements are currently covered under the following OMB Control numbers: 1506–0004 (Financial Institutions other than Casinosons), and 1506–0005 (Casinos and Card Clubs).

[2] Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56.

System of Records Notice relating to BSA Reports.[3]

Current Action: FinCEN completed a review of the BCTR in preparation for renewal under the PRA. During its review, FinCEN considered suggestions for improvements to the report received from our stakeholders and filers. A data quality review of previously filed BCTRs suggested a change in reporting schemes had occurred since the initial BCTR was placed in service in March 2011. In particular, over the period of four years, FinCEN observed an increase in the number of holding or parent companies filing for their subsidiary institutions. Prior to this, the BCTR was predominantly filed by the financial institution where the transaction occurred. The current BCTR was not designed to record different filing and transaction locations. Additionally, FinCEN noted an inability to record the dollar value of the transaction in Part III when multiple transactions were reported. FinCEN also was made aware that the current BCTR does not provide a means of indicating ''shared branching'' transactions. Under the ''shared branching'' transaction, the employee identification number (EIN) of the financial institution where the transaction was conducted may not be known to the filing institution, so an ''unknown'' check box has been added.

In response to these identified deficiencies, FinCEN is proposing the following adjustments to the BCTR. To support recording the dollar amount of the transaction at the transaction location, cash-in and cash-out fields have been added to Part III. A new Part IV, has been added to record the entity actually filing the report through the BSA E-Filing System. A check box has been added to Part III to indicate when the information in Part IV is the same for Part III. This change will reduce the burden for filing the BCTR in those cases where the filer and transaction locations are the same. In Part I, Item 2d has been changed from ''Courier Service (Private)'' to ''Common carrier'' to reflect defined terminology. FinCEN has been advised by several non-bank financial institutions that the reference to ''teller(s)'' in the instructions is confusing and misleading since non-bank financial institutions normally do not employ ''tellers.'' FinCEN appreciates this feedback and proposes to define ''teller'' for the purpose of completing a BCTR as follows: *Teller: An individual employed by a covered financial institution that accepts currency in the normal course of business at the covered financial institution.* Example titles (but not limited to) are ''cashier,'' and ''cage operator.'' Finally, the completion order for the report has been revised. Part IV will be completed first, followed by Part III. This facilitates using the check box in Part III when the information is the same. Part I is then completed followed by Part II. The BSA E-Filing Batch filing specifications will be revised to reflect the above changes.

Type of Review: Initial review of the proposed changes to the BCTR.

Affected public: Businesses or other for-profit and not-for-profit financial institutions.

Frequency: As required.

Estimated Reporting Burden: Average of 25 minutes per report and 20 minutes recordkeeping per filing. (The reporting burden of the regulations at 31 CFR 1010.310 is reflected in the burden for the form.)

Estimated Recordkeeping and Reporting Burden: 45 minutes.

Estimated number of respondents: 82,255 (Includes depository institutions, broker-dealers, future commission merchants, introducing brokers in commodities, money services businesses, mutual funds, and casinos and card clubs.)

Estimated Total Annual Responses: 15,522,084.[4]

Estimated Total Annual Reporting and Recordkeeping Burden: 11,641,563 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the BSA must be retained for five years.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information; and (f) the proposed definition of the word ''teller.''

Jamal El-Hindi,

Deputy Director, Financial Crimes Enforcement Network.

Appendix

The added or updated data items for the BCTR are as follows:

Part I Rename item 2d from ''Courier Service (private)'' to ''Common carrier''
Part II Add a checkbox to item 24 to reflect ''Shared Branching''
Part III ''Financial Institution Where Transaction(s) Takes Place'' add a checkbox after the title to read: If Part III information is the same as Part IV, Check this box.
Add item 40 ''Dollar amount of item 25 Total cash-in transacted at this location.'' $_____
Add item 41 ''Dollar amount of item 25 Total cash-out transacted at this location.'' $_____
Part IV Add a new Part IV ''Filing Institution Information''
Item 42 Primary Federal Regulator (Drop down box)
Item 43 Legal name of financial institution
Item 44 Alternate name, *e.g.,* trade name, DBA
Item 45 EIN
Item 46 Address (number, street, and Apt. or suite no.)
Item 47 City
Item 48 State
Item 48 ZIP Code
Item 50 Type of financial institution (Check only one)
a. Casino/card Club
b. Depository institution
c. MSB
d. Securities/futures
z. Other (Specify) _____
Item 51 If 50a is checked, indicate type (check only one)
a. State Licensed casino
b. Tribal auth. casino
c. Card Club
z. Other (specify) _____
Item 52 Financial institution ID number (check one box to indicate type)
a. CRD Number
b. IARD number
c. NFA number
d. RSSD number
e. SEC number
Item 52f ID number _____
Item 53 Contact office
Item 54 Phone number _____
Item 54a Ext. _____
Item 55 Date filed *MM/DD/YYYY*

[FR Doc. 2016–01825 Filed 2–1–16; 8:45 am]

BILLING CODE 4810–02–P

[3] Department of the Treasury bureaus such as FinCEN renew their System of Records Notices every three years unless there is cause to amend them more frequently. FinCEN's System of Records Notice for BSA Reports System may be reviewed at *http://www.fincen.gov/foia/files/FinCEN_79_FR_20969.pdf.*

[4] Numbers are based on actual 2015 filings as reported through the BSA E-Filing System as of December 31, 2015.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Orders 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing the names of 1 individual and 1 entity whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten To Commit, or Support Terrorism.''

DATES: OFAC's actions described in this notice are effective on January 7, 2016.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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

Notice of OFAC Actions

On January 7, 2016, OFAC blocked the property and interests in property of the following 1 individual and 1 entity pursuant to E.O. 13224, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism'':

Individual

1. CHARARA, Ali Youssef (a.k.a. SHARARA, Ali Youssef; a.k.a. SHARARA, 'Ali Yusuf), Ghobeiry Center, Mcharrafieh, Beirut, Lebanon; Verdun 732 Center, 17th Floor, Verdun, Rachid Karameh Street, Beirut, Lebanon; Al-Ahlam, 4th Floor, Embassies Street, Bir Hassan, Beirut, Lebanon; DOB 25 Sep 1968; POB Sidon, Lebanon; Gender Male (individual) [SDGT] (Linked To: HIZBALLAH).

Entity

1. SPECTRUM INVESTMENT GROUP HOLDING SAL (a.k.a. SPECTRUM INTERNATIONAL INVESTMENT HOLDING SAL; a.k.a. SPECTRUM INVESTMENT GROUP HOLDING; a.k.a. SPECTRUM INVESTMENT GROUP SAL HOLDING; a.k.a. SPECTRUM INVESTMENT HOLDING; a.k.a. ''SPECTRUM HOLDING''), Floor 17, Verdun 732 Building, Rachid Karameh Street, Verdun, Beirut, Lebanon; Verdun 732 Center, Rachid Karame Street, Beirut, Lebanon; P.O. Box 113–5333, Beirut, Lebanon; Business Registration Document # 1990106 (Lebanon) [SDGT] (Linked To: CHARARA, Ali Youssef).

Dated: January 7, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–01828 Filed 2–1–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

West Los Angeles VA Medical Center; Draft Master Plan

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: This **Federal Register** Notice announces publication of the Draft Master Plan for the West Los Angeles (WLA) Department of Veterans Affairs (VA) campus (hereinafter referred to as the ''Draft Master Plan''). This notice also responds to public comments received in response to the Preliminary Draft Master Plan that VA published on October 22, 2015.

SUPPLEMENTARY INFORMATION:

Introduction

On October 22, 2015, the Department of Veterans Affairs (VA) published a notice in the **Federal Register** (80 FR 64061), seeking public comments for 45 days ending on Monday December 7, 2015, on the Preliminary Draft Final Master Plan for the Greater Los Angeles (GLA) VA Medical Center. As indicated in the **Federal Register** announcement, the campus consists of approximately 388 acres in the heart of Los Angeles. It has approximately 104 buildings, 39 of which are historic, 12 which are in need of seismic improvements, and a number of which are currently vacant or closed.

A key purpose for VA to solicit the public comments was to inform the Department's ongoing process to revitalize the campus and make it more Veteran focused (particularly for homeless, severely disabled, aging, and female Veterans); help end Veterans homelessness in greater Los Angeles, in coordination with key stakeholders (including former plaintiffs in the Valentini v. McDonald lawsuit, pertinent federal, state, and local authorities, legislators, Veteran Service Organizations, Veterans, local community partners, outside experts, and philanthropic entities); receive input to determine ways to make the campus more of a welcoming and thriving environment for Veterans and their families, whether living on or off campus, as they engage with one another on a peer-to-peer level, and receive the healthcare, benefits, and other services that they earned for serving our country; improve the processes and procedures regarding the review, execution, and administration of third-party land use agreements on campus, to ensure that those agreements that are not Veteran focused and not central to VA's mission and operations are as appropriate, modified, or terminated in support of VA's ongoing campus revitalization efforts.

We are pleased to advise that as a result of this public process, VA received a record number of comments: 1,002. They contained invaluable feedback on a range of issues pertinent to the campus, notably regarding: the enhancement of arts, entertainment, and recreation facilities and opportunities; ways to improve campus circulation, parking, security, and transportation; ideas for improving campus integration with the surrounding community; suggestions for increased and expanded clinical care including therapeutic and holistic approaches; housing and campus restoration; ways to improve and address third-party when you see agreements on campus; ways to improve benefits and memorial services on campus, as well as other amenities such as childcare services, legal counseling services, financial management services, and parking; operational issues including improvements to the organizational and leadership structures for the campus, to maximize the potential and desire to better connect Veterans to the campus and give them more opportunities to provide true insight and feedback; emphasis on improving transparency and accountability regarding the spectrum of healthcare, benefits, memorial service, and third-party activities throughout the campus; options to improve access, reintegration, employment, counseling, family well-being, and other services for Veterans on the campus and within the surrounding community.

VA has received numerous letters of support for legislation that Senator Dianne Feinstein and Congressman Ted Lieu have introduced in Congress to support VA's plan to revitalize the campus. The bill is known as S. 2013 and HR 3484, and is title the ''Los Angeles Homeless Veterans Act of 2015.'' The legislation would enable VA

to provide much needed supportive housing and services on the campus for Veterans and their families. It would expressly prohibit VA from permanently transferring, selling, or disposing of any of the land on the campus, and would require leases to comply with applicable laws and regulations in conjunction to pertinent congressional notification, reporting requirements and Inspector General Reviews. VA is grateful to Senator Feinstein and Congressmen Lieu for their leadership and support during this exciting journey, and strongly supports this legislation as it will serve as a key driver in VA's ability to successfully implement the Draft Master Plan for Veterans in the Greater Los Angeles area.

As we proceed towards adoption of the Draft Master Plan and commence its implementation, we envision the GLA campus serving as an exemplary model for other VA facilities nationwide. We also look forward to working with all stakeholders to ensure that this campus transformation coincides with VA's I care values of integrity, commitment, advocacy, respect, and excellence, relative to VA's overriding objective of putting Veterans in control of how, when, and where they want to receive their healthcare and services. With your continued support we are confident that VA will be able to fulfill President Abraham Lincoln's promise: ''to care for him who she'll have born the battle, and for his widow, and his orphan,'' by serving and honoring the men and women who are America's Veterans.

To most efficiently review and respond to the 1,002 comments in the **Federal Register**, VA organized the responses into nine categories. Comments often addressed a range of topics, resulting in a single comment classified under multiple categories. While there were 1,002 total comments submitted to the **Federal Register**, there were 1,732 total comment categorizations to account for the comments that addressed multiple topics. Approximately 60% of the 1,002 total comments fell within the scope of a master plan, while the remaining 40% addressed topics that are outside the scope of a master plan. VA will address all comments, both within and outside the scope of a master plan, in this document. The table below shows the number of comments received for each subcategory.

Comment subcategory	Total comment categorizations *
Arts, Recreation & Entertainment	93
Campus Circulation	29
Clinical	145
Connectivity	155
Housing/Campus Restoration	137
Land Use Agreements	397
Parking	134
Transparency & Accountability	146
Veteran Access	341
General Support	124
General Discontent	31
Total Comment Categorizations *	1,732

* A single comment can be classified in as many as four subcategories, allowing for more total comment categorizations than total comments.

In addition to the nine categories addressed in this document there were 124 categorizations of non-specific comments expressing general support for the Draft Master Plan and revitalization of the GLA campus, and 31 categorizations of comments expressing general discontent with VA.

Arts, Entertainment, and Recreation

Definition of Arts, Entertainment, and Recreation subcategory: Any comments requesting the development of new or altering the existing artistic, entertainment, or recreational facilities on the VA GLA campus.

Response

The public submitted comments on a breadth of topics under the umbrella of Arts, Entertainment, and Recreation. These comments most prominently covered the type and availability of recreational activities on the Greater Los Angeles campus. Recreation-related comments generally fell under a couple different categories. The first category was comments seeking a centrally located recreation center and other athletic, recreational, rehabilitative, and therapeutic facilities established on campus. These comments will be taken into consideration in the development of the Zone 5 outer ring of the campus, and in each development which has been set aside for development into recreational facilities. The Master Plan focuses on developing supportive housing in conjunction with a healthy assortment of recreational facilities, to serve the future resident population on campus.

The second category was comments seeking the development of meditative gardens and walking paths for Veterans, their families, and their visitors. VA received several comments requesting arts and entertainment options available on campus, as well. Comments focusing on the arts either requested a centrally located arts facility or an artistic means of honoring Veterans on campus. Commenters requested that the former allow space to make and refine art, including but not limited to screening rooms, audition rooms, makeup studios, a graphic design lab, studio space, and hobby shops. As with the requested recreational facilities described above, an arts facility could be developed in Zone 4 of the campus. Commenters focusing on the latter requested either that artist installations honoring Veterans be placed throughout the campus or a public memorial be placed on campus to allow Veterans to reflect, while also educating the public on the Veterans' sacrifices. The feasibility of artist installations throughout the campus will be explored and expanded, but the Grand Lawn in the southwest corner of the north campus is intended to be a quiet memorial space where Veterans and the general public can come to reflect and learn. The last major topic focused directly on the entertainment options to be available on campus. These comments were dedicated mainly to development of three venues: An outdoor concert space, a movie theatre, and an auditorium. The Greater Los Angeles VA can provide these spaces, by leveraging existing and future facilities. These issues are further addressed in the Chapter II, Section B section of the Master Plan.

Campus Circulation

Definition of Campus Circulation subcategory: Any comments discussing transportation within and around the campus.

Response

Campus Circulation concerns the movement of people and vehicles around, to, and from the GLA campus. Many comments noted deficiencies in the internal circulation of the campus, the lack of signage, and problems of way-finding throughout the campus. Commentators believe that the campus can be improved in its spatial organization to create a more easily legible plan. Overall, the majority of comments concerning internal circulation on campus asked for a variety of transportation modes and supporting infrastructure including pedestrian and bicycle pathways or routes; an improved, reliable shuttle to connect the various campus centers with convenient stop locations; and sufficient parking distributed throughout the campus.

There were also many comments voicing concern for circulation beyond the GLA campus. Commentators noted that in the attempt to make the campus

a ''hub'' for regional services, it is important to make it accessible to all Veterans in the region. Some comments pointed out the difficulty of getting to and from services and those at the VA campus, particularly pointing out the desirability of a pedestrian and bicycle access route on Constitution Avenue between the UCLA Medical School and the VA Hospital. Comments expressed concern for the already grueling traffic conditions in the Westwood/Brentwood/Sawtelle neighborhoods that would only be added to with the increase of residents and visitors on the VA site.

Responses to the Preliminary Draft Final Master Plan commented on the poor quality of walkways, grade management, and visible bus stops. Many requests were made to improve roadway infrastructure in the surrounding areas particularly for safe and accessible bus/shuttle stops as well as safer and better-designed entrance/exit ramps, bicycle lanes and pedestrian infrastructure along Wilshire Boulevard.

Lastly, a number of comments to the **Federal Register** concerned the current poor traffic flow in the West LA area and the probable impact of the hundred or even thousands of new residents and visitors the campus could bring to the area. The majority of comments asked for the Draft Master Plan to carefully assess and plan for the growing traffic conditions in areas around the campus.

Circulation is one of the key factors in the Draft Master Plan even in its earliest conceptual development. Circulation considerations include road, bike, shuttle and pedestrian networks; it also considers site features, programming, security and accessibility concerns. The Draft Master Plan evaluates all of the existing conditions both inside and around the GLA campus based on available data. There are a number of further studies that the plan recommends in order to optimize the GLA campus circulation network designs, including a more in-depth traffic study. Still, the circulation plan must aspire to optimize development of the site and contribute to restoring the campus to its legacy as a Soldier's Home.

A key priority of the Draft Master Plan is to include various forms of transportation and to accommodate all Veteran needs on campus. Therefore, the Draft Master Plan includes campus network designs for pedestrian, bicycle, shuttle routes as well as a newly designed road network. The campus will be able to be navigated by pedestrian, bicycle, shuttle and vehicle routes. The design of these routes creates zones with different levels of accessibility and security. The road networks were designed to establish a hierarchy of routes that will allow the campus to be efficiently connected and navigated. The Draft Master Plan includes a design for a shuttle system with four routes that provide transportation to each end of the campus as well as beyond the campus boundaries. The shuttle routes radiate from key areas of Veteran services and interaction, such as the Town Center and each of the neighborhood centers.

The site's topography, including features such as the bluff and arroyo, had a great influence on the Draft Master Plan's road network design. The grade change throughout the campus was a concern for pedestrian circulation throughout the site. It was important that pedestrian circulation have a wide range of foot paths including routes that pedestrians with physical disabilities would be able to move throughout the campus. The Draft Master Plan proposed a pedestrian ''spine'' that runs to each end of the campus, including a pedestrian bridge over Wilshire Boulevard, that maintains a maximum grade change of 5%, serving as an important mode of accessibility.

The Draft Master Plan also proposed a 2.5 mile loop dedicated to non-vehicular traffic. This loop will provide much needed recreational space for the campus as well as contribute to the transportation network of the campus. Apart from the loop, the plan provides over 5 additional miles of bicycle routes or lanes throughout the campus.

The Draft Master Plan adds an access point to the campus along the north side and locates this point south of the Barrington Post Office in order to reduce impact on the already high traffic intersections around Brentwood Village. The Draft Master Plan adds access points along the west side of campus, both from the north campus onto Bringham Avenue and from the south campus onto Federal Avenue. The Draft Master Plan also uses the Constitution Avenue entrance from Sepulveda Boulevard for direct access into a proposed Reintegration Zone within the Industrial District on the east side. Lastly, there are additional access points to the south campus that run parallel to the existing access point from Ohio Avenue, offering alternative access to the southbound I–405 freeway. The update plan now includes a proposal for the Transit Authority to have a station stop on the campus that will have passenger portals with access to the medical section of the campus and to the industrial and cultural district of the campus.

To address the surrounding community's concerns about traffic, the plan aims to reduce potential negative impact of campus development by providing multiple points of entry and egress to distribute traffic among multiple route options. The Draft Master Plan encourages multiple forms of transportation to reduce the dependency on the car. The objective is for the campus to be completely accessible for all Veterans without use of a private vehicle.

Clinical

Definition of Clinical subcategory: Any comments discussing the GLA Medical Center clinical care as well as any comments discussing expanding clinical care to include therapeutic and/or holistic approaches to Veteran care.

Response

VA received numerous comments on clinical care and Veteran services on the GLA campus. The majority of comments that fell under this category focused on specific service areas, including: Self-care instruction and volunteerism; peer-support specialist services (including a concierge); family and caregiver support (including child-care); housing (emergency, triage, bridge, transitional and permanent supportive); integrative (non-traditional, alternative) healthcare; rehabilitative services and healing arts; forums for traditional and non-traditional spiritual practice; education, vocational training and job placement; benefits, financial coaching and a full range of legal services; on-site employment and entrepreneurism, and recreation (individual/team sports, entertainment and leisure. Veteran comments consistently requested enhancements to these service areas to provide a holistic, 21st Century approach to Veteran care.

As VA revitalizes and reinvigorates the physical plan of the GLA campus, it must also add to the service plan both on the campus and in the community. The goal is to create a vibrant, welcoming, Veteran-focused, outcomes-driven model for Veterans and their families. The services must be strength-based, holistic, and aimed at helping the Veteran and the Veteran's family beyond the traditional medical models. Practically speaking, it means ''how'', ''when'' and ''where'' services are delivered must conform to the needs of the Veteran. This is particularly relevant for Veterans who are aging, disadvantaged, and suffering from chronic debilitating illnesses like schizophrenia and other psychotic disorders, Post-Traumatic Stress Disorder (PTSD), addictions and/or

other medical complications that compromise the Veteran's quality of life. It is particularly relevant for female Veterans who need designated space and services to address their unique healthcare and preventative healthcare needs. The campus must also have capacity to address the wellbeing and preventative care concerns of younger veterans transitioning back to civilian life by addressing their employment, educational, familial and other reintegration issues. Lastly there is a need to ensure

Services must also be delivered in partnership with VA's academic affiliates, including UCLA, and other VA partners who have expertise in caring for homeless and other vulnerable Veteran populations. As part of the service enhancements, it will be critical to create improved access processes through not only more effective staff and volunteer efforts, but also through a resource center and the use of Veteran peer supports (concierges) that improves the ease with which various parts of the campus can be navigated.

VA also received numerous comments related to existing services provided at the GLA campus (*i.e.,* Mental Health Services). Comments of this nature were outside the scope of a master planning process; however, are still important feedback as VA evaluates and enhances GLA campus operations. Comments relating to existing services and providers on campus were grouped and forwarded to VISN leadership for consideration as VA continues to evaluate the GLA Medical Center organizational structure.

For more information on proposed Veteran services' enhancements, please refer to Chapter II, Section B of the Draft Master Plan.

Connectivity

Definition of Connectivity subcategory: Any comment on integrating the campus into the surrounding community, or public access to the campus.

Response

There were some conflicting ideas on campus/public connectivity submitted to the **Federal Register**. A small number of comment submissions expressed the need for the campus to be entirely and strictly returned exclusively to the Veteran community. Opposing comments expressed the desire for some of the land to be utilized or even bestowed for public or community use. However, the majority of comments asked for the campus to have permeable space throughout the campus that encourages Veteran/civilian interaction and community building.

At 388 acres, the campus is big enough to accommodate a wide variety of needs and conditions, but it must be used to service the Veteran community. This includes the facilitation of reintegration and community building desired by so many Veterans. The VA campus has provided valued resources for the communities of Los Angeles for decades. However, it is important that the Draft Master Plan focus on providing an accessible, community rich, therapeutic space for Veterans. The Draft Master Plan includes a variety of places that can create a sense of security and safety for Veterans, and other more permeable spaces that can be shared with others as appropriate in order to ''emphasize community, not campus''.

The Draft Master Plan focuses on making the campus a destination for all Veterans. The site is meant to be a home and a community. The planning process recognizes 21st century models for re-integration that connect with the community-at-large and the Draft Master Plan was devised to build connections not just in spatial design but also in the programming of supportive services on campus. The plan includes major advancements in campus programming aimed at drawing in Veterans of all demographics, as well as to give Veterans the opportunity to create programs that can include members of the public, working together to enhance the Veteran community on campus. For example, beyond the need for Veteran housing and services, the plan proposed to incorporate cultural activities, community spaces, recreation and entertainment, and Veteran employment opportunities. The intent is to discourage the isolation of Veterans by designating physical zones on campus that have directed purposes and uses with varying degrees of public and Veteran permeability.

The Draft Master Plan proposed five zones within the campus. The most open and accessible of the zones, Zone 5, forms a ring around Zones 2, 3, and 4 that hold the majority of non-medical Veteran services including most of the campus housing. This peripheral zone includes the campus recreational areas and green space as well as the campus industrial district and is intended to be the permeable outer ring of the campus. Although accessible and open, the outer ring also acts as a subtle barrier, wrapping the Veteran community within the exclusive core. The inner zones will be more exclusive areas that limit public access and even create some spaces only accessible to resident Veterans.

To address security concerns, the plan utilizes organizational and landscaping techniques to create soft barriers throughout the campus. This landscape and organization of the campus separates programs and areas that are exclusive to Veterans such as supportive housing and some counseling services. The organization of space as well as the use of landscape divides these spaces from the more permeable areas of the campus. In some particular situations, times or areas, a gate or access cards may be employed to further strengthen security of areas of the campus and select buildings.

The Veteran Vocational Enterprise and Cultural Center should be an important part of Veteran reintegration through public interface. This area of the campus should serve as a center of reintegration services and will include education, training and career counseling as well as entrepreneurial, employment and community spaces. As it is part of a public access zone, the area would include public infrastructure such as parking to accommodate its new uses. This area should utilize public interest and volunteers to form an urban space that will help to ease Veterans into civilian life in the Los Angeles area.

Also in Zone 5 is recreational and open space on the north end of the campus. Already acting as green space, with a more efficient use of space this area can provide the Veteran community and possibly the neighboring communities with open space, gardens and fields. For example, the area that is currently designated as the Veteran's parking lot servicing Brentwood Village, can be utilized by Veteran-owned businesses and still provide parking to the neighboring community. Central to this concept of public access is that it is Veteran-owned and Veteran controlled and the public is welcome to share it by invitation.

Housing & Campus Restoration

Definition of Housing & Campus Restoration subcategory: Any comments discussing housing development on campus, methods to foster a sense of community among the campus residents, or the physical revitalization of the campus.

Response

VA received numerous **Federal Register** comments related to housing for Veterans on the GLA campus. There was overwhelming support for providing housing for Veterans on the campus, and the majority of comments addressed the types of housing to be provided.

Some common housing themes in the comments received include (1) increase the amount of housing over the total units originally proposed (2) add housing units as quickly as possible (3) ensure all housing is low cost and affordable to Veterans (4) various types of housing (*i.e.* housing and neighborhoods with character) and (5) the need for permanent supportive housing. Some common themes also emerged regarding the target population for the housing which generally fall into the following three categories: (1) Ensure housing is open to those Veterans with the most need (2) provide housing for female veterans with and without dependents (3) allow access for Veterans in need but not identified in the specific target populations. Finally, the comments expressed a desire to build a sense of community with the housing as opposed to purely functional housing.

VA committed to bringing affordable housing for Veterans to the GLA campus, and the Draft Master Plan now includes housing for the projected need of 1200 units, based on the Housing Needs and Analysis contained in Chapter II. This accounts for 300 more units than was identified in the initial plan. Chapter II of the Draft Master Plan identifies specific target populations (severely disabled Veterans, including chronically homeless Veterans; aging Veterans; and female Veterans with and without dependents), but would be available to all Veterans in need. The Draft Master Plan has planned for this housing to be developed with a sense of 'community', which is described in detail in Chapter V of the Draft Master Plan.

Land Use Agreements

Definition of Land Use Agreements subcategory: Any comments discussing existing use of or proposing future use of land by a third party organization including UCLA, Brentwood School, Barrington Park operators, and the Westside Breakers.

Response

Feedback provided to VA during this master planning process from Veterans, Veterans Service Organizations, local authorities, congressional delegates, philanthropic organizations, the local community, and other stakeholders, expressed a consistent desire for the campus to: maximize the potential to reflect a transformed, strategic, and informed configuration and implementation focused on Veterans and their families; provide convenient access to facilities and resources via all pertinent modes of transportation; function effectively with appropriate levels and types of VA and non-VA care and staffing in pertinent and underpopulated disciplines; extend an inviting, warm, and welcoming environment to attract Veterans and their families across all spectrums; function effectively and in harmony with the surrounding community and business activities; and foster employment and career opportunities to help Veterans improve their lives and continue as productive members of society—all as envisioned in the 1888 deed that conveyed the campus to the United States.

Consistent with this appreciated feedback, VA's vision for the campus includes a goal to provide various types of housing on campus for Veterans and their families, particularly homeless, severely disabled, aging, and female Veterans. This will improve the choice for Veterans to either live on or off campus, in dignified facilities reflective of the sacrifices they have made for their country. If enacted, the Los Angeles Homeless Veterans Leasing Act of 2015 (*i.e.,* S. 2013 and H.R. 3484) that Congressman Ted Lieu introduced in the House on September 10, 2015, and Senator Dianne Feinstein introduced in the Senate on October 6, 2015, would allow VA to provide Enhanced-Use (EU) Leases at the GLA campus.

VA's EU Lease authority as contained in 38 U.S.C. 8161–8169, would enable us to outlease parcels on the campus to selected lessees for terms of up to 75 years, to develop, operate, and maintain ''supportive housing'' for Veterans and their families. The types of housing would be a myriad of housing options to strategically serve Veterans in need, regardless of era of service. Such housing types would consist of transitional housing, single room occupancy housing, congregate living housing, independent living housing, assisted living housing, and other modalities of housing. When using this authority, VA would be expressly prohibited from disposing of the land and improvements involved in the projects at the GLA campus. At the end of the lease term, the real property would revert back to VA. Currently at other VA campuses nationwide, VA has 1,909 units of EU Lease housing currently operational, 1,046 units under construction, and 494 units planned, for a total of 3,994 units.

These two bills would also help VA revitalize the campus, by allowing VA to grant leases for terms of up to 50 years, to provide amenities and services, where Veterans can engage with one another and their families, and pursue a wide range of activities centered on their social, entertainment, healing, spiritual, employment, recreational, and rehabilitative interests and well-being.

Examples include spaces to accommodate Veteran and family interaction, peer support, restaurants, eateries, child care, legal and benefits assistance, movie and play theaters, art studios, a Veteran employment center, sports fields, a gymnasium, swimming pool, golf course, bike paths, parking spaces, dog park and kennel, church services, weddings, funerals, internments, non-profit Veteran support centers, hotel, dentist office, motorcycle training, a metro stop, and retail areas.

The two bills would also allow VA to grant a lease to institutions of the state of California, for a term of up to 10 years, in return for the provision of services to Veterans. Such services may include activities to directly support the medical, clinical, therapeutic, dietary, rehabilitative, legal, mental, spiritual, physical, recreational, research, and counseling needs of Veterans and their families. In an effort to maximize that opportunity, VA will explore the viability of further leverages to the current medical and academic affiliation with the University of California Los Angeles (UCLA). The providing of such services for Veterans and their families on and off the Greater Los Angeles campus, including through sports, recreational, educational, employment, and entertainment activities at the existing Jackie Robinson baseball stadium, will be a force multiplier in VA's efforts to revitalize the campus.

It will enable UCLA to confirm and demonstrate its firm commitment going forward, to ensure that its relationship with VA, Veterans, the local community, and other stakeholders, is one of true unwavering significance and substance in those areas for Veterans, as well as for educating future generations of doctors, nurses, researchers, and academics at VA and UCLA sites of care. This synergy could provide a framework and model to improve other academic and medical affiliations between VA and other medical schools and educational institutions nationwide, and provide benefits that transcend the paradigm of VA, the universities, institutions, and Veterans involved. For example, it could assist VA with its other potential partners such as: The Brentwood School, which has offered to provide therapy and recreational opportunities on its campus, along with scholarships for children of Veterans; the Red Cross, which has offered to assist VA in its disaster preparedness responsibilities and obligations, which will help improve campus capabilities and ensure

sustainability; and bolster VA's ongoing implementation of key Veteran programs like the G.I. Bill.

While working to achieve this vision for the campus, VA will evaluate existing and future land use agreements to ensure they are ''Veteran focused.'' This means the arrangements must provide direct benefits to Veterans and their families, and provide negotiated fair market rent to VA. VA will also continue its ongoing efforts to terminate any existing third party use arrangements, which fall outside of providing direct benefits to Veterans. VA will do so in a manner that takes into account the legal parameters for doing so, based on the underlying contract provisions at issue, and the need for VA to be stewards of tax payer resources. And it will be VA's objective going forward, to work with Congress to ensure that if S. 2013 or H.R. 1543 is enacted, the revenues paid to VA from Veteran focused land use arrangements, will be directed to help renovate the GLA campus. Doing so will help us maintain and renovate the campus in accordance with applicable law and regulations, along with funding that VA receives through other prioritization, budgetary, congressional authorization and appropriation legislative, and enactment processes.

We will also effectuate these land use activities in a way that fosters ongoing engagement with and input from Veterans, Veteran Service Organizations, the local community, and other stakeholders, and ensures the continued safety of Veterans, VA personnel, and other persons traversing on and off the campus. And it is worth repeating that such reuse activities will not include VA selling or disposing of any of the land at the campus to third party entities. And the land use projects and activities will comply with all pertinent laws and regulations. This includes those regarding environmental and historic preservation, such as the National Environmental Policy Act (42 U.S.C. 4321–4370h); the National Historic Preservation Act (16 U.S.C. 470, *et seq.*); and the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601–9675).

Going forward, VA's efforts to revitalize the campus will only include 'Veteran focused' agreements, or agreements that result in additional healthcare, benefits, services, or resources being provided directly to Veterans and/or their families on the GLA campus. Monetary proceeds paid to VA alone will not constitute an acceptable agreement. Neither will agreements that only benefit the public at large, versus Veterans and their families. This concept will be a key consideration in terms of how existing and any future land use agreements are evaluated for approval, rejection, or termination.

VA's review of any proposed third party land use agreements will entail a linear, multilayered process, to ensure adequate due diligence occurs. At a minimum, each agreement will receive input from the following VA personnel:

(1) West LA Chief of Outreach
(2) VAMC Director
(3) VISN 22 Director
(4) SAO West Land Use Contracting Officer
(5) The San Francisco Regional Counsel Office (now known as the Pacific District (North))
(6) OGC's Real Property Deputy Chief Counsel in VA Headquarters

This Veteran focused intent for all land use agreements at GLA going forward is absolutely appropriate and warranted, particularly given the lessons learned from the August 2013 District Court for Central District of California decision in the *Valentini* v. *McDonald* case, which held that nine of the existing land use agreements were illegal as they did not constitute a valid sharing of ''health-care resources'' under VA's Enhanced-Sharing Authority. Given those two clear principles, and as part of the ''Principles for Partnership Agreement'' that settled the Valentini lawsuit in January 2015, VA Secretary Robert McDonald commissioned an extensive review of the land use agreements at GLA, including those nine voided agreements. The nine agreements voided under the Court decision were as follows:

1. Brentwood School
2. Sodexho Marriott Laundry Services
3. UCLA Regents (Baseball Stadium)
4. 20th Century Fox TV
5. Veterans Park Conservancy
6. Westside Breakers Soccer Club
7. Westside Services Parking
8. TCM Farmer's Market
9. Filming Agreement ESAs

All land use agreements at the GLA campus, including the above nine agreements, have or are being reviewed, to determine whether they are or can be made sufficiently Veteran focused (thru fair market value rent to VA and services directly benefitting Veterans and their families), and fit within the overall needs and vision for a revitalized campus. To date, the terminated agreements include Richmark Entertainment; various filming agreements; Sodexo laundry agreement; 20th Century Fox; Westside Breakers; TCM Farmer's Market; and Veterans Garden (Rancho Santa Ana). VA is also in negotiations with the principals of certain existing land use arrangements (*e.g.,* Brentwood School, UCLA, Westside Services, and Veterans Park Conservancy), to help assess the potential for Veteran focused consideration, and compatibility with the Draft Master Plan. As appropriate for those arrangements deemed to be Veteran focused, VA will seek to negotiate deals that are good for Veterans, their families, and our nation's tax payers, through a combination of fair market value rents, and Veteran focused consideration (such as in-kind consideration and use of existing and future facilities under those arrangements for purposes tied to recreation, rehabilitation, therapy, mental health support, legal and addiction services). The consideration generated will help VA significantly to transform and revitalize the campus into a state-of-the art model for other VA campuses nationwide.

Parking

Definition of Parking subcategory: Any comments discussing current or potential parking issues on campus including the Brentwood Village parking lot.

Response

VA received a number of **Federal Register** comments related to parking on the Greater Los Angeles campus. Parking related comments generally fell under one of two topics; comments requesting adequate parking for the main hospital building and comments regarding the Brentwood Village parking lot on the northern portion of the campus. The majority of comments regarding the Brentwood Village parking lot were in support of keeping this lot open for public use while simultaneously building Veteran focused partnerships with local community and businesses; however, there were also some comments that supported closing the Brentwood Village lot off to the general public.

VA is aware of the need for adequate parking at the main hospital building and throughout the campus, and as part of the implementation of the Draft Master Plan VA plans to improve the efficiency of the existing parking assets. Moreover, a critical component of the New Bed Care Tower (Replacement Hospital) project will be associated parking that should accommodate all parking demand for Veterans, employees, and visitors at the GLA Medical Center.

VA would not be opposed to keeping the Brentwood Village parking lot

operational, as long as any land use agreement is Veteran focused and complies with the land use procedures described in further detail in the Land Use Agreements section of this document.

To maintain flexibility for the potential of continued public use, VA has edited the Preliminary Draft Final Master Plan by relocating the campus access point that had previously required the demolition of the Brentwood Village parking lot. Additional information regarding the proposed parking can be found the Draft Master Plan, Chapter V, Section B—Master Plan Framework, Subsection Campus Mobility Plan.

Transparency & Accountability

Definition of Transparency & Accountability subcategory: Any comments discussing or raising issues to the VISN or VAMC level leadership as well as any comment proposing the implementation of an external campus oversight council.

Response

A number of Transparency & Accountability comments raised concerns regarding the transparency of VISN and VAMC during strategic decision making processes. These comments generally requested that procedures be put into place to ensure that VA leadership keep the local Veteran population apprised of developing changes within the VISN and on GLA campus. The other common thread among these comments stressed that VISN and VAMC level leadership must hold poorly performing employees accountable. Many of these comments were general in nature, but noted past unpleasant experiences at VISN 22 facilities or at GLA campus specifically. They asked that VISN and VAMC level leadership open themselves to criticism more frequently and respond quickly.

To address concerns over transparency, VA plans to augment its current efforts to provide stakeholder updates and open the floor to Veteran and civilian input through regular VSO meetings, congressional meetings, and Town Halls. The first of such meetings will be planned for 90 days after VA Secretary Robert McDonald adopts the Draft Master Plan. In collaboration with Veteran groups, community partners and other stakeholders, VA will periodically review and reevaluate the Draft Master Plan every three years, to ensure the plan continues to meet the evolving needs of Veterans. The feedback process will be continued as VA selects new leadership for the GLA Campus (*i.e.,* three senior executives—specifically the new GLA Medical Center Director; the Director of Land Use Agreement & Community Engagement and Reintegration Services; and Director of Community Based Care, including the Sepulveda campus and Community Based Outpatient Clinics).

To more promptly respond to criticisms of provided services, VA plans to strengthen the MyVA communities in the Los Angeles area. MyVA Communities are a collaborative network of Veterans, advocates, resources, and other stakeholders who organize through community Veteran Engagement Boards, to improve outcomes for Veterans, and their communities. The MyVA Communities model enables Veteran advocates, service providers, Veterans, and stakeholders to have a voice in providing input and feedback to VA, and identifying their goals and ways to engage and improve service delivery for Veterans and their families. The Los Angeles area Veteran Engagement Boards will carry the visions of the Draft Master Plan forward. Building and sustaining these avenues for continued Veteran feedback is a critical component of maintaining the Draft Master Plan, as a guiding resource for revitalizing and enhancing the GLA campus. All of this will be done to ensure appropriate oversight and Veteran collaboration while increasing transparency and accountability.

The Draft Master Plan document introduces the Community Veterans Engagement Board which is a collaborative, coordinated process to amplify the Veterans voice in matters that affect how, where, and when they receive care and services. Additional information can be found in Chapter III of the Draft Master Plan.

Veteran Access

Definition of Veteran Access subcategory: Any comments emphasizing the need to promote access of specific Veteran populations on campus or requesting additional services to eliminate barriers to accessing the campus. These comments also include various other operational requests to promote and enhance Veteran access to the campus such as Veteran employment and education opportunities, family services, Veteran Benefits assistance, Transition Center, legal counsel services, emergency preparedness services, extended hours of operations, etc.

Response

The public comments suggested that there should be no VA sale of any portions of the campus, to third parties for commercial uses. Other comments indicated a desire for a facility to add a focus aimed at assisting with the transition of active-duty military personnel to Veteran status. Other comments regarded the need to expand existing mental health, addition services, and transition services for active duty members entering the VA system. Comments also expressed desire for VA to collocate VBA onto the campus for improved ease to conduct business relating to VA's benefits system. Others want VA to establish a wellness or well-being center on campus, where Veterans can engage in peer to peer interaction and socializing, each other and their families. Other comments involved a need for support and special housing facilities for Veterans comprising the underserved populations—namely those that are homeless, severely disabled, aging, and women—particularly females with children, to assist in the recovery for those that have suffered sexual trauma, mental or physical abuse, or PTSD.

In response to these comments received, it is first important to note that neither VA nor the Draft Master Plan contemplated VA selling or disposing of any of the land and improvements at the Greater Los Angeles campus. VA envisions the development of supportive housing on campus pursuant to legislation Congress recently introduced in both houses of Congress—specifically, the Los Angeles homeless Veterans leasing act of 2015 (Senate Bill S. 2013 and corresponding house Bill HR 3484). VA has a phased development plan of 1,200 supportive housing units on the campus. The proposed timeline involves developing 60 units within the next 12 months, 150 units over the next 24 to 30 months, 280 units over the next 30 months, 280 units over the next 4 to 5 years, and 430 units over the next 6 to 10 years—all totaling 1,200 units. VA plans for those units to have special emphasis on homeless, severely disabled, aging, and female Veterans. The goal will be to strategically locate units designated for those underserved populations, in a manner to provide convenient access to the pertinent care and services that they will need, in a safe setting and environment. Along with development of those units would be Veteran focused supportive service leases, geared towards Veteran Health and wellness, nutrition and spiritual wellness, education, vocational training, skills building, peer activities, socialization, and physical recreation, assistance with legal issues and federal benefits,

volunteerism, family support services, child care services, and transportation.

Regarding the issue of helping active-duty service members to transition to Veteran status, VA plans to offer and provide transition services in the southwest corner of the VA campus, near the U.S. Army Reserve Center and Army National Guard Recruiter facilities adjacent to the GLA campus. VA understands that service members often encounter a series of needs as they transition out of the military. Such needs could include securing employment and housing, addressing physical or mental health issues, and adjusting to civilian culture. The ease through which this transition is made has a profound impact on post service well-being. To complement the planned transition services, VA has also established a new Welcome Center in Building 257, where Veterans have access to a facility and setting that facilitates peer to peer interaction and socialization, and VA and non-VA support providers. Improved transition into VA will heighten the existing need for expanded primary care and targeted hiring. VA plans to address those needs through more targeted VA hiring at the campus, and improved options for Veteran care through the Choice Act. For more information on these issues, see Chapter IV, Figure V–7, and Chapter V of the Draft Master Plan.

The Draft Master Plan is available to the public at *http://www.losangeles.va.gov/.*

Dated: January 29, 2016.

Michael Shores,

Chief Impact Analyst, Office of Regulation Policy & Management.

[FR Doc. 2016–01940 Filed 2–1–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Commission on Care

ACTION: Notice of Meeting

In accordance with the Federal Advisory Committee Act, 5 U.S.C., App. 2, the Commission on Care gives notice that it will meet on Tuesday, February 9, 2016, at the American Legion National Headquarters Office, 1608 K Street NW., 7th Floor Conference Room, Washington, DC, 20006. The meeting will convene at 8:30 a.m. and end no later than 5:30 p.m. This meeting notice is being provided with less than 15 calendar days of notice due to inclement weather, which delayed the meeting's final confirmation. The meeting is open to the public.

The purpose of the Commission, as described in section 202 of the Veterans Access, Choice, and Accountability Act of 2014, is to examine the access of veterans to health care from the Department of Veterans Affairs and strategically examine how best to organize the Veterans Health Administration, locate health care resources, and deliver health care to veterans during the next 20 years.

No time will be allocated at this meeting for receiving oral presentations from the public. The public may submit written statements for the Commission's review to *commissiononcare@va.gov*. Due to building security requirements, any member of the public wanting to attend must register their intention by emailing the Designated Federal Officer, John Goodrich, at *john.goodrich@va.gov,* no later than 5:00 p.m. on Friday, February 5, 2016.

Dated: January 28, 2016.

John Goodrich,

Designated Federal Officer, Commission on Care.

[FR Doc. 2016–01829 Filed 2–1–16; 8:45 am]

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Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 440

Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2348–F]

RIN 0938–AQ36

Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health

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

ACTION: Final rule.

SUMMARY: This final rule revises the Medicaid home health service definition consistent with section 6407 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to add requirements that, for home health services, physicians document, and, for certain medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes. This rule also aligns the timeframes for the face-to-face encounter with similar regulatory requirements for Medicare home health services. In addition, this rule amends the definitions of medical supplies, equipment, and appliances. We expect minimal impact with the implementation of section 6407 of the Affordable Care Act and section 504 of MACRA. We recognize that states may have budgetary implications as a result of the amended definitions of medical supplies, equipment and appliances. Specifically, this rule may expand coverage of medical supplies, equipment and appliances under the home health benefit. There will be items that had previously only been offered under certain sections of the Act that will now be covered under the home health benefit.

DATES: *Effective date:* This rule is effective on July 1, 2016.

Compliance date: Based on public comments, we recognize that there may be operational and budgetary implications with this rule and that states and providers may need time to implement this provision. To ensure that states and providers are implementing the rule appropriately, we are delaying compliance with this rule for up to one year if legislature has met in that year, otherwise 2 years.

Exception for State Legislation.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 *et seq.*), which the Secretary determines requires state legislation in order for the respective plan to meet one or more additional requirements imposed by this rule, the respective state shall not be regarded as failing to comply with the requirements of this rule solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature that begins after the date of enactment of this rule. For purposes of the previous sentence, in the case of a state that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature. States will be expected to be in compliance by July 1, 2017 or July 1, 2018 based on legislative timeframes as described above.

FOR FURTHER INFORMATION CONTACT: Ali Smilow, (410) 786–0790.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule implements section 6407 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148), which adds the requirement that physicians document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes when ordering home health services. More specifically, section 6407(b) of the Affordable Care Act applies to Medicaid face-to-face encounter requirements set forth in the Medicare statute. Additionally, on April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), became law. Section 504 of this law amended the underlying Medicare requirements at section 1834(a)(11)(B)(ii) of the Social Security Act (the Act) to allow certain authorized non-physician practitioners (NPP) to document the face-to-face encounter. This final rule adopts in large part the provisions proposed in the proposed rule issued on July 12, 2011 (76 FR 41032), but includes conforming changes to the provisions of the proposed rule to reflect the revisions made by MACRA to the underlying Medicare face-to-face encounter requirements. In addition, this final rule clarifies that Medicaid home health services and items are not limited to home settings, and makes additional changes to the requirements for coverage of medical supplies, equipment and appliances under the home health benefit.

2. Summary of the Major Provisions

The final rule requires that for the initial ordering of home health services, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires home health services occurred no more than 90 days before or 30 days after the start of services. The final rule requires that for the initial ordering of certain medical equipment, the physician or authorized NPP must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. The face-to-face encounter for home health and medical equipment may be performed by the physician or certain authorized NPPs. The final rule maintains the role of the physician in ordering Medicaid home health services and medical equipment.

The rule also codifies current Medicaid policies for coverage of home health services, including clarifying in the definition of medical supplies, equipment, and appliances that items must be suitable for use in any setting in which normal life activities take place, other than a hospital; nursing facility, intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Additionally, the rule defines home health supplies, equipment, and appliances, to better align with the Medicare program's definition of durable medical equipment (DME) at § 414.202.

The rule codifies the policies set forth in September 4, 1998 guidance, about the use of lists or other presumptions in determining coverage of items under the home health benefit for medical equipment, including the following three points: (1) States may have a list of preapproved medical equipment, supplies and appliances for administrative ease, but not as an absolute limit on coverage; (2) States must provide and make available to individuals a reasonable and meaningful procedure for beneficiaries to request medical equipment, supplies or appliances not on the list based on a showing of medical necessity; and (3) Individuals must be informed of their

right to a fair hearing to appeal an adverse action. Additionally, the rule clarifies our interpretation that the Medicaid statute does not permit absolute exclusions of coverage as medical equipment, supplies, or appliances.

These clarifications reflect the principles embodied in the holdings of *the Skubel* v. *Fuoroli, 113 F.3d 330 (2d. Cir. 1997)* and *Detsel* v. *Sullivan, 895 F.2d 58 (2d Cir.1990*) decisions into the requirements for the provision of home health services by clarifying that Medicaid home health services may not be limited to services furnished in the home and revising the current regulatory language to specify that home health services may be provided, as appropriate, in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.

3—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Total benefits
Physician and certain non-physician practitioners (NPP) for DME documentation of face-to-face encounter with the Medicaid eligible beneficiary within reasonable timeframes when ordering home health services.	Although this provision applies to Medicaid in the same manner and to the same extent as the Medicare program, no estimates (costs or savings) were noted for the Medicaid program as data to determine these estimates is unavailable. For Medicare, the overall economic impact of this provision is an estimated $920 million in savings to the Medicare program from 2010–2014 and $2.29 billion in savings from 2010–2019.	The overall benefit of this rule is the expected increase in program integrity resulting in more quality home health services for Medicaid beneficiaries. Additionally, this rule will potentially serve to provide individuals with disabilities a greater ability to engage in normal activities of daily living.

B. Background

Title XIX of the Act requires that, to receive federal Medicaid matching funds, a state must offer certain basic services to the categorically needy populations specified in the Act. Home health care is a mandatory services for Medicaid-eligible individuals who are entitled to nursing facility services, which includes the basic categorically needy populations who receive the standard Medicaid benefit package, and can also include medically needy populations if nursing facility services are offered to the medically needy within a state. Home health services include nursing services, home health aide services, medical supplies, equipment, and appliances, and may include therapy services (physical therapy, occupational therapy, speech pathology and audiology services). For a state to receive federal Medicaid matching payments for such services, current Medicaid regulations require a beneficiary's physician to order home health services as part of a written plan of care reviewed every 60 days.

At section 6407 of the Affordable Care Act, new Medicare requirements were set forth for face-to-face encounters to support claims for home health services, and for DME, which were also made applicable to Medicaid.

Specifically, sections 1814(a)(2)(C) of the Act under Part A of the Medicare program, and section 1835(a)(2)(A) of the Act under Part B of the Medicare program were amended to require that the physician, or certain allowed NPPs, document a face to-face encounter with the individual (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act), before making a certification that home health services are required under the Medicare home health benefit. Section 1814(a)(2)(C) of the Act indicates that in addition to a physician, a nurse practitioner (NP) or clinical nurse specialist (CNS) (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by state law), or a physician assistant (PA) (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters before the start of home health services.

Section 6407 of the Affordable Care Act also amended section 1834(a)(11)(B) of the Act to require that physician orders for DME must be supported by documentation by the physician of a similar face-to-face encounter with a physician or specified NPPs. The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for DME as for home health services, except that certified nurse-midwives are not included.

The timing of the face-to-face encounter for either home health or DME is specified as being within the 6-month period preceding the written order for DME, or other reasonable timeframe specified by the Secretary.

Section 6407(d) of the Affordable Care Act, provides that the requirements for face-to-face encounters in the provisions described above shall apply in the case of physicians making certifications for home health services under title XIX of the Act in the same manner and to the same extent as such requirements apply in the case of physicians making such certifications under title XVIII of such Act.

The purpose of this regulation is to implement this statutory directive in the Medicaid program.

II. Summary of Provisions of the Proposed Rule

1. New Home Health Face-to-Face Requirements

In the proposed rule, we sought to implement the face-to-face requirements of section 6407 of the Affordable Care Act in a manner consistent with existing Medicaid requirements and practices. For example, in implementing the face-to-face encounter requirements of section 6407 of the Affordable Care Act with respect to home health services generally, we took into consideration the longstanding regulatory requirements under § 440.70 that provide that a physician must order an individual's services under the Medicaid home health benefit. We read the term ''order'' to be synonymous with the Medicare term ''certify.'' For purposes of this rule, we used the term ''order'' in place of the Affordable Care Act's use of ''certify.''

We did not view implementation of section 6407 of the Affordable Care Act as supplanting these existing Medicaid regulatory requirements related to physician orders; the new face-to-face process is consistent with those requirements. We proposed amending the Medicaid regulations at § 440.70 to incorporate both the general home health and the medical equipment face-to-face requirements. Because DME is

not a term used in Medicaid in the same manner as in Medicare, we proposed to use the Medicaid term ''medical supplies, equipment, and appliances'' or the shortened version ''medical equipment.'' Additionally, we proposed that the face-to-face encounter can be performed through the use of telehealth, which is described in more detail in section I. of this final rule.

As previously indicated, we proposed that for home health services, the face-to-face encounter occurred no more than 90 days before or 30 days after the start of services. To align with Medicare timing requirements at § 424.22(a)(1)(v), we revised the timeframes for medical equipment and the final rule requires that for the initial ordering of medical equipment, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. These timeframes are applicable to face-to-face encounters performed through telehealth.

2. Specification of Non-Physician Practitioners (NPPs) Authorized To Perform Face-to-Face Encounters

Under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, face-to-face encounters for home health services may be conducted by a NP or CNS (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by state law), or a PA (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician. A similar definition of NPPs applies for DME under section 1834(a)(11)(B) of the Act, with one exception: Certified nurse-midwives are not included in the list of NPPs.

3. Other Medicaid Home Health Policy Changes

a. Codification That Home Health Services Cannot Be Restricted to Individuals Who Are Homebound or to Services Furnished Solely in the Home

We proposed that home health services may not be subject to a requirement that the individual be ''homebound.'' In addition, we proposed that home health services cannot otherwise be restricted to services furnished in the home itself. These policies reflect longstanding CMS interpretations of the scope of the home health policy and were discussed in a July 25, 2000 letter to State Medicaid Directors, Olmstead Update No. 3 setting forth federal interpretations of applicable law relevant to state efforts to comply with the requirements of the Americans with Disabilities Act (ADA) in light of the Supreme Court decision in *Olmstead* v. *L.C., 527 U.S. 581 (1999).* In Attachment 3–g to that letter, we set forth our interpretation that a requirement that home health recipients be homebound was inconsistent with the mandatory nature of the home health benefit, and the longstanding regulatory provisions at 42 CFR 440.230 and 440.240. These regulatory provisions provide that mandatory benefits must be sufficient in amount, duration and scope to reasonably achieve their purpose, may not be arbitrarily denied or reduced in scope based on diagnosis, type of illness, or condition, and that the same amount, duration and scope must be available to any individual within the group of categorically needy individuals and within any group of medically needy individuals.

We also proposed that Medicaid home health services may not be limited to services furnished in the home. This policy reflects the principles set forth in prior court cases on whether home health services and private duty nursing can be limited to services furnished in the home. In *Skubel* v. *Fuoroli, 113 F.3d 330 (2d. Cir. 1997)* the court found that the Medicaid statute did not address the site of care for the mandatory home health benefit. The court found that the state could not limit coverage of home health services to those provided at the individual's residence. Previously, in 1990, the Second Circuit had applied similar principles to invalidate a regulation that limited the provision of private duty nursing services to an individual's residence. The case, *Detsel* v. *Sullivan,* 895 F.2d 58 (2d Cir. 1990), involved children suffering from severe medical conditions. Following the *Detsel* case, CMS, then the Health Care Financing Administration, adopted the court's standard and issued nationwide guidance eliminating the at-home restriction on private duty nursing. To date, we have not issued similar guidance requiring nationwide adoption of the *Skubel* ruling.

b. Clarification of the Definition of Medical Supplies, Equipment, and Appliances

An important component of the Medicaid home health benefit is coverage of medical supplies, equipment, and appliances, under § 440.70(b)(3). The current regulation does not further define the terms, except to indicate that the items should be suitable for use in the home. Although CMS has read this phrase to refer only to the type of items included in the benefit (excluding those types of items that are only furnished in institutional or provider settings), it has been susceptible to reading as a prohibition on use of covered items outside the home. We proposed revisions to this section to clarify that it is not a limitation on the location in which items are used, but rather refers to items that are necessary for everyday activities and not specialized for an institutional setting. Thus, we proposed to indicate that the items must be suitable for use in any non-institutional setting in which normal life activities take place. This would clarify that although states may continue to establish medical necessity criteria to determine the authorization of the items, states may not deny requests for the items based on the grounds that they are for use outside of the home.

Current Medicaid regulations do not contain any specific definition of medical supplies, equipment, and appliances under the home health benefit, other than the language discussed in the prior paragraph. States have adopted reasonable definitions of those terms, for example, based on the Medicare definition. But in the absence of a generally applicable definition of the term, there has been confusion as to the proper scope of the benefit.

We believe that greater alignment of the definitions of home health medical supplies, equipment and appliances with the Medicare definition of DME will help to streamline beneficiaries' access to receive needed items and provide clear and consistent guidance to states to ensure the use of the appropriate benefit category. Therefore, we proposed to define home health supplies, equipment, and appliances, to better align with the Medicare program's definition of DME at § 414.202, as items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable. Unlike Medicare, however, we did not propose to define the expected life of a piece of equipment and did not propose to limit equipment to items used in the home. We also proposed to define supplies as health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, based loosely on Medicare principles, but we did not propose to require that supplies be incidental to other covered services.

The proposed standard definitions were intended to ensure that such items

will be available to all who are entitled to the mandatory home health benefit, and not restricted to individuals receiving targeted benefits through section 1915(c) home and community-based services (HCBS) waivers or the section 1915(i) HCBS state plan option. Items that meet the criteria for coverage under the home health benefit would be covered as such.

c. Other Issues

In the proposed rule, we noted that we were considering whether other clarifications to the home health regulations were warranted. In particular, we invited comments on whether it would be useful to include language to reflect the policies set forth in a September 4, 1998 letter to State Medicaid Directors, responding in part to a Second Circuit decision in *DeSario* v. *Thomas, 139 F. 3d 80 (1998),* about the use of lists or other presumptions in determining coverage of items under the home health benefit for medical equipment. In that letter, we indicated our interpretation of the mandatory coverage provisions to mean that a state could use such lists or presumptions as an administrative convenience but not as an absolute coverage limitation, and must provide individuals the opportunity to rebut the list or presumption using a process that employs reasonable and specific criteria to assess coverage for an item based on individual medical needs.

In addition, in the May 5, 2010 **Federal Register** (75 FR 24437), we issued the ''Medicare and Medicaid Programs: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements'' interim final rule which was effective on July 6, 2010. Although we did not incorporate changes in the proposed rule to the scope of providers that may order medical supplies, equipment, and appliances in the Medicaid program, as section 6405(a) of the Affordable Care Act was not applicable to Title XIX of the Act, we specifically solicited comments through this rule on the merits of doing so. We will address comments received below.

III. Analysis of and Responses to Public Comments

We received a total of 94 timely items of correspondence from home health provider representatives and other professional associations, State Medicaid Directors, states, beneficiaries, and other individuals. Comments ranged from general support or opposition to the proposed rule, to specific questions and detailed comments and recommendations regarding the proposed changes. A summary of the public comments and our responses are set forth below.

A. General

Comment: Some commenters expressed general support for the rule. One commenter supported CMS' goal of promoting accountability and program integrity. Other commenters supported the efforts of the Department to move toward consistency between the Medicare and Medicaid programs and ensure that home health services are delivered in accordance with sound clinical guidelines and recommendations.

Response: We appreciate the commenters' support.

Comment: Many commenters recommended that CMS specify that Medicaid home health services cannot be contingent upon a beneficiary needing skilled nursing care or therapy. Other commenters suggested revising § 441.15(c) to specify that Medicaid home health services cannot be contingent upon the beneficiary needing skilled nursing care or therapy.

Response: We have revised § 440.70(b) to clarify that coverage of Medicaid home health services cannot be contingent upon the beneficiary needing nursing or therapy services. We do not believe it is an accurate reading of section 1902(a)(10)(D) or the Act, or § 441.15 to impose such a requirement; the language of those provisions requires that the state provide the home health benefit to individuals whose benefit package includes nursing facility services, but does not require that the individual actually need such services. While it is beyond the scope of this rule to clarify and revise § 441.15(b), the clarification in § 440.70(b) will inform the reading of § 441.15(b).

Comment: Many commenters proposed that CMS amend § 440.230, which governs amount, duration, and scope to include language that reflects the policies set forth in the 1998 State Medicaid Director's letter related to the *Desario* case.

Response: We agree with commenters that the principles set forth in that letter should be incorporated into Medicaid regulations, although we disagree that these principles should be incorporated into § 440.230 as opposed to the Medicaid home health regulation at § 440.70. Accordingly, we are revising § 440.70 to include the three points made in that letter: (1) States may have a list of preapproved medical equipment, supplies, and appliances for administrative ease but not as an absolute limit; (2) States must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and (3) Individuals are informed of their right to a fair hearing.

Comment: Several commenters requested that CMS specify that states cannot require a 60-day plan of care for medical supplies, equipment and appliances. The commenters also requested that CMS specify that states may not impose additional state restrictions that are not part of the federal requirements for supplies, equipment, and appliances such as requiring that they be limited to services for temporary recovery from specific incidents, be limited to non-routine supplies necessary for the delivery of a participant's nursing care and described in the plan of care, or any other state requirement that is not a federal requirement for receiving equipment and supplies.

Response: As stated in the existing provisions of § 440.70(a)(2), home health services are required to be provided to a beneficiary on his or her physician's orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3). That exception states that a beneficiary's need for medical supplies, equipment, and appliances need only be reviewed on an annual basis, with more frequent review to be determined on a case-by-case basis based on the nature of the item prescribed. It would be inappropriate for states to require additional review of medical equipment, supplies, and appliances except where indicated on a case-by-case basis (for example, for supplies that are needed on a short term basis).

Additionally, states may place limits on the amount and duration of medical equipment, supplies and appliances, but the limits must meet sufficiency requirements set forth at § 440.230. And, as with all Medicaid services, states are not required to cover medically unnecessary services, and have the discretion to develop medical necessity criteria, but these must be based on accepted medical practices and standards.

Comment: Some commenters suggested that CMS apply the proposed prohibition on applying a ''homebound'' limitation to all Medicaid home care related program benefits, with one commenter suggesting that CMS audit state Medicaid programs for noncompliance with the homebound prohibition rule. That commenter stated that CMS should specifically review whether those state programs that

utilize a medical necessity standard as proxy for homebound.

Response: It is beyond the scope of this regulation to revise the requirements or definitions applicable to services other than home health care services. We are prohibiting the application of a homebound requirement for Medicaid home health because we have concluded that the resulting benefit would be insufficient to meet the needs of the population, and would not achieve the purposes of the mandatory benefit. We appreciate the commenters' suggestion and will take under advisement as part of our overall compliance strategy. We are revising § 440.70(c)(1) to codify the homebound prohibition for Medicaid home health services.

Comment: One commenter requested that CMS pursue the expansion of the Medicaid provision of home health services to meet the needs of our elderly citizens.

Response: Medicaid enrollees, regardless of their eligibility category, are not required to be homebound to qualify for home health benefits. Therefore, the clarification of the definition of medical equipment and supplies, and the requirement that home health services cannot be restricted to the home helps support the ability of Medicaid to best meet the needs of all eligible individuals, including the elderly.

Comment: One commenter believed that models for health care homes that compensate medical practices for complex care of chronically ill Medicaid beneficiaries should be promoted.

Response: We agree with the commenter. We have provided states with guidance and technical assistance on many initiatives that promote better care for the beneficiaries with chronic illness, including disease management strategies, health homes, and primary care case management systems. In 2014, we established the Medicaid Innovation Accelerator Program to support and focus resources on such models. More information can be found on our Web site at *http://www.medicaid.gov/state-resource-center/innovation-accelerator-program/innovation-accelerator-program.html.* Related guidance is also found on our Web site at *http://www.medicaid.gov/state-resource-center/innovation-accelerator-program/related-tools-and-guidance/related-tools-and-guidance.html.* Such models are beyond the scope of this regulation but we *intend to continue our efforts to provide technical assistance and guidance on these models.*

Comment: One commenter recommended that states be required to cover certification of home health care (at least initial certification) and ongoing care plan oversight as a medical benefit for Medicaid beneficiaries and to compensate physicians consistent with Relative Value Units for such work.

Response: Physician certification of the need for home health care could be covered by the state as a physician service or could be covered as a component part of home health care services. States have substantial flexibility to design payment methodologies for covered services. These payment methodologies can be tailored to the service delivery system in each state.

Comment: One commenter indicated that the rule should note that states must develop a strategy to educate physicians about the extension of the face-to-face requirement to Medicaid.

Response: We recognize the importance of education and expect states to educate the physician community on the new requirements implemented through the Affordable Care Act. We disagree that this administrative activity should be included as a requirement in the regulation. It is implicit with any regulation change to a benefit or to provider responsibilities that states educate impacted providers and beneficiaries about the new requirements.

Comment: One commenter endorsed adding the phrase ''medically necessary'' to § 440.70(b), to read as ''Home health services include the following medically necessary services and items.''

Response: We agree that states may limit covered services to only include medically necessary services. This flexibility is already provided in regulation at § 440.230(d). Medical necessity is not determined by us, but is determined by medical professionals. Many states employ medical professionals to establish medical necessity criteria and then review individual circumstances in light of those criteria. The phrase suggested by the commenter suggests that we would review medical necessity determinations. We do not intend to do so, and thus we are not accepting the suggestion.

Comment: One commenter indicated that there are no Current Procedural Terminology (CPT) or International Classification of Diseases (ICD) codes that specifically represent an evaluation for home health services; therefore, another model of demonstrating that a face-to-face encounter took place is needed.

Response: The face-to-face encounter can be demonstrated through the pre-existing ''evaluation and management'' codes.

Comment: One commenter expressed concern about how this provision will be implemented for those that are dually eligible for Medicare and Medicaid. Another commenter urged CMS to consider regulatory waivers, demonstrations or other initiatives to consolidate services for a dual eligible into a separate program for those beneficiaries with proportional funding from the existing federal and state programs. The commenter also indicated that CMS should undertake a significant education and outreach campaign to reach state officials, physicians, hospitals, home health providers, and organizations representing beneficiaries. The focus of the campaign would include Medicaid face-to-face requirements, and important similarities and differences with the Medicare face-to-face requirements.

Response: To the maximum extent possible, we have intentionally aligned the Medicaid rule with the Medicare requirements to reduce disparities in care and coverage for individuals who are eligible for both programs and to make it easier for providers to understand and implement the applicable rules. Currently, we are working on and publicizing a number of initiatives that speak directly to dual eligibles, increasing their continuity of care, and addressing ways in which Medicaid and Medicare rules might be better aligned. Such initiatives are out of the scope of this rule.

Comment: One commenter requested that CMS clarify or amend the definition of home health services such that this rule would not be applicable to non-medical services such as personal care attendant services.

Response: Personal care services are separately defined at § 440.167. We recognize the potential overlap between personal care services and home health aide services authorized under § 440.70. However, we disagree with the commenter's suggestion that this rule should not be applicable to services qualifying as home health aide services.

Comment: One commenter requested that CMS provide a significant amount of time before making effective, or enforcing, the final rule so that the state may prepare an accurate budget with sufficient funds for implementation and compliance.

Response: The requirements of section 6407 of the Affordable Care Act were effective upon enactment, and applied for home health services certified after January 1, 2010, as

specified in the Affordable Care Act and CMCS Informational Bulletin dated July 13, 2011; *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-7-13-11.pdf.* However, we will be delaying compliance for up to one year from the effective date of the rule if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule within the timeframes explained above. We intend to work collaboratively with states to ensure compliance with these requirements within a reasonable timeframe.

Comment: One commenter recommended that more productive emphasis be placed on training physicians in the home health assessment process so that physicians are held accountable for ordering appropriate services. The commenter also recommended that a process be put into place to audit home health services, and if a home health agency is abusing the system by providing questionable services, then a heightened authorization system be put into place for those identified high-risk agencies.

Response: As previously stated, it is implicit with any regulation change to a benefit that states inform impacted providers of new requirements and procedures. In response to the second comment, home health agencies must meet conditions of participation as determined through our survey process. The structures are designed to ensure that such agencies are qualified to furnish high-quality services that are medically necessary. To the extent that any provider, including a home health agency, is determined through the survey process to be furnishing inappropriate or unnecessary services, compliance actions can be pursued.

Comment: One commenter believed that home health services should be delivered in a consumer directed manner; the individual should be allowed to choose an agency or a consumer directed delivery option.

Response: A service plan based on a person-centered philosophy will support the beneficiary in achieving personally defined outcomes in the most integrated community setting available. This approach will reflect what is important to the individual receiving the services in terms of personal preferences and choices to meet identified support needs. Formal participant direction requirements for a home health service plan may be required by states as they determine appropriate, and consistent with the service delivery and payment system used by the state. We did not propose to change the requirement that certain components of the home health benefit (specifically nursing, home health aide services, and therapy services) must be furnished by a home health agency. This requirement is based on the premise that these services must be properly supervised and coordinated, consistent with the beneficiary's plan of care. Changing this requirement is beyond the scope of this rulemaking.

Comment: One commenter sought CMS guidance on the responsibility of the Medicaid Agency as it relates to oversight and monitoring of home health agencies to ensure compliance with the regulations.

Response: Overall compliance with home health agency certification requirements is conducted by the state's survey agency, in partnership with us. It is expected that State Medicaid Agencies collaborate with State Survey Agencies to ensure compliance of all home health providers with appropriate requirements, including all aspects of this regulation.

Comment: Some commenters discussed transportation costs. One commenter requested clarification on Medicaid coverage of physician non-medical transportation costs for face-to-face encounters. One commenter stated that the increased need to provide transportation services for the face-to-face encounters will result in increased costs. Another commenter raised a concern related to the problem of transportation costs, stating that the mandate of existing § 431.53 ''that the Medicaid agency will ensure necessary transportation for beneficiaries to and from providers,'' when read in connection with the proposed § 440.70(c)(1), significantly increases the states' financial obligation for service delivery. Additionally, the commenter requested that CMS clarify that § 431.53 does not apply for location-independent providers such as home health agencies.

Response: States are required under § 431.53 to assure necessary transportation for beneficiaries to and from medical providers, and that applies to transportation costs necessary for face-to-face encounters. This requirement includes transportation to and from an appointment with a physician or allowed NPP to receive an evaluation for home health services. States may reimburse physicians for transportation costs when necessary to make house calls through payment rate adjustments. Physicians cannot claim separately for transportation costs, since Medicaid reimbursement is not available specifically for physician transportation costs. However, many states factor in the costs of doing business into the payment rates for physician services, and may have higher payment rates to reflect physician house calls. Additionally, in response to the commenter's concern about transportation, we would note that the face-to-face encounter can be performed through the use of telehealth, and states may have payment rates that apply specifically for telehealth services and take into account the costs of communication lines and other necessary components of a telehealth encounter (on both sides of the telehealth encounter).

Comment: Two commenters requested that CMS specify that medical supplies, equipment, and appliances are a separate stand-alone home health service. The commenter also suggested that CMS emphasize that, even if a particular item cannot be covered as medical equipment, supplies, or appliances, states should determine whether it can be covered under another Medicaid service category, such as prosthetics or rehabilitation services. Additionally, the commenter suggested that CMS should state explicitly that satisfying the criteria of either one of the two definitions (equipment and appliances, or supplies) is sufficient to require coverage when the item is medically necessary.

Response: We appreciate the commenter's suggestions. As indicated in the proposed rule, items and services that meet the criteria for coverage under the home health benefit must be covered according to home health coverage parameters. To ensure full coverage for medical equipment and appliances, we will require that, to the extent that there is overlap in coverage with another benefit, states must nevertheless provide for the coverage of these items under the mandatory home health benefit. We understand that this policy may require that some states revise their claims processing systems, and we will work with those states to assist them in meeting this requirement. We reiterate that individuals only requiring medical equipment and appliances, and not other components of the home health benefit, may receive those services from DME providers authorized by the state, without necessitating a relationship with a home health agency. The nature of medical supplies and their ability to be provided in a variety of situations calls for a more flexible approach. Supplies incident to another mandatory benefit, such as physician services or an inpatient benefit such as hospital or nursing facility, may be covered under that benefit category. Additionally, supplies incident to the clinic benefit may be covered under that benefit

category. However, regardless of coverage category, the expectation remains that individuals receive all medically necessary medical supplies meeting the definition finalized under this regulation. We are available to provide technical assistance to states to work through operational issues.

We added this clarification to the regulatory text at § 440.70(b).

Comment: Two commenters indicated that the substantial number of hours required for compliance with this rule, in combination with the relatively low reimbursement typical for care of Medicaid beneficiaries, will lead to barriers to compliance among physicians. Commenters anticipated resistance from practitioners and physicians due to the additional administrative time it will take to meet the face-to-face requirement. One commenter indicated that many doctors are stating that they do not like the additional documentation requirements and are simply not ordering home health services. One commenter stated that early indications from the Medicare requirements are that physicians have been hostile to the new requirement, particularly the documentation standards. Another commenter stated that already there are many doctors who do not accept Medicaid beneficiaries. The commenter believed that adding additional paperwork and documentation requirements like this means there will likely be even more doctors who do not participate or who do not order home health services. One commenter reported that the home health industry is having problems with some doctors not wanting to do the face-to-face, therefore they are refusing to refer any beneficiaries to home health. One commenter indicated that since the Medicare requirement went into effect their members have seen a significant drop in referrals, some as much as 25 percent. The commenter further stated that unlike Medicare, Medicaid is actually 50 different programs with varying sets of rules from state to state. The commenter expressed concern that this will cause uneven application of the rule across the country and could lead to more problems with access to care.

Response: We fully expect that physicians will comply with the requirements and that they will be reasonably compensated for the time needed to provide and document the face-to-face encounter. The face-to-face encounters can be performed by NPPs, as well as done through telehealth. Additionally, as previously indicated, for medical equipment, NPPs are now authorized to complete the documentation requirements. To the extent that physicians may be avoiding ordering home health services, or are not cooperating with the home health industry on face-to-face documentation requirements, these may be temporary responses stemming from the unfamiliarity of the requirements. States, home health agencies and DME suppliers may need to work with physicians and NPPs to help them to understand the requirements. In particular, home health agencies and DME suppliers may need to develop ongoing relationships with physicians and NPPs to ensure that face-to-face encounters occur and are properly documented.

Comment: We received many comments pertaining to access to care. Commenters expressed that the face-to-face requirement in Medicare seems to be doing little to improve oversight of the benefit and is instead reducing access to home health for otherwise eligible patients, as physicians either refuse to accept the additional paperwork burden or do so only after agencies spend additional time and resources to obtain the documentation. One commenter believed the manner in which CMS is implementing the statutory requirement will significantly affect Medicaid beneficiaries' access to care. The commenter further stated that they can cite anecdotal examples of physicians who have simply decided to no longer refer individuals for home health services because of the hassle involved. One commenter believed that Medicaid beneficiaries will be the victims of this proposal because citizens who are elderly and those with disabilities are at risk for not receiving home health services if agencies have concerns about compliance with the face-to-face requirement and cannot deliver care. One commenter supported the need to align Medicare and Medicaid rules whenever possible, but was concerned about requirements that cause barriers to access by requiring a face-to-face encounter to initiate and receive payment for home health services. Another commenter was not supportive of applying the face-to-face requirements under Medicare to Medicaid. Another commenter believed that this requirement will negatively impact access and serve as a barrier to care because of the additional administrative burden to physicians filling out the face-to-face form. One commenter indicated that physicians, hospitals, discharge planners, home health agencies, and beneficiary groups agree that the physician requirements are a barrier to access to home health care for bona fide beneficiaries who meet coverage standards. One commenter believed that the face-to-face requirement is reducing access to home health for otherwise eligible individuals. One commenter was concerned that the face-to-face requirement will impede access and provide marginal benefit as a tool to eliminate ordering of questionable services.

Response: The face-to-face requirement is mandated by statute. We have attempted to permit maximum flexibility in how the statutory requirement can be met and believe that the requirement can be accommodated without significant additional burden. We are aligning Medicaid requirements with Medicare requirements to maximize consistency in service delivery, as well as reduce administrative burden on the provider community. As discussed in this final rule, we expect states to offer appropriate provider training and for states and providers to work together to ensure this provision is implemented in a manner that supports the goal of ensuring program integrity while not serving as a barrier to access to medically necessary services.

Comment: One commenter stated that well-mom and baby visits do not meet the intent of the physician face-to-face encounter for establishing the primary reason for which home health services are required and which will ultimately result in the development of a home health plan of care.

Response: If, in the course of such a visit, the physician or other practitioner determines that home health services or medical equipment is required to address the condition of the mother or child, such a visit could be the basis for a documented face-to-face encounter to the extent that the visit involves examining the condition of the mother or child.

Comment: One commenter believed that the proposed rule fails to take into account the fact that a significant proportion of home health services furnished to Medicaid beneficiaries under managed care programs are primarily the financial responsibility of managed care organizations. Another commenter suggested that, given the increased cost associated with the face-to-face encounter requirements, CMS should query states as to how they will be adjusting rates paid to managed care plans to adjust for the increased costs in an actuarially sound manner. Other commenters requested clarification regarding the application of the regulation to home health services

provided through Medicaid managed care plans.

Response: As previously stated, neither the law nor this rule requires that the face-to-face requirement apply to Medicaid managed care. We defer to states to determine the application of the face-to-face requirement in managed care plans to best meet the needs of their beneficiaries.

Comment: One commenter was concerned that more services will be shifted to personal care attendant services resulting in potential Medicare savings at the expense of state Medicaid budgets.

Response: We believe that the concern about potential cost shifting between Medicare and Medicaid can be address by ensuring that home health plans of care include all needed home health aide services. Additionally, as indicated in a previous response, to the extent that there is overlap in coverage with an optional benefit, states must provide for the coverage of services that meet the parameters of home health services under the mandatory home health benefit.

Comment: One commenter stated that the proposed rule at § 440.70 goes well beyond the scope of statutory authority and should not be issued. This commenter requested that CMS revisit its position that home health services are a mandatory service.

Response: We disagree with the commenter. Section 1902(a)(10)(D) of the Act sets forth the requirement that a state plan for medical assistance must provide for the inclusion of home health services for any individual who, under the state plan, is entitled to nursing facility services. Because nursing facility services are mandatory for categorically needy individuals and the medically needy—if a state chooses to cover the medically needy—home health services are mandatory for the populations.

Upon consideration of public comments received, we are finalizing § 440.70 with the following revisions:

- We are revising § 440.70(b) to state that home health services cannot be contingent upon the beneficiary needing nursing or therapy services.
- We are revising § 440.70(b) to codify that items and services that meet the criteria for coverage under the home health benefit must be covered according to home health coverage parameters.
- We are incorporating into § 440.70(b)(3)(v), three basic points set forth in our 1998 guidance relating to the *DeSario* decision: (1) States may have a list of preapproved medical equipment, supplies, and appliances for administrative ease but not as an absolute limit on coverage; (2) States must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and (3) Individuals must be informed of their right to a fair hearing. Additionally, we are including in the final rule the underlying interpretation implicit in these principles that the mandatory coverage of this benefit prohibits absolute exclusions of coverage as medical equipment, supplies, or appliances.
- We are revising § 440.70(c)(1) to codify our longstanding policy that home health services may not be subject to a requirement that the individual be homebound.

B. Introductory Text—Medical Supplies, Equipment, and Appliances (§ 440.70(b)(3))

Section 440.70(b)(3) proposed to revise the wording of the regulation to further define medical equipment, supplies, and appliances as suitable for use in any non-institutional setting in which normal life activities take place. We also proposed in § 440.70(b)(3)(i) and (ii) more detailed definitions of the terms ''medical supplies, equipment, and appliances''.

Comment: We received many comments in support of revising the introductory text of paragraph (b)(3). Several commenters supported the policy that medical equipment cannot be restricted to items that are useful in the home. One commenter further stated that potentially essential products are necessary not only for individuals to function in the home but to carry out activities of daily living while out of the home and in the community. One commenter stated that such standard is consistent with the requirements under the Americans with Disabilities Act, the Supreme Court Decision in *Olmstead* v. *LC,* and good healthcare policy. Another commenter stated that substituting suitable for use in any non-institutional setting in which normal life activities take place will improve understanding of this required characteristic of medical supplies, equipment, and appliances. Another commenter stated that this acknowledges that individuals engage in daily activities in which they may need such equipment not only in their homes, but also as they go about their daily activities in the community. Another commenter suggested including this language not only in the preamble, but also in the final regulations. Additionally, several commenters commended CMS for its statement in the preamble to the proposed rule that ''[i]tems that meet the criteria for coverage under the home health benefit must be covered as such. States will not be precluded from covering items through a section 1915(c) HCBS waiver service, such as home modification, or through a section 1915(i) state plan option. However, the state must also offer those items as home health supplies, equipment, and appliances.''

Response: We appreciate the perspectives the commenters had in support of the proposed revisions to the introductory language in § 440.70(b)(3). This language has been included in the final regulation.

Comment: Many commenters requested clarification of the phrase ''normal life activities.'' One commenter requested that CMS clarify or define normal life activities as absent a definition there will likely be considerable confusion between this term and activities of daily living. Another commenter reported that some states include the terminology of activities of daily living in their DME definition which enables a focus on a defined area of medical necessity. The commenter suggested that this standard is more clearly defined and thus preferable. Another commenter indicated that the term ''normal life activity,'' if not clearly defined, will result in duplication of services and increased expenditures. Another commenter indicated that ''in which normal life activities take place'' is a subjective statement where the state's administration may have to continually define and defend its interpretation in utilization management practices.

Response: To clarify, the phrase ''normal life activities'' refers to activities that could occur in or out of an individual's home. We proposed to revise the phrase ''suitable for use in the home'' to ''suitable for use in any non-institutional setting in which normal life activities take place'' to clarify that although states may continue to establish medical necessity criteria to determine the authorization of the items, states may not deny requests for the items based on the grounds that they are for use outside of the home. This clarification would not preclude states from continuing to use activities of daily living as medical necessity criteria.

Comment: One commenter indicated concern with the proposed ''expansive'' new definition of Medicaid supplies, equipment, and appliances which appears to require states to provide supplies, equipment, and appliances in any non-institutional setting. Thus, states would be required to provide, as just one example, wheelchair ramps in

settings outside the home as well as in the home.

Response: The new definition of Medicaid supplies, equipment, and appliances establishes a framework to serve as a companion to the requirement that the benefit is not limited to services and/or items suitable for use in the home, rather it is a benefit that is available to people in any setting in which normal life activities take place, other than facilities specified at § 440.70(c)(1). States may not deny requests for the items based on the grounds that they are for use outside of the home. States will continue to have flexibility to establish a reasonable definition of medical supplies, equipment and appliances that is consistent with the regulatory framework, to apply medical necessity criteria, and to have reasonable utilization control standards. We note that we do not regard this definition to expand the scope of medical equipment to include environmental or structural housing modifications. Nor does it include equipment that is designed to have a general use and will serve more people than just the Medicaid beneficiary. And a state's medical necessity and utilization control standards could reasonably preclude coverage of duplicative items or could provide coverage for rental rather than purchase of items when cost effective.

Comment: One commenter stated that what CMS characterizes in the proposed rule as clarifying language in § 440.70(b)(3) is a substantive change to the rule that goes well beyond what is statutorily allowed under Medicaid. The commenter stated that the present language of § 440.70(b)(3) correctly sets forth the scope of coverage of medical supplies and equipment as being ''suitable for use in the home'' as home health care is the purpose of this coverage category.

Response: We disagree that the proposed changes go beyond the statutory authority for CMS to interpret the meaning of the home health benefit and establish a framework for states to implement that benefit. In addition, while the changes are substantive, the changes incorporate principles that have been applied to Medicaid coverage in a number of court cases and CMS guidance, as discussed in the Background section above. As a result, the changes update the regulations to incorporate principles that are already applicable in practice.

Comment: One commenter raised concern regarding DME issues related to abuse of the equipment provided to Medicaid beneficiaries, or requests for equipment that exceeds the practical needs of the member.

Response: States may review requests to ensure that only medically necessary equipment is covered. The proposed provisions do not replace the existing Medicaid regulatory requirements at § 440.70(a)(2) and § 440.70(b)(3)(i) related to physician ordering and review of necessary medical equipment. An additional safeguard against unnecessary utilization is the face-to-face requirement and subsequent documentation requirement, which provides that physicians must describe how the health status of the beneficiary at the time of the face-to-face encounter is related to the primary reason the beneficiary requires home health services. This process should identify requests for equipment that exceed the practical needs of the individual. With regard to abuse of equipment provided to Medicaid beneficiaries, we believe it would be reasonable for states to require that the face-to-face encounter include instruction on how to properly use and care for the medical equipment at issue.

Comment: One commenter requested clarification as to whether the existing 16-bed or fewer size standard for determining whether a residential setting is an institution will be considered in determining whether supplies are suitable for use in ''non-institutional settings'' and the applicability for DME that would be used in a school setting.

Response: This provision does not change the standard for determining whether a residential setting is an institution (the16-bed standard discussed by the commenter applies only to whether a setting is an institution for mental diseases, not whether it is institutional). Home health services do not include services for individuals receiving inpatient services in a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or other setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Home health services would be covered for individuals residing in other types of facilities in accordance with this regulation.

Comment: Several commenters requested clarification about whether a state that offers a unique service under a section 1915(c) waiver or section 1915(i) state plan amendment must also offer those items as home health supplies, equipment, and appliances. Commenters stated that on its face, this would suggest the addition of all unique section 1915 services would also become regular home health services, available to all state plan beneficiaries. If this is the intent, it would seem a welcome expansion of services, if it is not, then clarification would be helpful. Another commenter requested clarification that HCBS waiver beneficiaries are exempt from the proposed rule under § 440.310. Another commenter asked if the assumption is correct that certain equipment and appliances may require installation and would be included in the cost of the equipment and appliances. If so, the commenter requests a distinction be made between basic installation required for equipment and appliances (medical supplies) and structural modifications required for HCBS home and vehicle modification.

Response: States may not restrict access to equipment that meets the criteria for coverage under the home health benefit by carving certain equipment out of home health and offering it only to individuals who qualify for services under a state's section 1915(i) and section 1915(c) program. States may implement standards to determine coverage under the home health benefit of medical equipment based on medical necessity and utilization control. While a state can use presumptions in applying medical necessity and utilization control criteria, which CMS does not review, the state must provide an opportunity for an individualized hearing as to whether the item is medically necessary in the particular circumstances. There will be items currently coverable under sections 1915(c) and 1915(i) that will instead be covered under the home health benefit, but there are other items that will not meet the new federal or state definitions of home health medical equipment or that may be outside of the coverage limitations in the state's approved state plan. These latter items may remain covered under a section 1915(c) or 1915(i) benefit. In response to the commenter's inquiry regarding the exemption of HCBS waiver beneficiaries, to clarify, the requirement of this rule applies to all individuals receiving state plan home health services, including those eligible for state plan services based on enrollment in a HCBS waiver program. We defer to states to establish medical necessity criteria to meet the needs of their beneficiaries.

Comment: One commenter stated concern about the implication that states cannot limit the home health benefit to those services and items that are sufficient to achieve the purpose of the benefit, as is well established in statute, regulation, and case law and

that the final regulation should clarify that only those items that the state chooses to cover within the home health benefit must be provided to Medicaid enrollees. The commenter also stated that they were concerned about the implication that some home modifications may be mandatory through the home health benefit. The commenter suggested that CMS should consider limiting that statement to the installation of certain appliances and equipment such as grab bars and other items that are available through home health agencies, and clarify that home remodels and other expensive modifications are not included in the home health benefit.

Response: This regulation clarifies the permissible scope of the home health benefit, particularly as it relates to medical supplies, equipment, and appliances. But this regulation does not remove state flexibility to adopt a reasonable definition of medical supplies, equipment, and appliances that is consistent with the regulatory framework; nor does it preclude state flexibility to include coverage limitations that do not interfere with the overall sufficiency of the benefit. Home health is a mandatory benefit and was so before this rule or the statutory changes that led to this rule. States may establish limits on mandatory benefits in their approved state plan, but must demonstrate that, despite the proposed limits, the covered benefits are sufficient in amount, duration, and scope. In addition, as we discussed in our *Desario* guidance, because of the unique nature of medical supplies, equipment and appliances, scope limitations within the applicable federal and state definitions are not consistent with sufficiency of the benefit. States should not be implementing policies that unreasonably restrict access to specific items of medical equipment. We are available to provide technical assistance to states looking to implement amount, duration, and scope limitations in home health.

In response to the commenter's concern about the implication that some home modifications may be mandatory through the home health benefit, we would like to clarify that costs of structural home modifications are not covered under the home health benefit because they would not be within the new regulatory definition of medical equipment, but instead would be costs of shelter. Similarly, vehicular modifications are not within the definition of medical equipment; they are a component of a vehicle that is not medical in nature.

In addition, we are clarifying that states may implement standards to determine coverage of equipment based on presumptions about medical necessity and utilization control, but must provide for an opportunity for individuals to have an individualized medical necessity analysis that takes into consideration the individual's person-centered plan of care. While a state can use presumptions in making applying medical necessity and utilization control criteria, which CMS does not review, the state must provide an opportunity for an individualized hearing as to whether the item is medically necessary in the particular circumstances.

Comment: One commenter stated that the source of confusion as to the proper scope of the DME benefit has not been the state's DME definition. Since CMS is proceeding on an assumption without factual basis, the commenter does not support the proposal to establish a regulatory definition of DME.

Response: This final rule does not define medical equipment, supplies and appliances; rather it sets out a framework under which a state can adopt a reasonable definition of these items. The framework provides some criteria which the state must include in its reasonable definition. We believe this framework will provide a more consistent approach to categorizing home health medical supplies, equipment, and appliances that with this guidance, states will ensure the sufficiency of the benefit so that beneficiaries will receive needed items. We have aligned the Medicaid definition of medical equipment, supplies, and appliances to the best extent possible using key components of Medicare's definition which we believe will achieve consistency for beneficiaries, providers, and program administration and ensure that beneficiaries are receiving needed items.

Comment: One commenter raised a concern with home modification equipment. Specifically, the commenter stated that home modification equipment currently is not considered DME in the commenter's state and has been covered as an additional service under HCBS waiver programs. The commenter asserted that inappropriately expanding the definition to non-medical services will deplete public funding requiring states to again look at the services they provide and the rates they pay to maintain balanced budgets.

Response: As discussed above, home modifications are not a part of this new definition of medical supplies, equipment, and appliances.

Comment: One commenter stated that the current definition of medical supplies, equipment, and appliances includes the verbiage ''suitable for use in the home'' which is consistent with Medicare's requirement ''appropriate for use within the home.'' This definition does not restrict the beneficiary to the home but defines the type of equipment that is appropriate for reimbursement under the DME outpatient program.

Response: We believe that the revision to the definition of medical supplies, equipment, and appliances will clarify the breadth of the current definition to include covered items outside of the home.

After consideration of the public comments, this section is being finalized without revisions.

C. Definition—Medical Supplies, Equipment and Appliances (§ 440.70(b)(3)(i) and (ii))

In § 440.70(b)(3)(i) and (ii), we proposed to revise the current regulation text to define what constitutes medical supplies, equipment, and appliances.

Comment: Some commenters expressed support of the revised definition. Commenters supported the alignment with Medicare's definition of DME. One commenter specifically supported CMS's effort to streamline and standardize the requirements for DME across the Medicare and Medicaid program, especially as they may apply to dual eligible beneficiaries. Another commenter believed the changes will promote consistency among different payer groups. A few commenters supported the concept advanced by CMS to define medical ''equipment'' separately from medical ''supplies.''

Response: We appreciate the support of the commenters.

Comment: Many commenters requested that CMS further clarify the proposed definition of medical equipment and appliances. CMS's proposed language defining medical equipment as ''reusable or removable'' could be interpreted by states to allow exclusion of items that are custom made or customized, such as wheelchair components for the seating and positioning for individuals with the most severe orthopedic impairments. The commenters recommended that CMS eliminate this restrictive criterion from its definition of medical equipment. Many commenters further requested the substitution of the term ''reusable'' with ''non-disposable.'' One commenter requested that this rulemaking process clarify that items of DME that meet an established definition of the service must be covered by

Medicaid when medically necessary. Additionally, the commenter requested that the rules clarify that states cannot characterize items of DME as non-covered through the home health benefit because this equipment may be eligible through HCBS waiver programs.

Response: As stated in the preamble to the proposed rule, we have set out a framework for the definition of medical equipment and appliances to align with Medicare to achieve consistency for beneficiaries who may be eligible in both programs, simplify program administration and ensure that beneficiaries are receiving needed items. But, we have left considerable flexibility for reasonable state definitions of the benefit within that framework. We do not agree that the terms ''reusable or removable'' should be deleted from the framework for medical equipment because these terms have meanings that are generally understood based on use in the Medicare program. Although we appreciate commenters raising the concern that these terms could be read to prohibit the customization of equipment, we do not agree that customization would necessarily make the items unusable for other individuals.

In response to the further comment, the home health benefit is distinct from items and services that may be available through HCBS waiver programs. Medicaid coverage of medical supplies, equipment, and appliances under the home health benefit is mandatory and must be provided under the state plan to HCBS waiver enrollees. To the extent that items are not included under the approved state plan, extended coverage could be provided under section 1915(c) waiver programs. We also reiterate our statement from the proposed rule that items meeting the state plan definition of a medical supply, equipment or appliance must be provided under the home health benefit, and may not be restricted to enrollees under a section 1915(c) HCBS waiver.

Comment: We received many comments pertaining to the language ''illness or injury.'' Many commenters requested that CMS clarify this definition to ensure that individuals with congenital conditions or developmental disabilities are not denied coverage of equipment or appliances because a state determines that they do not have an illness or injury.

Response: It is not our intent to deny coverage of supplies, equipment, or appliances to individuals with congenital conditions or developmental disabilities. We expect that anyone who is determined, based on medical necessity, to need medical supplies, equipment, and appliances will receive it. Therefore, in accordance with the comments, we are revising the regulation text to include ''disability, illness, or injury.''

Comment: Many commenters raised concern with the proposed criteria defining home health supplies, equipment, and appliances to better align with the Medicare program's definition of DME. Several commenters were concerned that states may take the adoption of a regulatory definition for medical supplies, equipment, and appliances as a signal to make their policies for covering medical equipment, appliances, and supplies more restrictive than they are at present. Commenters urged CMS to state in the preamble that this is not the intention of adopting this definition. Additionally, the commenters specified their concern that the intent to align the definition with the Medicare program will lead states to erroneously deny coverage of home health services because Medicare does not cover them. Commenters further stated that one of the primary purposes of the Medicaid program is to ''furnish . . . rehabilitation and other services to help such families and individuals attain or retain capability for independence and self-care'' and there is no corresponding requirement in the Medicare Act. One commenter stated that he strongly disagrees with the alignment with the Medicare definition and that distinct definitions of ''medical equipment and appliances'' between the two programs are warranted. Another commenter stated that in the instance of defining medical equipment and appliances, alignment between the Medicare and Medicaid definition is ill-advised and unnecessary. Another commenter stated that he does not believe this clarification meets the goal of better alignment with Medicare's program definition and that, in fact, this proposed change will cause fragmentation between Medicare and Medicaid.

Response: We appreciate the commenters' concerns, but we believe that a consistent approach to categorizing home health medical supplies, equipment, and appliances will ensure beneficiaries are receiving needed items and provide clear and consistent guidance to states to ensure the use of the appropriate benefit category. Additionally, we believe that the alignment with Medicare's definition is useful to help minimize inconsistencies between the two programs. We confirm that it is not our intent to have this standard restrict the receipt of medical supplies, equipment, and appliances, and we have included language in the regulation indicating that Medicaid coverage of medical equipment is not restricted to items covered as DME in the Medicare program. Furthermore, states may choose to cover items that are not within the coverage under the home health benefit under other authorities, including section 1915(c) waivers or section 1915(i) state plan; nothing in this regulation is meant to curtail a state's innovation or expansion.

Comment: Several commenters recommended revisions to the definition. One commenter recommended revising the definition to state: ''equipment and appliances are defined as items that are used to serve a medical purpose for the beneficiary, can withstand repeated use, and can be reusable or removable''. Many other commenters recommended revising the definition of medical equipment and appliances to state that equipment and appliances are defined as items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury or disabling condition, can withstand repeated use, and can be reusable or removable. Another commenter recommended utilizing the current industry accepted Medicare definition: (1) Can withstand repeated use; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to an individual in absences of an illness or injury; and (4) Is appropriate for use in the home.

Response: We appreciate the commenters' suggestions and we made a change in this final rule that responds to the second suggestion by incorporating a reference to disability. We did not accept the first suggested revision because it would require coverage of items that were not generally regarded as medical in nature, and we did not accept the third suggested revision because it would exclude coverage of items that would be used in normal life activities outside the home (such as, for example, walkers or wheelchairs). As indicated above, we are revising the definition of equipment and appliances to reference ''disability, illness, or injury.'' Otherwise, we will not be revising the definitions in the proposed rule.

Comment: One commenter disagreed with the proposed definition of equipment and appliances. The commenter stated that the proposed definition is improperly dependent upon how equipment and appliances are ''primarily and customarily used,'' and how they might be ''generally'' not

useful in the absence of an illness or injury. The standards should be dependent upon how equipment and appliances are needed by the particular Medicaid beneficiary. Another commenter stated that the proposed rule defines covered medical equipment by how an item is ''primarily and customarily'' or ''generally'' used, rather than adopting a person-centered approach that recognizes that people might have different medical needs.

Response: While we agree that the need for equipment and appliances should be based on an individual's needs in accordance with a person-centered plan of care, we are not accepting the suggested change because it would require coverage of items that were not generally regarded as medical in nature.

Comment: One commenter stated that the proposed definition of medical equipment and appliances would allow individuals in need of certain devices greater chance of approval.

Response: We appreciate the commenter's perspective, but it is not clear how the proposed definition would favor some devices over others. While a covered device must be within the scope of the definition of medical equipment and appliances, the approval of devices within that scope is based on a physician judgment of medical need and any state prior authorization review process. Moreover, as discussed elsewhere in this preamble, we have revised the final regulations to make clear that it sets forth a framework for coverage but that there is flexibility within that framework for states to define the precise scope of the benefit.

Comment: One commenter recommended adding language to further support the use of medically necessary and appropriate DME that has a well-established history of efficacy or, in the case of novel or unique equipment, valid peer-reviewed evidence that the equipment corrects or ameliorates a covered medical condition or functional disability. The commenter also suggested that the definition of DME should include equipment that is proven, safe, and appropriate for the treatment of a medical condition or illness.

Response: We do not believe that this additional language is necessary. This rule does not change the requirement that medical equipment must be ordered by a physician. We expect that the physician would determine medical necessity based on individual need. We further expect that physicians would order appropriate and safe medical equipment for individuals that have demonstrated effectiveness. Nothing in this rule, however, would preclude a state from establishing a prior authorization process to review claims for medical equipment (denying authorization when medical necessity is not established, subject to the individual's right to an appeal) and to initiate a dialogue with the treating physician to ensure appropriate treatment and control unnecessary utilization.

Comment: Some commenters indicated that state Medicaid programs should not be restricted to the definition of equipment that is consistent with items covered as DME under the Medicare program. The commenters recommended that CMS amend the proposed rule to set the Medicare coverage standard as the minimum scope of benefits relative to coverage of medical equipment, but allow states to provide more expansive coverage. Many other commenters cautioned the Secretary in applying Medicare's medical equipment definition to Medicaid because of the different standards that apply to the coverage of their respective home health benefits. The commenters further stated that Medicaid's definition of ''equipment and appliances'' should be flexible so that beneficiaries' needs can be met.

Response: We believe that this Medicaid framework for equipment and appliances is flexible so that individuals' needs can be met. But, in response to this and other comments, we have revised the final regulation text to make clear that coverage of medical equipment and appliances under state Medicaid programs are not restricted to the items covered as DME in the Medicare program. The alignment of the Medicaid framework with the Medicare definition is intended to achieve consistency for beneficiaries who are eligible in both programs, simplify program administration and ensure that beneficiaries are receiving needed items. The final regulation text makes clear that coverage of medical equipment and appliances are items that meet the listed criteria, but that states can elect to cover other items, including items that are not covered under the Medicare DME benefit.

Comment: Many commenters encouraged CMS to include language in the final regulation to reflect the policies set forth in the September 4, 1998 State Medicaid Director letter responding to the *DeSario* v. *Thomas* decision. One commenter stated that it is essential that CMS restate the validity of the *DeSario* SMD letter: That states may not use exclusive lists or irrefutable presumptions to limit or bar coverage of items under the DME benefit; and that states must have a reasonable process for requesting coverage of items the state has not otherwise expressly identified as covered. Another commenter stated that language should be provided in this rule if action is necessary to prevent states from employing lists and presumptions to deny coverage of appropriate medical equipment. Many commenters stated that it is necessary that the Secretary incorporate the letter's policy into regulation. Several commenters commended CMS for reemphasizing in the preamble that states may not use lists or presumptions in limiting coverage of items under the home health benefit unless states have a reasonable process for requesting exceptions to such lists or presumptions that are based upon specific criteria. One commenter further stated that codifying the interpretation by CMS contained in its State Medicaid Director Letter of September 4, 1998 would enable more people with Medicaid who rely upon DME to remain in their homes and active in their communities. Another commenter believed that it would be highly beneficial to include the principles espoused in the September 4, 1998 State Medicaid Director letter in the regulation. Another commenter supported the suggestion that federal Medicaid regulations should require that if states confine allowable medical equipment to items from a list, they allow beneficiaries to appeal for items not on that list by demonstrating that the items are medically necessary. One commenter stated that CMS appears to conflate a state's ability to limit the amount, duration, and scope of a benefit, with a determination of whether an item or service falls within the state's definition of a covered item or service. The commenter further stated that if CMS chooses to add the 1998 guidance to the regulation, it should clearly distinguish between benefit exclusions and the use of administrative lists for classes of supplies and equipment that are covered under the state's benefit.

Response: We have revised the final rule at § 440.70(b)(3)(v) to make clear that the principles we set forth in the 1998 SMD are still applicable. If a state has a predetermined list of covered, supplies, equipment and appliances, it must have a reasonable process, with an opportunity for a fair hearing to allow beneficiaries to request and receive items that are not on the state's list. Beneficiaries must be afforded the opportunity to establish that the item in question is medically necessary and within the overall state definition of covered medical equipment, and

consistent with the federal regulatory framework.

Comment: One commenter believed that the use of presumptions by their very nature moves coverage determinations away from individual-based considerations and substitutes efficiency for person-based, medical necessity determinations.

Response: Coverage determinations for medical supplies, equipment, and appliances should be based on medical necessity criteria as established by the state as applied to the individual's particular needs. The need for medical supplies, equipment, and appliances should be identified by the physician and reviewed at least annually.

Upon consideration of the public comments received, we are finalizing § 440.70(b)(3)(ii) with revisions. We are revising the definition of equipment and appliances to include the term ''disability'' and to specify that state Medicaid programs are not restricted to the items covered under DME in the Medicare program. Additionally, we have clarified that structural or home modifications are not covered under the Medicaid home health benefit and that states may not limit access to equipment eligible for coverage under home health benefits by restricting some items to only those who qualify for section 1915(i) or (c) programs. States may implement standards to determine coverage of the specific items previously funded under sections 1915(c) or (i), such as ceiling lifts or chair lifts, that could now be seen in appropriate circumstances to meet the home health definition and be medically necessary for an individual. We have also clarified that medical equipment and appliances already coverable under the home health benefit will continue to be covered. Not all medical equipment and appliances currently coverable under section 1915(c) and section 1915(i) will be coverable under the state plan under the standards set forth in this rule.

D. Setting Description (§ 440.70(c)(1) & (c)(2)

To reflect the principles expressed by the courts in both the *Skubel* and Detsel decisions discussed above, we proposed to incorporate in regulation the longstanding policy that home health services may not be subject to a requirement that the individual be ''homebound.'' In addition, we proposed to clarify that home health services cannot otherwise be restricted to services furnished in the home itself. Additionally, in an effort to not limit the ability of states to offer a more robust home health benefit, we propose to allow states the option to authorize additional services or hours of services to account for this flexibility.

Comment: Many commenters supported the proposal to specify in the regulations that Medicaid home health services must not be limited to beneficiaries who are ''homebound.'' Additionally, many commenters supported the conclusion that Medicaid home health services should not be limited to services furnished in the home. One commenter indicated that this proposed change provides flexibility for adults to receive medically necessary services at the workplace and children to participate in the community with their families while receiving necessary supports. The commenter further stated that allowing people to access home health services in the community will contribute to overall health and a reduction in costs for acute services. Commenters stated that the clear ability of people with disabilities to use their home health benefit in ''any non-institutional setting in which normal life activities take place'' will make community integration feasible for many people.

Response: We appreciate the perspectives the commenters provided about medically necessary home health services. We also believe that with home health services provided in conjunction with other optional state plan and section 1915(c) waiver services people can be supported to fully integrate into their communities.

Comment: Many commenters recommended that the regulatory language specifically indicate that a homebound requirement is not permitted. One commenter suggested revising § 441.15(c) to establish clearly that Medicaid home health coverage cannot be contingent on the beneficiary being ''homebound.'' Other commenters suggested the following language: ''Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any non-institutional setting in which normal life activities take place or to permit a state to require that an individual be homebound or unable to leave his home to receive home health services.'' One commenter recommended that the final regulation amend paragraph (a)(1). The commenter believed that it is contradictory and confusing in paragraph (a)(1) to state that home health services must be provided ''[a]t [the beneficiary's] place of residence,'' and then in paragraph (c)(1) to state that services can be provided ''in any non-institutional setting in which normal life activities take place.'' The commenter also recommended that the proposed language for paragraph (c)(2) be revised to specify that services and/or service hours must be authorized to account for medical needs arising out of the home.

Response: We are revising § 440.70(c)(1) to indicate that a homebound requirement is not permitted. We believe this revision also addresses the request to revise § 441.15(c), as § 441.15(c) cross-references § 440.70. In response to the request that we amend paragraph (a)(1) as it is contradictory and confusing when read with paragraph (c)(1), we do not believe that this revision is necessary as § 440.70(a)(1) references paragraph (c) to specify ''place of residence.'' While we understand the recommendation that the language for paragraph (c)(2) be revised to specify that services and/or service hours must be authorized to account for medical needs arising out of the home, as long as the amount and duration limits applied by the state are either authorized under the approved state plan as consistent with a sufficient benefit, or based on an individualized medical necessity determination, we do not think such language is appropriate. We would, however, allow states the option to authorize additional services or hours of services to account for this flexibility to make clear that such a policy would not violate comparability requirements.

Comment: One commenter expressed concerns regarding homebound status and beneficiaries who are dually eligible for Medicare and Medicaid. The commenter stated that they support the ability of Medicaid-enrolled individuals to receive home health services without an artificial barrier based on their homebound status. However, because the prohibition on requiring a homebound status does not apply to the Medicare program, the commenter raised concern about how this will be implemented for those that are dual eligibles.

Another commenter stated that the regulation would require that certain programs revise or update existing policies to reflect that home health services cannot otherwise be restricted to services furnished in the home itself.

Response: Individuals who are dually eligible for Medicare and Medicaid will benefit from this regulation. While the prohibition on requiring a homebound status in Medicaid is not new to this regulation, codifying the prohibition and strengthening the community integration philosophy of the home health benefit will ensure the individuals receive quality Medicaid home health services. Individuals eligible for both Medicare and Medicaid

who are not determined to be homebound may not qualify for Medicare home health services. Such individuals would still qualify for Medicaid home health services, if they meet the state's medical necessity criteria for the service. We understand that some state program policies may have to be modified or updated to comport with the rule, but do not believe that this task will be overly burdensome.

Comment: One commenter recommended against using the phrase ''normal life activities.'' The commenter believed that it contains a value judgment and could be read as devaluing people who are living in institutional settings as not ''normal.'' Therefore, the commenter recommended striking the term ''normal'' and simply using ''life activities.''

Response: The phrase ''normal life activities'' is used in this rule to clarify that home health services cannot be limited based on the location in which home health services are used. We do not believe that the term ''normal'' needs to be removed from this phrase. There is no negative connotation intended.

Comment: One commenter suggested a new classification of care. Rather than ''home care,'' the commenter suggested that care for beneficiaries of covered home-care services when the beneficiary is not homebound be called ''community care.'' The commenter further stated that better distinguishing between home care and not-at-home-but-in-the-community care will help with the application of that care. While a community-based benefit can be provided within the existing infrastructure of home health care, it needs to be administered with more scrutiny and monitoring of beneficiaries. Just tracking where the care is to be delivered will require more scheduling and monitoring.

Response: Developing a new classification of care is beyond our statutory authority.

Comment: Some commenters suggested prohibiting any home care coverage standard that results in a different and/or greater scope of benefits for beneficiaries residing in facility-type residences than the scope of benefits for individuals in their own private homes. Commenters recommended that CMS clarify its suggestion/allowance that states can provide a higher level of home care benefit to individuals who reside outside an individual private home such as a rest home or assisted living facility. As written, it may be possible for a state to interpret the CMS reference on higher levels of coverage for such individuals as permitting states to have a different benefit for Medicaid beneficiaries in a facility-type residence than for those in a private home.

Response: This rule does not affect or change comparability rules, and therefore, we do not believe that individuals will receive a different and/or greater scope of benefit based on where an individual resides. We also remind commenters that the scope of a benefit that a beneficiary is authorized to receive is based on medical necessity, not the setting where the beneficiary resides. States have the flexibility to determine medical necessity criteria and therefore, the level of services a beneficiary receives is based on medical necessity, not setting.

Comment: One commenter indicated that CMS should clarify in regulation that Medicaid home health services should not be limited to services furnished in the home.

Response: We clarify that home health services cannot be limited to services furnished in the home. Additionally, we have revised § 440.70(c)(1) to indicate that home health services can be provided in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Therefore, we believe that we have sufficiently communicated and regulated the prohibition on restricting services to the home.

Comment: One commenter requested that CMS clarify whether states can specify settings in which home health care can be received. The commenter stated that states should be allowed to specify that skilled tasks associated with bathing be limited to the client's place of residence.

Response: The purpose of this provision is to ensure the delivery of home health services not only in the home, but also in the community when the beneficiary is participating in normal life activities. It is not meant to mandate service provision in any particular setting. We are also permitting states to authorize additional hours of home health services to account for medical needs that arise in the setting furnished. And, while states may set limits on the amount, duration, and scope of home health services, subject to our approval, we do not agree that states may put arbitrary limits on the places where home health services can be received.

Comment: One commenter asked, if a child is approved for services which will be provided in a school setting, is the school responsible for the nursing services, or will a nurse from the approved home health agency be required to provide services in a school setting.

Response: This does not change policy for Medicaid services provided in schools. Under the existing rule, nursing services under the home health benefit must generally be provided by a home health agency. The rule does not limit agreements and arrangements between home health agencies and schools to facilitate the provision of such services. Nor does it preclude coverage of nursing services provided in schools under another benefit category.

Comment: One commenter reported that currently their state does not contract with out-of-state home health providers and inquired as to whether a state home health nurse would be required to travel with the family, how the state would reimburse the nurses' travel.

Response: Nothing in this final rule specifically addresses this issue but, in general, nursing services are provided under the home health benefit only when provided through a home health agency in accordance with an physician's order as part of a written plan of care. To the extent that there is a medical need documented in the plan of care for out of state travel accompanied by a home health nurse, and the service can be provided consistent with the approved state plan, payment would be made to the home health agency as set forth in the approved state plan. We note that coverage of out-of-state services may be limited by a state as long as the requirements of 42 CFR 431.52 are met.

Comment: One commenter requested that the plan of care designate the home health services as In-Home or Out-of-Home services after a physician evaluation of medically necessary accommodations and staffing levels to insure the safety of beneficiaries and success of out of home services. One commenter raised concern with settings that cannot be evaluated as safe, and settings that may result in unnecessary duplication of services. The commenter also was concerned with access to care issues related to out of state care, as current state policy requires that the setting be a safe setting, and may not approve services if all health and safety issues cannot be met in the setting. The commenter believed that the rule does not address any limitations of services outside of the home and wondered whether states would be permitted to

restrict certain services. Another commenter requested that CMS consider further clarification of the site of care for home health services to acknowledge and reduce the personal risks to health care workers and to ensure the site of care selected is appropriate for the safe delivery of home health services.

Response: The plan of care should assist in identifying services and settings appropriate for the individual's need. Assessment of receipt of the services is based on medical necessity. This regulation does not set forth detailed requirements for plans of care; there are other resources for guidance on the best practices for person-centered care planning. We understand and appreciate the commenters' concerns for the personal safety of home care workers. Such concerns exist with any home care program, and are not new with this regulation. We encourage home care agencies to take measures to reduce risks to employees. With regards to duplication of services, section 1902(a)(30)(A) of the Act requires that payments are economic and efficient; payments which duplicate payment for the same service would not be economic and efficient, and therefore, would not comport with federal statute.

Comment: We received many comments pertaining to costs within this component of the regulation. One commenter stated that Medicare regulations continue to require that a beneficiary be ''confined to the home'' to qualify for Medicare-covered home health services. Therefore, for any dual eligible, state Medicaid programs will bear the entire financial burden for home health services provided in another setting outside the home. Another commenter believed that the proposed regulation goes beyond states' limits and would appear to apply to waiver and state plan benefits alike. The commenter was concerned about the potential downstream effect of expanding services available through HCBS waivers, which are case managed, to coverage of state plan benefits, which are not case managed. The commenter also stated that expanding beyond the current case-managed limitations on services or service hours would have a real and substantial fiscal effect on the state's Medicaid program. One commenter expressed concern that the new requirement would result in a large increase in cost for Medicaid home health services. Another commenter indicated that deleting the existing ''at home'' requirement for Medicaid home health services represents a substantial and unjustified expansion of states' financial liability for home health services.

Response: While most of the Medicare/Medicaid rules are aligned, this is an area in which there is a statutory difference between the programs. As a result, the rules differ. Sections 1814(a) and 1835(a) of the Act impose the Medicare homebound requirement for home health services, but there is no parallel homebound requirement under Medicaid. We understand that there may be consequences for Medicaid programs, but these consequences do not arise from this rulemaking; they are inherent in the difference between the two statutes. Additionally, we note that we would permit states the flexibility to authorize additional hours of home health services to account for medical needs that may arise outside of the home.

Comment: One commenter stated that while the proposed regulation purports to incorporate and comply with federal court decisions, the new provisions go beyond anything required or contemplated by the decisions. The commenter further stated that the proposed regulation would vastly expand the program so that the health care provided to Medicaid beneficiaries far exceeds anything available to the general population. Under the proposed regulations, a beneficiary could receive health care anywhere, including the grocery store, a museum, or even an amusement park. The proposed regulations essentially transform Medicaid from a health care program to a social services program. The commenter also believed that the proposed regulations appear to be based on an incorrect interpretation of the *Olmstead* decision. *Olmstead* cannot reasonably be read to require the dramatic expansion that would follow from the final issuance of the proposed regulations. The commenter stated they believe that the proposed regulations are not supported by the cost-neutral rationale espoused by the *Skubel* decision, and they establish a more expansive coverage policy (both substantively and geographically), when compared to the *Detsel* and *Skubel* decisions and CMS's own stated policies.

Response: This final rule does not mandate provision of services in any particular setting, but removes a barrier to the provision of home health services outside of the home itself. Removal of this barrier may permit individuals whose medical needs are such that they require home health services to participate in normal life activities not to be restricted to the home. The community integration underpinning of the home health benefit is appropriate for the Medicaid program and we refer to the principles set forth in court cases discussed herein as support for this final rule. Those principles are based on readings of the Medicaid statute, and we are adopting those readings. Furthermore, in response to the comment that we are expanding the scope of coverage more than is required by the court cases, to the extent that this is the case it is because such expanded coverage is consistent with both the overall purposes of the Medicaid statute, as section 1901 of the Act specifies to help families and individuals attain or retain capability for independence or self-care, and under section 1902(a)(19) of the Act that specifies care and services will be provided, in a manner consistent with simplicity of administration and the best interests of beneficiaries.

Comment: Some commenters disagreed with the proposed revision to the setting description. One commenter stated that the term ''home health care services'' as used in federal Medicaid law has never been further defined. In the absence of a definition, it should be assumed that the Congress intended it to mean exactly as written—health care services delivered in a beneficiary's home. Nothing in the ''face-to-face'' provision or elsewhere in the Affordable Care Act suggests the Congress intended to depart from the clear meaning and long-standing interpretation of this term. The commenter also believed that that the suggestion that covering home health services outside the home is necessary for compliance with ADA as interpreted in the *Olmstead* decision is without foundation. The proposed rule's directive that states cover home health services in non-home settings directly contravenes the flexibility that was at the heart of the *Olmstead* decision. Additionally, the commenter stated that as CMS acknowledges in the preamble, under the proposed rule, ''home health services may not be limited to services furnished in the home,'' and ''states may not limit home health services to services delivered in the home.'' Any language in the proposed rule suggesting a contrary result is misleading, and presumably intentionally so. Another commenter stated that the proposed regulations go well beyond long-established policy and the decisions in *Detsel* and *Skubel,* as well as CMS's own stated policies.

Response: As we have indicated previously, we are adopting the principles underlying the holdings of the *Skubel and Detsel* court decisions in this final rule. We believe this reading is consistent with the purposes of the Medicaid statute. We are being clear

that home health services may not be limited to services literally provided in the home. But we are not mandating that services be provided in any particular setting; that is an issue that must be addressed in a plan of care that accounts for the individual's needs, and may be subject to review by the state.

Comment: One commenter reported that the regulation would require that the Children's Services Program of the state revise or update existing policies to reflect that home health services cannot be otherwise restricted to services furnished in the home itself.

Response: While we understand that some state policies may need to be revised; such as the restriction of home health services to an individual's home. We do not believe that this will be overly burdensome.

Comment: One commenter was concerned with the lack of control in non-institutional settings. The commenter believed that issues may arise in certain settings considered non-institutional such as college dormitories. Additionally, the commenter believed restrictions based on funding, safety, distance of travel, and practical feasibility need to be addressed.

Response: Home health services are authorized based on medical necessity, not setting. However, we do recognize that there may be circumstances in which an individual and/or provider's health or welfare may be at risk, and we urge home health agencies and states to address the issues on an individual basis should they occur. We are available to provide technical assistance and guidance as needed.

Comment: One commenter stated that, under proposed § 440.70(c)(1), home health services would be significantly broadened by offering services in ''any non-institutional setting in which normal activities take place.'' The commenter was concerned that this new requirement would result in a large increase in cost for Medicaid home health services and DME, prosthetics, orthotics, and supplies.

Response: As previously stated, home health services, including DME, are authorized based on medical necessity, not setting. We acknowledge the increased cost associated with our standardizing the definition of medical supplies, equipment, and appliances, both narratively, and in our characterization of the proposed rule as being economically significant, with a likely financial impact of greater than $100 million. However, we continue to stand by the necessity of the regulatory revisions to ensure that beneficiaries receive the home health benefits to which they are entitled under the Medicaid statute.

Upon consideration of the public comments received, we are revising § 440.70(c)(1) to indicate that a homebound requirement is not permitted. Additionally, we are clarifying the settings in which individuals may receive home health services. Specifically, individuals may receive home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.

E. Face-to-Face Encounter (§ 440.70(f))

Section 440.70(f)(1) specifies that for the initial ordering of home health services, the physician must document that a face-to-face encounter that is related to the primary reason the individual requires home health services has occurred no more than 90 days before the start of services. We recognize, however, that there may be circumstances when it may not be possible to meet this general requirement, and the individual's access to needed services must be protected. To account for these circumstances, we proposed to allow an opportunity to meet the face-to-face encounter requirement through an encounter with the beneficiary within 30 days after the start of home health services.

Comment: Some commenters supported the proposed timeframes. One commenter stated that they believe that this timeframe is appropriate for authorization of most types of home health services. Another commenter stated that the requirements for face-to-face encounters with an individual's physician or NPP for approval of home health services 90 days prior or 30 days after administration will allow for the most up-to-date patient information to be incorporated into their plan of care.

Response: We appreciate the commenters' support of the proposed timeframes.

Comment: Many commenters requested that CMS delay implementation. Commenters stated that with regard to Medicare, CMS delayed implementation of the regulation to afford sufficient time for beneficiaries, physicians, hospitals and other providers to understand the parameters of the new rule. The commenters recommended that CMS employ the same caution in implementing the face-to-face requirement for Medicaid's home health benefit. One commenter further suggested delaying implementation at least one year.

Response: We recognize that there may be operational and budgetary implications with this rule and that states and providers may need time to implement this provision. In order to ensure that states and providers are implementing the rule appropriately we have revised the effective date of the rule to July 1, 2016 and will delay compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

Comment: Many commenters expressed opposition to the face-to-face requirement with one commenter requesting that CMS drop the face-to-face requirement altogether. The commenter believed that it has only been a barrier to service for beneficiaries who need care and cannot get in to see their physician. Another commenter urged CMS to remove the face-to-face requirement for home health services in the Medicaid program. One commenter stated that his state expresses opposition to CMS' proposed expansion of face-to-face requirement to Medicaid at this time. Another commenter stated that CMS's conclusion that the Congress intended the face-to-face requirement to apply to physicians' orders for home health under Medicaid is unreasonable. The commenter further stated that to require a face-to-face encounter within a prescribed period of time before a physician orders or prescribes a particular course of care or treatment calls into question the physician's exercise of professional judgment under applicable state practice acts, and undermines the physician-patient relationship. One commenter indicated that he does not support the need for a face-to-face contact by a physician or other designated health professional prior to the initiation of home health services. The commenter stated that the proposed regulation cites no substantive reason for this requirement. The commenter also recognized that this requirement may be specifically mandated by the Affordable Care Act, but reported that he does not see how such a requirement will actually serve any beneficial purpose for the beneficiary.

Response: We believe that our interpretation of the applicability of the face-to-face requirement in the same manner and to the same extent as it applies to Medicare is consistent with,

and required by, section 6407 of the Affordable Care Act.

Comment: One commenter supported aligning the timeframes with similar regulatory requirements for Medicare home health services. Another commenter specified that any face-to-face requirement for Medicaid should mirror in timing, information and signature requirements for the Medicare program and the one exception should be the requirement of homebound criteria which the commenter agrees should not be required for Medicaid beneficiaries. Another commenter recommended that the Medicaid requirement match the Medicare requirement, which would be the 6-month timeframe. One commenter recommended that CMS remove the 90-day timeframe and replace it with the 6-month timeframe found in the statute. One commenter stated that CMS halving the permissible timeframe for the face-to-face encounters from 6 months to 90 days is inconsistent with Congressional intent. The commenter also stated that requiring a face-to-face encounter within 90 days of a physician ordering home health services for a Medicaid beneficiary is not consistent with the nature and needs of the Medicaid population. Additionally, the commenter believes that the provision of the proposed rule that would allow for a face-to-face encounter ''within the 30 days after the start of the services'' is inconsistent with the purpose of the Medicaid rule requiring a physician order for coverage of home health services. One commenter urged CMS to maintain the timeframe window to be 6-months preceding the start of care to 30 days after the start of care under Medicaid.

Response: We agree with commenters who asked for alignment between Medicare and Medicaid face-to-face timing requirements. In this final rule, Medicaid requirements for the timeframes of the face-to-face requirement for home health services generally are aligned with timeframes adopted for Medicare home health. To maximize the alignment between the programs, in this final rule we have also aligned with Medicare the timeframe for the face-to-face encounter for Medicaid medical equipment, which is 6 months prior to the start of service.

Comment: A commenter stated that the proposed timeframes for face-to-face encounters may prove problematic if the visit can occur up to 30 days after the start of home health services, because under the fee-for-service system, authorizations for services would be already approved and there would be no easy way to make sure this visit, complete with documentation requirements was performed. Another commenter stated that the timeframes will be much harder to comply with for the Medicaid population.

Response: To clarify, we have extended the face-to-face encounter timeframes to permit the encounter to occur within 30 days after the start of home health services to account for individual circumstances. But we would expect that ordinarily the face-to-face encounter would occur before the start of home health services. We understand that in the individual circumstances, when the face-to-face encounter occurs after the start of services, additional coordination of the medical/home health team may be required to ensure that the visit, along with the required documentation was performed. We encourage states to work with the home health provider community to incorporate the face-to-face visits in creative and flexible ways to account for individual circumstances. We are available to provide technical assistance to states in achieving this goal.

Comment: One commenter suggested allowing longer timeframes for Medicaid face-to-face encounters and extending the 30-day post-start of care, especially for beneficiaries without a primary care physician.

Response: The timeframes proposed in this rule are aligned with Medicare's timeframes to promote consistency. Additionally, we do not agree that the 30-day post-start of care timeframe should be extended. The expectation of the rule is that that the timing of the face-to-face encounter in normal circumstances should occur within the 90 days before the receipt of services. We are providing for the 30-day post-start of care timeframe to accommodate extenuating circumstances that require immediate commencement of home health services before a physician encounter can be scheduled.

Comment: One commenter suggested that CMS state that CMS encourages the face-to-face encounter occur within 90 days prior to the start of home health services.

Response: We do not believe that a change in regulation language is necessary. We emphasized in the proposed rule and in the responses to comments that the timing of the face-to-face encounter in normal circumstances should occur within the 90 days before the start of home health services.

Comment: We received many comments regarding the face-to-face encounter for individuals who are dually eligible for Medicare and Medicaid. One commenter asked whether CMS would accept documentation of a face-to-face encounter reimbursed under Medicare when a dually-eligible individual begins home health services under Medicare and transitions to Medicaid. Specifically, since Medicaid does not require the beneficiary to be homebound, the commenter questioned whether another face-to-face encounter would need to be completed for Medicaid home health services. Several commenters recommended that CMS amend the proposal to deem the Medicare qualifying face-to-face encounter documentation as meeting Medicaid face-to-face requirements or establish a standard that the switch to Medicaid as the payer is not a ''start of care'' that would require a Medicaid qualifying face-to-face encounter. Commenters requested that CMS clarify whether there are circumstances under which an additional face-to-face encounter would be needed when beneficiaries move between Medicare and Medicaid coverage. One commenter noted that some individuals are dually eligible and may face greater challenges accessing care and services.

Response: To clarify, the face-to-face encounter is required for initial orders for home health services and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. OASIS is the ''Outcome and Assessment Information Set'' applicable for Medicare home health services and Medicaid home health services. If a face-to-face encounter was performed at the start of home health services, or to support the order for medical equipment, a new face-to-face encounter is not required if the source of payment has changed to Medicaid. Therefore, if a dually eligible individual begins home health services under Medicare and transitions to Medicaid, the Medicare face-to-face encounter documentation will meet the Medicaid face-to-face requirement. Our expectation is that Medicaid providers are aware that there is no homebound requirement to be eligible for Medicaid home health services. Dually-eligible individuals not meeting Medicare's homebound criteria would not be eligible for Medicare home health, but could still be eligible for Medicaid home health, assuming medical necessity criteria are met. In these cases, the beneficiary's physician or authorized NPP would conduct and document the face-to-face encounter, and Medicaid home health reimbursement would be appropriate.

Comment: Some commenters encouraged CMS to provide states with flexibility to extend the permissible period for the Medicaid beneficiary to secure the required encounter after the

start of care because of the unique problems often facing Medicaid beneficiaries in accessing a physician. This can be done by extending the allowable timeframe for compliance or permitting states to apply an exception process. Commenters recommended that CMS revise the proposal and specifically provide for exceptions, or provide direct authority to the states to do so. Some suggestions for exceptions included: (1) Medical contraindications to the beneficiary leaving his or her home to see a physician/NPP; (2) the beneficiary resides in a frontier area; (3) the beneficiary resides in an area designated as medically-underserved by the state; (4) the beneficiary was discharged from an inpatient setting directly into home health services; (5) the home health agency is not at fault in the failure to meet the face-to-face requirement and noncompliance is beyond the control of the agency; (6) the beneficiary enters the hospital before the encounter; or (7) the beneficiary is referred to home health from a school nurse or elder service networks.

Another commenter urged CMS to give specific guidance to states maximizing the flexibility in timing of face-to-face encounters, allowing the timeline to be extended, and allowing states to provide a good cause exceptions process in cases where beneficiaries have not been able to meet this requirement. One commenter viewed good cause exemptions as extremely important and urged that they be put in place immediately. Such good cause exemptions might include, but not be limited to, situations where the state or federal government declares a state of emergency such as a natural disaster or terrorist attack. In such a circumstance, lack of electricity, phones and equipment, and navigable roads might delay the achievement of a face-to-face encounter for more than 30 days. Another commenter indicated that there needs to be more flexibility in the timeframes after the start of care.

Response: We appreciate the comments, but do not believe revising the regulation to build in exceptions to the timeframes is necessary. We believe that the proposed timeframes will provide states, providers, and beneficiaries with the necessary flexibility to meet the face-to-face requirement. On an individual basis, circumstances beyond control (natural disaster, terrorist attack, etc.) would be taken into account if the timeframes for a face-to-face encounter for home health services were not met.

Comment: One commenter requested adding some special circumstances that allow for payment to the home care agency for efforts made to get the face-to-face documentation completed and/or get the beneficiary to seek the encounter appointment, but circumstances outside the control of the agency occur and the encounter is not completed. Another commenter stated that there needs to be flexibility in those situations where a Medicaid beneficiary is accepted for care in good faith that a face-to-face requirement will be met by the close of the qualifying period yet circumstances beyond provider control occur that result in failure to comply with this requirement on a timely basis. One commenter requested that the final rule provide good-cause exceptions in cases where beneficiaries have not been able to meet this requirement despite the best efforts of the agency seeking to serve them. Another commenter believed there needs to be clearer discussion of a hold harmless provision that would allow temporary services to be put into place pending the face-to-face encounter.

Response: We disagree that there is a need to add circumstances or situations that allow for payment to home care agencies based on unsuccessful efforts made to timely obtain the necessary face-to-face documentation, or to otherwise allow for good-cause exceptions. The timeframes provided allow enough flexibility to meet the face-to-face requirement in a timely manner. We encourage home health agencies to document efforts to facilitate face-to-face encounters before home health services are furnished, and to collaborate with physicians to ensure timely completion of encounter documentation.

Comment: One commenter stated that in certain circumstances, it should suffice that the personal physician's original diagnosis of the condition for which the individual needs home health services was based on a face-to-face encounter, irrespective of when the face-to-face encounter took place.

Response: The statute requires that a face-to-face encounter must occur within prescribed timeframes in relation to the ordering of home health services. Therefore, it is beyond our authority to allow an encounter that took place outside of those timeframes to suffice.

Comment: One commenter recommended a more flexible approach for states and health plans to follow in verifying the need for home health services.

Response: We believe that the rule provides states and health plans with flexibility while adhering to the statutory requirements.

Comment: One commenter indicated that clarification is necessary regarding the face-to-face encounter in reference to the ''start of services'' and ''initiation of services,'' because home health services can be intermittent, even though the services relate to the same episode. The commenter recommended that the face-to-face encounter for a service or item can relate back to an encounter with the primary care provider that occurred outside the 6-month timeframe, if the service or item relates to the same episode of care that occurred within the 6-month timeframe.

Response: To clarify, we are aligning Medicaid face-to-face requirements with Medicare's face-to-face requirements. A face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. However, as previously stated, this rule does not replace current regulatory requirements, and therefore, the physician should be reviewing the plan of care for home health services every 60 days.

Comment: One commenter questioned what CMS's guidance would be on the face-to-face documentation when the medical condition of the beneficiary changes before recertification. The primary reason for ordering home health will be different than what was indicated on the initial certification of the face-to-face encounter. The commenter further questioned if another face-to-face would be required to continue home health based upon the change in the individual's condition. The commenter also asked what the penalty is if the beneficiary is not able to see the physician within the 30 days after the start of care. Another commenter questioned whether long-term beneficiaries that receive certified nursing assistant (CNA) visits need a face-to-face encounter, and if so, whether it would be a one-time requirement or have to be renewed.

Response: A face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. and must be related to the primary reason the patient requires home health services. If an individual's medical condition changes and this results in the need for an additional home health service, our expectation is that the Home Health Agency would communicate the need with the ordering physician who would revised the plan of care/orders accordingly. An additional face-to-face encounter would not be required. In response to the issue regarding a penalty if the beneficiary is not able to see the physician within the 30 days after the start of care, we clarify that no payment

for home health services can be made for which a timely face-to-face encounter was not documented. However, we believe that the flexibility included in the regulations, allowing NPPs in addition to physicians to perform the face-to-face encounter, as well as allowing the use of telehealth, should prevent the scenario from happening in a majority of cases. The timeframes established in this final rule meet the program integrity and quality goals associated with the provision. In response to the question about CNA visits, all beneficiaries needing home health services are subject to the face-to-face requirement.

Comment: One commenter requested clarification of the effective date for the face-to-face requirement for certification for Medicaid home health and DME.

Response: The statutory provision became effective upon enactment on March 23, 2010, but for home health the statute indicated that the face-to-face requirements applied to physician certifications after January 1, 2010. The provisions specific to this regulation are applicable prospectively starting on the effective date. We intend to work with states and the provider community to ensure compliance. As previously indicated, we are delaying the effective date to July 1, 2016 and compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

Comment: Commenters requested that CMS clarify the circumstances where it is acceptable to perform the face-to-face encounter within 30 days after the start of home health services. One commenter requested clarification regarding the definition or description of circumstances precluding a face-to-face visit within the 90 days prior to the start of home health services. One commenter recommended that CMS clarify that the ''under normal circumstances'' standard reflects permission to allow a state flexibility to extend the encounter timetable, but not make it more restrictive. Alternatively, the commenter suggested that the phrase should be removed to avoid the imposition of stricter timetable standards. Another commenter requested that we not use the wording ''under normal circumstances,'' as unless this term is defined, it can lead to different and varied interpretations and confusion and could possibly allow states to impose a strict guideline on allowing the encounter within 30 days after the start of care.

Response: We do not agree that it is necessary to be prescriptive in defining ''under normal circumstances'' or the circumstances in which it is acceptable to perform the face-to-face encounter within 30 days after the start of home health services. Allowing flexibility in these terms is in the best interest of the beneficiaries. There could never be an exhaustive list of circumstances or parameters defining the term, and while we encourage face-to-face encounters to occur before the start of care, we do not want to unnecessarily restrict the ability of the encounter to occur within 30 days after.

Comment: A few commenters requested that CMS clarify whether the face-to-face encounter is only required for the initial visit or for recertification as well. Another commenter asked whether the rule would also identify recertification timelines such as an annual face-to-face thereafter and whether the physician would be required to see the beneficiary to reevaluate the need for care after 6 months or the proposed 90 day face-to-face encounter timeline. One commenter indicated that the requirement that the face-to-face encounters be related to the primary reason the beneficiary requires home health services will result in additional office visits. The requirement would seem to not consider beneficiaries with chronic conditions, as persons with chronic, even lifelong conditions would not need such regular monitoring for some home health services. One commenter requested clarification regarding whether or not the proposed face-to-face visits will be a billable item for providers. Another commenter requested that CMS clarify or amend the definition of home health services such that this rule would not be applicable to non-medical services such as personal care attendant services.

Response: As previously stated, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. There is no recertification face-to-face requirement. This final rule has not changed current Medicaid regulations which require an individual's physician to review the individual's plan of care every 60 days. In response to the commenter's question regarding billing for the face-to-face encounter, the encounter will be a billable item for providers, under the Medicaid physician benefit or the benefit authorizing payment for services provided by licensed practitioners. Amending or clarifying the definition of home health services in this rule is beyond our authority.

Comment: One commenter requested additional clarification to address differences between Medicare and Medicaid regarding ''episode of care.'' The commenter indicated that many states use systems other than Prospective Payment Systems (PPS) and stated that in these cases, additional guidance on the frequency of face-to-face encounters may be warranted.

Response: Regardless of the payment methodology system used by states, as indicated in the response above, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment.

Comment: One commenter indicated that their current state Medicaid rules require parents to supplement care up to 8 hours in addition to the approved direct services hours and questioned whether the proposed rule would revise the parent supplementation of care requirement.

Response: The Medicaid program, rather than the beneficiary or the beneficiary's family, is responsible for the provision of medical assistance for covered benefits. Although a state can take into account available resources in determining the amount of medical assistance required by the beneficiary, including any legal liability of third parties to provide care, it cannot impose requirements for parents to provide care as a condition of a child receiving Medicaid benefits. Nor can a state impose an in-kind deductible charge (requiring the provision of a certain amount of services as a condition for coverage of other services. The face-to-face encounter requirement does not change these requirements.

Comment: Some commenters requested clarification pertaining to managed care plans. One commenter requested that CMS clarify that the Medicaid face-to-face requirements for home health services required under the proposed regulations apply only for home health services provided through fee-for-service, and not to home health services provided under a Medicaid managed care plan. Another commenter requested clarification on how this rule would apply when members are enrolled in Medicaid managed care plans and the responsibility of plans to report physician encounters to the state.

Response: To clarify, at a minimum, benefits offered in managed care must be the same as the benefits offered in the state plan. Therefore, the approved state plan home health benefit must be offered in managed care. States must

follow statutory and regulatory requirements related to the benefits.

Comment: Commenters were concerned that the face-to-face encounter requirement will erect a barrier to timely care for individuals who are homebound and have difficulty traveling to a provider. Another commenter wanted to ensure that the face-to-face visit requirements do not impede access to necessary home health care.

Response: We recognize that some individuals may have difficulty meeting the face-to-face requirement. We believe we have accounted for these circumstances while meeting statutory requirements, by extending the timeframe of the face-to-face encounter to 30 days after the start of home health services, by allowing for NPPs to complete the face-to-face encounter, and by encouraging telehealth as an alternative for ensuring that this new requirement is implemented in a way that protects continuity of services. Additionally, as previously stated, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment.

Comment: One commenter recommended that CMS create a standard that establishes eligibility for Medicaid coverage of home health services 30 days prior to the face-to-face encounter.

Response: Home health services may be covered by Medicaid for up to 30 days before the face-to-face encounter is conducted; but such services are not covered if the required face-to-face encounter is not conducted within those 30 days. Furthermore such services are not covered in the absence of a physician order for the services, or a written plan of care. Medicaid payment is not available if these conditions are not met.

Comment: One commenter urged CMS to provide guidance to health professionals who order such care and providers who deliver the care to encourage them to include their mutually shared beneficiary in the process of creating the service order and care plan. The commenter also urged implementation that reasonably encourages a robust three-way dialogue among the beneficiary, the ordering health care professional and the service provider to promote person-centered and efficient care driven by the needs and preferences of the beneficiary.

Response: We agree with the commenter. It is our expectation that services are provided to individuals in a person-centered manner and that all providers work collaboratively to ensure that services are meeting the needs of the beneficiaries.

After consideration of the public comments, we are revising this section to clarify that for the initial ordering of Medicaid medical equipment, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. Additionally, we are clarifying that a face-to-face encounter is required for initial ordering of both home health services and medical equipment. Furthermore, for home health services, a face-to-face encounter is required for the initial order and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. We have also delayed compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

F. Practitioners (§ 440.70(f)(2))

The statute describes NPPs who may perform this face-to-face encounter as an NP or CNS, as those terms are defined in section 1861(aa)(5) of the Act, who is working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by state law), or a PA (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician. The statutory provision allows the permitted NPPs to perform the face-to-face encounter and inform the physician, who documents the encounter. Based on the reasoning outlined in the Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012; Final Rule (76 FR 68525), for beneficiaries admitted to home health upon discharge from a hospital or post-acute setting, we proposed to also allow the physician who attended to the beneficiary in the hospital or post-acute setting to inform the ordering physician regarding their encounters with the beneficiary to satisfy the face-to-face encounter requirement, much like an NPP. We proposed to add a new § 440.70(f)(2) to list the practitioners that may perform the face-to-face encounters.

Comment: Some commenters supported this interpretation of the face-to-face encounter requirement.

Response: We appreciate the support of the commenters.

Comment: Several commenters requested clarification on the guidelines for patients having a face-to-face encounter from a physician in another state. One commenter requested that CMS clarify whether a state may, through a state plan amendment, choose to limit the performance of the face-to-face encounter to a subset of the allowed NPPs. Many commenters requested that the rule clarify whether the Medicaid face-to-face must be performed by a physician, and also if that physician must be registered in the CMS PECOS or any other system. If so, the physician community should be alerted, instructed and registrations confirmed well before the rule goes into effect.

Response: Many states have reciprocity agreements with neighboring states, which allow Medicaid beneficiaries in one state to receive services in another state. Section 431.52 provides the federal requirements for payment for services furnished out of state. If the beneficiary has a face-to-face encounter with a physician in a neighboring state that has a reciprocity agreement, then this would be allowed. If a physician practices in a different state that does not have a reciprocity agreement, the physician would need to be a qualified Medicaid provider in the state in which the beneficiary resides. States cannot choose to limit the NPPs approved to complete the face-to-face encounter, as the practitioners are mandated through statute. We are also clarifying that the face-to-face encounter does not need to be conducted by a physician. Per the regulations, any physician would need to be qualified to furnish physician services. It should be noted that for dually-eligible individuals, the Medicare program will likely reimburse for the encounter itself, whether conducted by a physician or NPP. Therefore, the practitioners would need to adhere to Medicare provider qualifications.

Comment: One commenter stated that for beneficiaries participating in section 1115 demonstrations or section 1915(c) HCBS waivers requiring an encounter by a physician or one by the proposed list of NPPs, it may be problematic for benefits such as non-skilled home health, DME, and supplies. Physicians may not always be able to visit beneficiaries in the settings where the benefit determinations are made (for example, assisted living, nursing homes, and other residential care settings). The commenter also stated that the assumption under this proposed rule is that a physician would be the health care professional who orders home health services. However, for non-medical in-home services such as

personal care, the healthcare professional ordering the service is often not a physician.

Response: Section 6407 of the Affordable Care Act has changed the requirements for a person to receive Medicaid home health services. As a condition of receiving covered home health services, a physician or NPP must conduct a face-to-face encounter, and the home health services must be ordered by a physician. These requirements are applicable regardless of where a person lives. Usually people who reside in assisted living facilities and residential care settings are still responsible for arranging for and attending their own doctor's visits. Although dependent upon state licensing standards, assisted living facilities and residential care settings are not likely to have physicians on staff. Physicians are available by arrangement to people who reside in nursing homes if the person does not have a physician in the community. The physicians could conduct the face-to-face encounter and order the home health service on behalf of the person who lives in the nursing home but is transitioning to a setting that comports with § 440.70(c)(1). We clarify that personal care services are outside the scope of this regulation and are not subject to the face-to-face requirements. Any component of home health services would need to be authorized in accordance with the requirements.

Comment: One commenter reported that NPs and PAs can be primary care providers in some states for Medicaid.

Response: Although NPs and PAs may be primary care providers in some states, the law requires the certifying physician to document that the physician or an allowed NPP has had a face-to-face encounter with the beneficiary.

Comment: Many commenters recommended that CMS establish standards to permit physician residents to meet the face-to-face requirements for Medicaid beneficiaries, permit Medicare enrolled physicians to perform the face-to-face for dual eligible beneficiaries, and permit physicians with limited Medicaid and/or Medicare beneficiaries, including federally-employed physicians to utilize an abbreviated enrollment process.

Response: Physician residents would be permitted to perform the face-to-face encounter as long as state law in which the resident is practicing recognizes residents as physicians. We would defer to states to make this determination. We recognize the potential issues surrounding dually-eligible individuals and the face-to-face requirement. To clarify, if a Medicare enrolled physician has completed the face-to-face requirement for a dually-eligible individual, an additional face-to-face requirement would not be needed by a Medicaid enrolled physician, should the benefit change to Medicaid services, as long as there was no new start of care. However, if a new face-to-face encounter is needed under Medicaid, the physician must be Medicaid-enrolled. This rule does not change any requirements of the laws surrounding the provider enrollment process.

Comment: Many commenters suggested allowing any physician to conduct a face-to-face encounter and certify eligibility for home health services, regardless of whether that physician or another physician is responsible for the plan of care.

Response: Any physician enrolled as a Medicaid provider (or in the case of a beneficiary dually eligible for Medicare and Medicaid, enrolled in the Medicare program) can perform the face-to-face encounter and order home health services, provided they also develop the written plan of care in accordance with § 440.70.

Comment: One commenter recommended that CMS clarify that the ordering/prescribing physician who completes the plan of care also be allowed to rely on the in-person assessment of an emergency department physician or of a physician working on behalf of an inpatient rehab or skilled nursing facility prior to the beneficiary's discharge.

Response: To clarify, the commenter's understanding is accurate.

Comment: Commenters suggested allowing any physician to work with another physician colleague sharing the face-to-face encounter and documentation responsibilities along with the certification authority.

Response: We see no reason to prohibit this arrangement.

Comment: Commenters suggested that audiologists and podiatrists be permitted to conduct the face-to-face encounter and then communicate the information to the physician who is responsible for documenting the face-to-face encounter.

Response: This is beyond our authority as statute did not include audiologists and podiatrists as NPPs.

Comment: One commenter stated that it is imperative that the Medicaid home health face-to-face encounter requirements mirror those of the Medicare program in allowing PAs to personally perform the face-to-face visits.

Response: Under the supervision of the physician, PAs are authorized to perform the face-to-face encounter for Medicaid home health.

Comment: One commenter proposed that the regulation specifically state that home care and DME providers can contract with physicians (for example, medical directors) or NPP/physician collaborating teams to complete the necessary face-to-face visits in the patient's home. The home health agency or DME provider should be permitted to compensate time associated with such visits in a manner that would allow the physician or NPP to earn hourly compensation consistent with community standards.

Response: Such an arrangement would need to include a physician who would continue to oversee the provision of home health services in accordance with the written plan of care, as specified in § 440.70.

Comment: Some commenters recommended increasing the role of advanced practice nursing in the ordering of home health services. One commenter also suggested allowing a wider range of practitioners to certify home health care (for example, nurses in advanced practice). One commenter suggested allowing states to determine whether physicians need to order home care and endorse the performance of a face-to-face encounter.

Response: Section 6407 of the Affordable Care Act requires the ordering physician to document that the physician or an allowed NPP has had a face-to-face encounter with the patient. However, the Medicare Access and CHIP Reauthorization Act of 2015 allows for certain authorized NPPs to document the face-to-face encounter for medical equipment. We are using this final rule to conform with this change to statute. With regard to the ordering of services, a change in the statute and current regulatory requirements would be required to allow an NPP to order home health services.

Upon consideration of the public comments received, we are revising this section to clarify that any physician, including the physician who attended to the beneficiary in the hospital or post-acute setting may serve as the ordering physician for home health services provided that, in accordance with § 440.70, the ordering physician also completes the written plan of care.

G. NPP Communication to Ordering Physician (§ 440.70(f)(3))

We proposed to add § 440.70(f)(3) to indicate that if an attending acute or post-acute physician or allowed NPP conducts the face-to-face visit, the attending acute or post-acute physician or NPP is required to communicate the

clinical findings of the face-to-face encounter to the physician, for the physician to document the face-to-face encounter accordingly. We indicated that this requirement is necessary to ensure that the physician has sufficient information to determine the need for home health services, in the absence of conducting the face-to-face encounter himself or herself. We proposed to specify that the clinical findings must be reflected in a written or electronic document included in the beneficiary's medical record (whether by the physician or by the NPP).

Comment: Many commenters requested additional information regarding communication. Several commenters suggested that the rule should clarify if there are any limits on what would constitute ''communication'' under the Medicaid rule with regards to moving information from the face-to-face physician to the ordering physician. Commenters wondered whether such communications would include fax, phone, voice, text, etc., and recommended the broadest definition of communication to help assure access for the Medicaid population. One commenter asked for CMS to clarify what type of communication would be expected to occur between the NPP conducting the face-to-face visit and the ordering physician who is documenting the face-to-face encounter. One commenter requested that CMS elaborate or further define what constitutes communication between the inpatient physician/hospitalist and community physician. The commenter inquired whether communication necessarily meant a verbal conversation or could it also include receipt or access to the beneficiary's discharge summary from the hospital. One commenter indicated that the regulation does not specify what documentation is to be sent to the ordering physician or specify what documentation the home health agency must secure.

Response: We are not prescribing at the federal level what constitutes communication, rather we simply require that the clinical findings of the face-to-face encounter must be communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries.

Comment: One commenter advocated for reducing documentation requirements. The commenter believes it is critical that any additional changes made to the Medicare rule are also made at the Medicaid level. One commenter suggested that CMS consider very clear documentation requirements for when a hospitalist would complete a face-to-face document and report off to the ordering physician who would sign the orders. Another commenter supported that the proposed rule gives states flexibility on the content and form of documentation for the Medicaid face-to-face. The commenter stated that the proposed rule allows states to continue to use their existing form or improve their forms to reflect the face-to-face encounter and that this approach reduces confusion.

Response: Our philosophy is to align face-to-face requirements across the two programs to the extent feasible and practical. In response to the commenter who requested clear documentation requirements for a hospitalist completed face-to-face encounter, as indicated above, our rule permits states considerable flexibility to allow this information to be included in clinical and progress notes and discharge summaries. We appreciate the support of the last commenter.

Comment: One commenter believes that the statement ''this enhanced communication will result in an improved transition of care from the hospital or post-acute setting to the home health setting'' is not true. In fact it has decreased the effectiveness of discharge planning and cost home health agencies a great deal of time tracking down the forms.

Response: The intent of this provision was not to delay transitions from hospitals to community settings. We recognize the importance of smooth transitions that do not negatively impact individuals. As previously stated, we are clarifying in the final rule, that in accordance with § 440.70, home health services must be ordered by the individual's physician. We encourage all parties to collaborate in ensuring timely transitions to community care, including home health services.

Comment: One commenter stated that the proposal requiring the (inpatient) physician to communicate the clinical findings of the face-to-face to the (community) physician is not clear. The commenter asked whether CMS was now precluding the facility physician from documenting the face-to-face encounter and certifying the beneficiary. Additionally, the commenter stated that the proposal requires the findings be communicated to the physician and be in the beneficiary's medical record and asked how this documentation will be assured.

Response: As previously stated, we are finalizing this rule to indicate that any physician can order home health services, provided that the ordering physician also establishes the written plan of care in accordance with § 440.70. Additionally, the ordering physician must document that the face-to-face encounter requirements were met regardless of whether the physician performed the face-to-face encounter himself or herself. It is the physician's responsibility as a provider to ensure that the appropriate medical records are kept. Additionally, the home health agency should maintain a copy of the face-to-face documentation.

Comment: One commenter urged CMS to clarify this provision to clearly state that a NP may conduct the face-to-face evaluation and provide written or electronic documentation that will meet the requirements of both communicating the clinical findings to the physician and including them in the beneficiary's medical record.

Response: We confirm that the commenter's understanding is correct.

Comment: Some commenters requested clarification pertaining to physicians in the hospital setting and the face-to-face requirement. One commenter requested that CMS clarify that it will still be acceptable for an inpatient physician or hospitalist to initiate the plan of care for home health services, conduct the face-to-face encounter, complete and sign the face-to-face form (or support personnel completes the form based upon the physician's documentation in the medical record and then the inpatient physician or hospitalist signs it) and upon the beneficiary's discharge, the community physician develops and signs the plan of care and oversees beneficiary care. Another commenter questioned why a hospital-employed physician cannot complete a face-to-face document on a home health beneficiary.

Response: To clarify, the inpatient physician or hospitalist may also serve as the ordering physician and establish the plan of care. If this is the case, then the community physician's role in the commenter's scenario would be removed. A hospital-employed physician can also complete the face-to-face documentation for a home health beneficiary. Additionally, as previously stated, we are clarifying that the hospital-employed physician may also order home health services in accordance with the written plan of care.

Comment: One commenter stated that § 440.70(f)(3)(v), which stated ''those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record,'' lacks clarity. The commenter stated that normally, documentation of clinical findings would be carried out by the NPP or inpatient physician in his

or her own patient medical record, then applicable information extracted and transmitted to the ordering physician to incorporate into his or her own medical record, followed by extraction of the information required at § 440.70(f)(5)(i) into a document that is sent to the home health agency for its medical record.

Response: We agree with the process outlined in this scenario and believe that the regulatory requirements support this process.

Comment: One commenter reported that the inpatient physician refuses to provide the necessary information to document a face-to-face encounter to an ordering physician frequently, necessitating another face-to-face encounter once the beneficiary returns to the community.

Response: We are establishing a process that meets statutory requirements and aligns with Medicare requirements. Issues of physician cooperation are beyond the scope of this regulation, and would be better raised on an individual, institutional, or state level. While we agree that care should be provided in the most effective and efficient manner, this rule does not mandate specific roles for treating physicians.

Comment: One commenter suggested removing the documentation requirements for beneficiaries who have been in the hospital and instead require a statement from the inpatient or post-acute physician that the beneficiary had the encounter. Another commenter questioned why CMS is requiring the face-to-face encounter at all, since the hospital attending physician obviously saw the beneficiary 90 days prior to the start of care.

Response: We thank the commenters for their suggestions. However, there is a value to the statutorily required documentation of a specific face-to-face encounter that informed the physician ordering the home health or DME service. We do not think a blanket exception for hospital discharges would ensure that the ordering physician was informed by a face-to-face encounter.

Comment: One commenter recommended that the regulation clarify that it is permissible for the home care or DME provider to obtain the documentation of a recent face-to-face visit in acute or post-acute care and to make that documentation available upon request by the ordering physician, rather than require that the acute or post-acute physician routinely communicate directly to the ordering physician.

Response: We believe that it is essential that the practitioner who completed the face-to-face encounter communicate the clinical findings to the ordering physician to ensure that the physician has sufficient information to understand the need for home health services in the absence of conducting the face-to-face encounter himself or herself. As indicated above, we are not prescribing the communication at a federal level. This information can be included in clinical and progress notes and discharge summaries. To permit otherwise would not only violate the statute, it would facilitate disconnect between beneficiary health status and ordering of home health services.

Comment: One commenter indicated that the rule regarding communication of the clinical findings of the encounter to an ordering physician, should not apply to Medicaid unless there is a physician involved in the beneficiary's care.

Response: Current regulations at § 440.70(a)(2) require an individual's physician to order home health services as part of a written plan of care reviewed every 60 days. Therefore, the expectation is that there is always a physician involved in the beneficiary's care as a physician is required to order home health services.

Comment: Some commenters stated that NPPs should also be allowed to certify the need for home health services.

Response: The statute sets forth the requirement that only a physician is authorized to order the need for home health services. It is beyond our statutory authority to expand the role of NPPs.

Comment: One commenter stated that the proposed policy implies that NPs are somehow incapable of authorizing the ordering of appropriate home health services. The commenter indicated that states should have the flexibility to allow NPs to order home health services as well as conducting the face-to-face encounter.

Response: We disagree that this proposed policy implies that NPs are incapable of authorizing the ordering of appropriate home health services. Furthermore, the proposed rule does not replace the existing regulatory language requiring that a physician order home health services. We believe that the statute recognizes the role of NPs working in collaboration with the physician by including NPs as NPPs authorized to complete the face-to-face encounter. The statute requires that physicians order (certify) home health services.

Comment: One commenter suggested that if a physician extender performs the encounter, such as an NP or PA, the extenders should be permitted to document on the face-to-face encounter form itself, sign and date, followed by a separate physician face-to-face form review, signature and date section. The commenter also suggested that reference to attached documentation showing that an encounter within the 90 day time period occurred (such as an office note), should be permitted.

Response: As indicated above, we are not prescribing at the federal level the communication procedures, rather the requirement that the clinical findings of the face-to-face encounter are communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries. There is no federal prohibition on a NPP documenting the face-to-face encounter and having the physician sign the documentation.

Comment: Commenters stated that CMS should clarify that inpatient physicians retain the authority to perform both the face-to-face encounter and complete the documentation and certification for the beneficiary's plan of care.

Response: We agree with the commenters and are revising the final rule to clarify that inpatient physicians may perform the face-to-face encounter, complete the documentation, and order home health services as documented in a written plan of care.

Comment: One commenter suggested that there should be one universal form for everyone.

Response: To provide states flexibility in administering and managing their Medicaid programs, we are not mandating utilization of a common form in the documentation of Medicaid services. However, there is no prohibition on states agreeing to utilize a common form to facilitate standardization.

Comment: One commenter supported a collaborative relationship between a physician and NPP.

Response: We agree with the commenter.

Comment: Some commenters expressed concern regarding the scope of providers that may order medical supplies, equipment, and appliances in the Medicaid program. One commenter believed that home health agencies should be permitted to include medical supplies in Medicaid beneficiaries' plan of care and be separately paid for those medical supplies. Another commenter stated that they believe increasing the role of advanced practice nursing would make a valuable contribution to the ordering of all service modalities under both Medicare and Medicaid.

Response: There is no prohibition on home health agencies being reimbursed for medical supplies, equipment, and appliances provided to a Medicaid beneficiary. They are part of the home health benefit, and can be included in a plan of care when ordered by a physician, as required in § 440.70. We agree with the value added to the provision of health care by advanced practice nurses; their role in the ordering of services depends on the benefit authority being utilized. In the provision of home health services, services must be ordered by a physician.

After consideration of the public comments and to align with Medicare's requirements we are finalizing this section with clarifications. Specifically, we are clarifying that we are not prescribing the communication between the NPP who performed the face-to-face encounter and the physician, rather the requirement that the clinical findings of the face-to-face encounter are communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries. Additionally, we have clarified that attending acute or post-acute physicians may serve as the ordering physician of home health services.

H. Physician Documentation of the Face-to-Face Encounter (§ 440.70(f)(4))

In § 440.70(f)(5)(i), we proposed to require that the physician's documentation of the face-to-face encounter must be either a separate and distinct area on the written order, an addendum to the order that is easily identifiable and clearly titled, or a separate document easily identifiable and clearly titled in the beneficiary's medical record. The documentation must also describe how the health status of the beneficiary at the time of the face-to-face encounter is related to the primary reason the beneficiary requires home health services. In § 440.70(f)(5)(ii), we proposed to require that the physician's documentation of the face-to-face encounter be clearly titled, and state that either the physician himself or herself, or the applicable NPP, has conducted a face-to-face encounter with the beneficiary and include the date of that encounter.

Comment: One commenter appreciated the modifications to the documentation rules and the clarification regarding the ''homebound'' requirement.

Response: We appreciate the commenter's support.

Comment: We received many comments pertaining to documentation requirements. One commenter suggested limiting documentation of a face-to-face encounter to a statement that services are medically necessary, the date of the encounter, the statement that the primary reason for home health services was addressed during the encounter, physician's signature and date. Another commenter suggested limiting documentation of a face-to-face encounter to a physician, NPP, or physician resident signature and date, and the date of the encounter. One commenter suggested that the face-to-face encounter be documented through a check box on the plan of care rather than a separate document. One commenter stated that documentation of any face-to-face encounter needs to be flexible enough to permit the physician or a physician designee to complete the form, prior to the physician review and signature. One commenter advocated for reducing documentation requirements. The commenter stated that it is critical that any additional changes made to the Medicare rule are also made at the Medicaid level. One commenter suggested that the documentation be limited to a few basic fields: The identity of the physician or NPP who performed the encounter; confirmation that the clinical findings support the need for home health care; the date of the encounter; and if documentation is by a different physician, the name of the physician who sent the documentation. One commenter suggested that a more broad certification requirement stating that the physician has personally reviewed the examination and certifies the need for home health care would be a more appropriate and effective use of the physician's time and efforts. One commenter believed that the requirement is simply duplicating documentation already on the plan of care where the physician is certifying the need for skilled care, the services needed, and the diagnoses supporting the need.

Response: To clarify, we are revising the proposed documentation requirements to remove the requirement that the documentation be either a separate and distinct area on the written order, an addendum to the order that is easily identifiable and clearly titled, or a separate document easily identifiable and clearly titled in the beneficiary's medical record and specify what is required which is described in § 440.70(f)(5)(i) and (ii). We are not proscribing a specific method of capturing the requirements. The documentation should support the need for what was ordered. We defer to states for details; we do not see any federal barriers to making the documentation requirements administratively simple.

Comment: One commenter stated that leaving the discretion to state Medicaid programs to determine what constitutes appropriate documentation flies in the face of the desire of attempting to bring greater consistency to regulatory requirements. Another commenter stated that varying standards for documentation will create problems for all. The commenter recommended an effort to create a national standard, with an allowance for states to apply for a waiver. One commenter requested further clarification prohibiting state from requiring additional face-to-face documentation. A few commenters indicated that states should not be permitted to require additional face-to-face documentation. Some commenters urged CMS to rescind guidance that allows states to require information in excess of what is proposed by CMS to document the face-to-face encounter. One commenter stated that CMS should limit, rather than encourage, a state's opportunity to impose additional documentation requirements on home health agencies beyond those already included in the regulation. Some commenters indicated that with regard to the additional flexibility already proposed under the Medicaid face-to-face regulation, such as the opportunity for states to limit the face-to-face documentation requirements, they certainly support and would encourage CMS in the final rule to maximize the flexibility given to the states to be more accommodating in their own interpretation of the Medicaid face-to-face rule.

Response: As indicated above, we are revising the proposed documentation requirements as described in § 440.70(f)(5)(i) and (ii). From the federal perspective, our goal is to ensure that required documentation by the state is sufficient to make the linkage between the individual's health conditions, the services ordered, an appropriate face-to-face encounter, and actual service provision. We encourage documentation requirements established by states to meet this goal, while not imposing additional actual or perceived administrative burden. Electronic Health Records may be of use to support the operational requirements and provide a clear audit trail.

Comment: One commenter believed that the ordering physician should be able to rely on the discharge summary identifying a beneficiary's need.

Response: As stated in the proposed rule, we believe that it is necessary that clinical findings of the face-to-face encounter are communicated to the

ordering physician to ensure that the physician has sufficient information to determine the need for home health services, in the absence of conducting the face-to-face encounter himself or herself. We are not proscribing the acceptable form of communication to meet this requirement.

Comment: One commenter indicated that residents, NPs, and Pas should not only be allowed to perform the face-to-face encounter but complete the necessary documentation. Another commenter encouraged CMS to honor the laws of states that permit advanced practice registered nurses (APRNs) to manage beneficiaries independently and allow APRNs not only to conduct the face-to-face visit, but to document that they have done so. Another commenter stated that PAs and other NPPs authorized to personally perform the face-to-face encounter should be able to document the results of the exam in the patient's medical record.

Response: As previously indicated, effective April 16, 2015, for medical equipment, certain authorized NPPs are authorized to document the face-to-face encounter. For home health services, residents, NPs, and PAs, as NPPs defined in statute can complete the necessary face-to-face documentation, but the physician must sign off as the practitioner responsible for ordering home health services.

Comment: Many commenters indicated that the rule should limit the documentation required, and specify where the record of the Medicaid face-to-face encounter must be maintained or if there is a requirement in that regard. One commenter stated that CMS should revise the physician documentation requirements regarding the face-to-face encounter to reduce the paperwork burden on physicians. This approach would allow the use of the model Physician Certification and Plan of Care form with a modification of the form's certification language to include certification of the encounter date and reason related to the need for home health care. The commenter also stated that physicians, hospitals, discharge planners, home health agencies, and beneficiary groups agree that the physician requirements are a barrier to access to home health care for bona fide beneficiaries who meet coverage standards. Additionally, the commenter stated that CMS has unnecessarily expanded the scope of the required documentation. The additional documentation is not needed because the physician is already required to compose a detailed plan of treatment that sets out the patient's clinical condition and prescribed care. One commenter stated that proposed changes help to ease the burden by a small amount; however, it still creates redundant and unnecessary paperwork by requiring a certifying physician to restate the findings of the hospitalist and/or discharging physician. The commenter stated that do not understand how adding a second layer of physician review serves the purpose of CMS or the needs of beneficiaries. One commenter believed that this requirement will negatively impact access and serve as a barrier to care because of the additional administrative burden to physicians filling out the face-to-face form. Another commenter stated that many doctors are stating that they do not like the additional documentation requirements. One commenter indicated that physicians have been hostile to the new requirement, particularly the documentation standards. The face-to-face-encounters and documentation create unnecessary roadblocks to care. Another commenter reported that physician compliance with the documentation requirements has been ''horrific.'' One commenter stated that face-to-face documentation itself is viewed as an additional burden by physicians. Some commenters stated that CMS must guard against an increase in resistance and opposition from community physicians who may view the new rule as shifting documentation burdens from one physician sector to another.

Response: We agree with the goal of assuring the program requirements are not overly burdensome. In general, the documentation requirements and specifically the provision that the community physician retain documentation that describes how the beneficiary's health status warranted the ordering of home health services is consistent with current standard practice of care. However, we recognize that requiring a certifying physician to restate the findings of the hospitalist and/or discharging physician could create an additional burden. As previously stated, we are revising the final rule to allow any attending physician to order home health services, therefore, reducing the documentation requirements between inpatient physician and community physician as indicated in the proposed rule.

Comment: A few commenters requested better clarification of the requirement that the documentation of the face-to-face encounter be separated from the order. Specifically, the commenters requested that the regulation explicitly state that a copy of the face-to-face encounter documentation which contains required elements be considered valid documentation.

Response: Based on comments we are removing the requirement that the face-to-face documentation be on a separate and distinct area on the written order. In response to the commenters' second request that a copy of the face-to-face encounter documentation be considered valid documentation, it is not clear exactly what is intended. The documentation of the face-to-face encounter is not necessarily sufficient to document the physician order for home health services, which should be part of the plan of care. But if the question is whether a state would require an original or a copy, while we generally defer to states on the operational details, we expect that the documentation will generally be included in an individual's electronic health records.

Comment: One commenter stated that CMS should refrain from requiring physicians to document a face-to-face visit using specific language or by including specific criteria; record of the visit should be sufficient. The commenter also discouraged CMS from requiring detailed descriptions of the beneficiary's needs for the item the doctor orders, as it would be inconsistent with typical physician practices and could result in decreased beneficiary access. Another commenter suggested that CMS remove the requirement that the physician document how the health status relates to the primary reason the individual needs home care. The commenter believed that the clinical findings are sufficient to describe this necessity and that this section adds a documentation burden for the physician when the diagnosis and/or medical condition is already included on the plan of care the physician signs.

Response: Based on comments and Medicare requirements, we are revising the documentation requirements to align them as much as possible with Medicare documentation requirements. Specifically, for home health services, the physician responsible for ordering the services, and for medical equipment, the physician responsible for ordering services or certain authorized NPPs must document that the face-to-face encounter was related to the primary reason the patient requires home health services, occurred within the required timeframes, was performed by an authorized practitioner, and include the date of the encounter.

Comment: One commenter stated that it should suffice that the individual's physician saw the individual, and based on that visit and the physician's and

other health care providers' records of the individuals health diagnoses and needs, the physician ordered home health care. The particular ''primary reason'' for the face-to-face encounter between the individual and the physician should be of no relevance to the validity of the physician's order and plan of care. The commenter believed that with regard to § 440.70(f)(5)(i) it should suffice that documentation is made in a manner that is useful to health care providers and can be explained to state and federal authorities upon request.

Response: It is important to achieving the purposes of the requirement that the face-to-face encounter focus on the medical issues that result in the need for home health services. An encounter that focuses only on unrelated issues will not ensure accountability and utilization control. Therefore, we are retaining the proposed requirement that documentation of the encounter include an explanation of how the individual's observed health status relates to the primary reason the home health services are needed.

Comment: One commenter suggested expanding the physicians who may document this encounter to include partners of the certifying physician or urgent care center physician (for non-acute inpatient settings). If a patient goes to an outpatient clinic and sees an alternate physician, this alternate physician should be allowed to document the encounter and hand off to the primary physician to sign the plan of care. The commenter also stated that the homebound documentation requirement is not clearly addressed. The commenter suggested removing this requirement from both Medicare and Medicaid regulations and requested that CMS add to the rule that if this section is completed by the physician, it is to be disregarded.

Response: To be able to attest to the completion of the face-to-face requirement, an urgent care physician must satisfy the general requirements of § 440.70 in terms of physician development of plan of care and review of the plan of care every 60 days. Otherwise, an additional physician performing the functions must be brought in. We interpret physician to include partners as well. The homebound requirement is an area of disparity between Medicare and Medicaid as the homebound requirement is prohibited by Medicaid. However, this requirement is part of Medicare statute which we cannot waive.

Comment: One commenter expressed that specifying the guidelines for documentation at the federal level provides an opportunity for greater alignment with Medicare requirements.

Response: We agree and as indicated above, we are revising the proposed documentation requirements to align with Medicare requirements.

Comment: One commenter suggested that the face-to-face document be permitted to be completed by physician designees, who should sign and date the form, followed by the physician reviewing, signing, and dating. The commenter also stated that if a physician extender performs the encounter, the extenders should be permitted to document on the face-to-face encounter form itself, sign and date, followed by a separate physician face-to-face form review, signature, and date. One commenter requested clarification regarding whether or not an NPP can write an order and a physician can simply sign the order, rather than writing the order himself or herself.

Response: We are not prescribing who completes the documentation, but the documentation requirements must be met. As previously stated, administrative simplification is supported.

Comment: One commenter indicated that further clarification is needed from CMS on the documentation that is required from the beneficiary's primary physician, when the face-to-face encounter is conducted by NPs or PAs.

Response: The physician documentation requirements are described in § 440.70(f)(5)(i) and (ii). This documentation is required regardless of whether the physician or one of the permitted NPPs performed the face-to-face encounter.

Comment: One commenter requested guidance from the federal government regarding whether or not a physician must approve findings and referrals of NPs in cases where a NP is unable to obtain a physician's documented approval of findings to authorize an order of home health services.

Response: To clarify, we are retaining the requirement under § 440.70(a)(2) that covered Medicaid home health services must be supported by a physician order, as part of a written plan of care, regardless of whether NPs are authorized under state law to order home health services. That order should be based on the physician's own professional judgment after reviewing all available information, which can include the findings of the NP and patient medical records.

Comment: One commenter indicated that the documentation requirements are not found in statute.

Response: In accordance with section 6407 of the Affordable Care Act, the physician's order must document and be based in part on a face-to-face encounter. While it does not specify the form in which the face-to-face encounter must be documented, it clearly requires such documentation.

Comment: Some commenters stated that the person-centered-plan of care process described will add more quality and integrity to the Medicaid services than insisting that physicians add more paperwork.

Response: We agree that the person-centered-plan of care process is integral to ensuring quality Medicaid services are not inconsistent with requirements for physician orders, face-to-face encounters, and a written plan of care.

Comment: One commenter requested that CMS consider further clarification or definition of the person-centered philosophy with regard to the home health plan of care requirements for children and youth under the age of 18. The commenter indicated that their state program does not discuss clients' protected health information, including their medical treatment plans, with non-legal caregivers.

Response: We have not yet issued guidance on person-centered planning as it relates to home health. However, this process should be implemented consistent with other federal requirements that protect confidential health information such as Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Comment: One commenter stated that the need to collect additional documentation could delay urgently needed care and payment for services.

Response: We are confident that providers can determine ways that they can work together without delaying services to beneficiaries.

After consideration of the public comments and to better align with Medicare requirements, this section is being finalized with the following revisions:

- We are revising the documentation requirements to remove the requirement that the documentation be either a separate and distinct area on the written order, an addendum to the order that is easily identifiable and clearly titled, or a separate document easily identifiable and clearly titled in the beneficiary's medical record.
- We are clarifying the documentation requirements and specify what is required which is described in § 440.70(f)(5)(i) and (ii).
- We are clarifying that for medical equipment, in addition to the physician, the allowed NPP, as described in

paragraph (f)(3)(ii) through (v) are authorized to document the face-to-face encounter.

I. Face-to-Face Encounter Through Telehealth (§ 440.70(f)(6))

Proposed § 440.70(f)(6) outlined that the face-to-face encounters may be performed through the use of telehealth.

Comment: Several commenters expressed support of the provision. One commenter supported CMS's proposal on the use of telehealth to conduct a home health face-to-face encounter. Another commenter was encouraged that CMS stated that states should ''implement [the telehealth] provision in a way that does not result in barriers to service delivery'' and that states should ''work with the home health provider community to incorporate the face-to-face visits in creative and flexible ways to account for individual circumstances.'' The commenter was also pleased that CMS is ready to offer technical assistance to state Medicaid agencies to use telehealth as an alternative so that the requirement may be implemented in a way that protects the continuity of services. One commenter supported CMS's decision to permit the face-to-face encounters to occur through the use of telehealth. Another commenter viewed the provision of allowing a telehealth encounter instead of a face-to-face encounter as a positive development and would like to see this option expanded whenever possible. Yet, another commenter appreciated that the proposed rule allows states that currently use telehealth or telemedicine when delivering services under Medicaid to be able to use the techniques to fulfill the face-to-face encounter. One commenter appreciated that the coverage of telehealth is discretionary.

Response: We appreciate the support of the commenters.

Comment: Commenters believed that the allowance to use telehealth or telemedicine should extend to all forms of electronic communication in compliance with the face-to-face requirement for home health services. Conversely, one commenter indicated that the proposed regulation as written could allow managed care plans and FFS providers to bill for telephone calls, emails, and faxes with another provider when the beneficiary is still at the originating site or not present in the room at all, and stated that this would have to be built into capitation rates for managed care plans. One commenter indicated that telehealth and telemedicine are two different approaches in providing health care. The use of the term ''telehealth'' implies that the provider will be able to use a telephone, email or other telecommunications to contact the beneficiary to provide the face-to-face requirements. It is unclear if it is the intention of CMS to allow telephone calls and emails to replace a face-to-face visit. One commenter commended us for the use of the term ''telehealth,'' which correctly describes the universe of health services provided by the diverse array of providers, versus ''telemedicine,'' which can be interpreted to focus on a more limited array of services offered by a particular set of providers.

Response: Telehealth and telemedicine are service delivery modalities that have very specific protocols that ensure quality patient care, and do not include all electronic communications. We recognize that there may be confusion surrounding the terms ''telehealth'' and ''telemedicine'' as the terms may have different meanings as recognized by a state in accordance with Medicaid policy, and as recognized under the Medicare statute and regulation. The Medicaid ''telemedicine'' description is modeled on Medicare's definition of telehealth services located at § 410.78, but allows states flexibility in keeping with their general authority to regulate the medical professions. It is not our intention to allow telephone calls or emails to replace the face-to-face encounter. In other words, telehealth and telemedicine are service delivery models and do not replace the requirement that a physician or NPP must have a face-to-face encounter with a beneficiary. Rather, the face-to-face encounter can be met though a telehealth delivery model that is recognized by the state as a physician or NPP encounter under its approved state plan. See *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html*.

Comment: Commenters urged CMS to allow states to define the form and extent of telehealth that can be used for meeting the face-to-face requirements. The commenters suggested that the rule should be amended to state: ''states can permit the use of any two-way audio/video communication medium as allowed by state law to connect the beneficiary to the physician/NPP to meet the face-to-face requirements.'' One commenter stated that telehealth services should be defined in a way that allows a beneficiary to meet the face-to-face encounter requirements through modern technologies available in their home, including two-way audio and video communications. Another commenter recommended that federal telehealth policy be revised to make the home an approved site and to encourage state Medicaid programs to pay for telehealth visits. Other commenters recommended that CMS require state Medicaid programs (and the Medicare program) to allow face-to-face encounters to take place via telehealth technology deployed in beneficiaries' homes and reimburse agencies and practitioners for the costs involved. One commenter expressed concern that the face-to-face encounter requirement will erect a barrier to timely care for beneficiaries who are homebound and have difficulty traveling to a location that is equipped with telehealth technology. One commenter requested that for special circumstances, CMS broaden the definition to include Skype encounters with beneficiary/physician or allow home monitoring devices used by home care agencies to be established in physician offices. One commenter believed that it is important that CMS maintain the telehealth flexibility which state Medicaid programs currently have of not limiting telehealth to rural health professional areas. One commenter recommended that the use of telehealth be an option in non-rural areas, in addition to rural areas. One commenter requested that CMS clarify whether a state may, through a state plan amendment, limit the use of telehealth for conducting the face-to-face encounters to rural or other geographic areas where there are issues related to transportation or access to practitioners. One commenter believed that there are many regulatory and procedural constraints which will need to be amended to enable full and successful implementation of telehealth services by all healthcare providers. One commenter stated that the telehealth requirement for Medicaid purposes should include sites of service where the patient may receive the home care or use the DME. For example, a home visiting or adult day care nurse should be permitted to establish a video visit to an office based physician, allowing the physician to assess the beneficiary's need for home care or DME. Existing tablet computer and wireless technologies make such visits practical in any setting. In rural areas, without broadband cellular service, portable videoconferencing tools that use ''plain old telephone service'' exist for this purpose. One commenter stated that the benefits of this provision are limited for Medicaid beneficiaries due to restrictions on the use of RPM (remote patient monitoring) in Medicare law.

The commenter indicated that CMS should include a provision for dual eligibles to have care coordinating access to RPM technologies under Medicare and Medicaid.

Response: In the absence of specific Medicaid statutory requirements, we are hesitant to proscribe the locations and/or technologies that states may use to meet the face-to-face requirement through telehealth. Under Medicaid policy, states have the flexibility to define coverage of telehealth including what types of telehealth to cover; where in the state it can be covered; and how it is provided. Our expectation is that care delivered using various technologies will lead to good outcomes and meet the needs of the individual while adhering to privacy requirements, including the requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We recognize the need for updated Medicaid telehealth guidance, which will be forthcoming. In the meantime, we are available to provide technical assistance.

Comment: One commenter indicated that video or recording used in telehealth or telemedicine should be confidential and done in a manner to protect beneficiary's rights.

Response: We agree with the commenter. As previously stated, the use of telehealth or telemedicine does not negate HIPAA or Medicaid privacy requirements.

Comment: One commenter stated that CMS should monitor and make known which state Medicaid agencies permit face-to-face encounters via telehealth for certification of home health services under Medicaid. The commenter also recommended that CMS develop and implement a mechanism to track which states permit the face-to-face encounter to occur through telehealth. The commenter believed that CMS should know whether and to what extent Medicaid beneficiaries have access to services via telehealth. Additionally, the commenter stated that for those state Medicaid programs that do not permit the face-to-face encounter prior to the ordering for home health services to occur via telehealth, CMS should endeavor to learn what barriers exist to prevent the use of telehealth and assist states to overcome those barriers. The commenter stated that CMS should be proactive in determining what states need to realize the goal of expanding the use of telehealth services and that CMS should encourage state Medicaid agencies to take advantage of the relative flexibility they have regarding implementing and paying for telehealth services under Medicaid. The commenter stated that when possible, CMS should adopt the innovative and cost-saving telehealth systems, as developed and implemented by states, into the Medicare regulations and policy for telehealth services. Additionally, the commenter indicated that CMS should hold state Medicaid agencies accountable for dual eligibles' access to telehealth services in general and the face-to-face pre-certification encounter in particular.

Response: We will consider the recommendations of the commenter for future action. We recognize that there are differences between Medicare and Medicaid on the issue of telemedicine and telehealth. But the general requirements for telehealth and telemedicine are not the subject of this rulemaking.

Comments: One commenter appreciated allowing telehealth as a means of meeting the face-to-face requirement, but was concerned that it will not be enough.

Response: We recognize that there may be individual circumstances and we encourage states to work with the home health provider community to incorporate the use of telehealth to meet the face-to-face requirement in creative and flexible ways to account for individual circumstances. We are available to provide technical assistance to states in achieving this goal.

Comment: Some commenters requested clarification. One commenter requested clarification on Medicaid coverage of telehealth equipment, facilities, and transmission costs. Another commenter requested that CMS clarify that telehealth encounters would qualify for FFP as a reimbursable visit.

Response: Medicaid does not reimburse for telecommunications equipment or facility costs separately. However, states could build reimbursement for the costs into the rate and states can include in the rate a separate amount for such costs. Reimbursement for services provided through telehealth is voluntary on the part of state Medicaid agencies as they are viewed as alternative methods of providing services, not as a separate type of service. Therefore, reimbursement is only available if the state has chosen to cover services provided via telehealth or telemedicine and only in the circumstances selected by the state.

After consideration of the public comments, this section is being finalized as proposed.

J. Face-to-Face-Encounter for Medical Supplies, Equipment and Appliances (§ 440.70(g))

As proposed, § 440.70(g) applies all of the requirements of § 440.70(f) to the provision of medical supplies, equipment and appliances as described in § 440.70(b)(3), to the extent that a face-to-face encounter would be required under the Medicare program for DME, with one exception from the requirements at § 440.70(f). Per the statute, as amended by the Affordable Care Act, certified nurse midwives are not permitted to conduct face-to-face encounters required for the items, as proposed at § 440.70(g)(2). To maximize consistency between the Medicaid and Medicare programs and reduce the administrative burden on the provider community, we proposed to limit the face-to-face requirements to items that would be subject to such requirements as DME under the Medicare program. Thus, we would only require that, for items of DME specified by CMS under the Medicare program as subject to a face-to-face encounter requirement, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires the item has occurred no more than 90 days before the order is written or within 30 days after the order is written. Medical supplies, equipment and appliances for which a face-to-face encounter would not be required under the Medicare program as DME, would not require a face-to-face encounter before the ordering of items under the Medicaid program. The items will be of a smaller dollar value, and at a decreased risk for fraud, waste, and abuse.

Comment: Some commenters supported the proposed requirement that a face-to-face encounter must be performed prior to a physician ordering medical supplies and DME. One commenter applauded CMS' decision to limit the applicability of the face-to-face encounter requirement to the medical equipment, supplies, and appliances that are included on the Medicare program list of specific DME. Another commenter supported the consistency with Medicare timeframes for orders for DME.

Response: We appreciate the support expressed by the commenters We agree that there should be consistency with the timeframes for the face-to-face encounter for DME in Medicare and medical equipment in Medicaid. Since the proposal and comment period of this rule, Medicare has finalized their DME face-to-face rule requiring the face-to-face encounter for DME to occur no

more than 6 months prior to the start of services. Therefore, we have revised the Medicaid medical equipment face-to-face timeframes to align with the Medicare timeframe.

Comment: One commenter asked that we clarify the effective date for the face-to-face requirement for certification of Medicaid DME services. Additionally, the commenter requested clarification as to whether the face-to-face encounter for DME applies to DME furnished solely as a home health benefit or whether it also applies to DME paid for by Medicaid that is not covered as part of the home health benefit. Another commenter requested that CMS clarify whether a state may choose to extend the face-to-face requirements to include equipment, supplies, or appliances that are covered under the state's Medicaid program, but are not Medicare benefits. One commenter requested that CMS clarify that the proposals, if finalized, would not apply to medical equipment under the Medicaid program until CMS has issued a final Medicare face-to-face rule.

Response: The provisions of section 6407 of the Affordable Care Act became effective in 2010 and added the requirement that physicians document the existence of a face-to-face encounter for home health services including medical supplies, equipment and appliances. However, as previously indicated, we are delaying the effective date of this rule to July 1, 2016 and we are allowing states and providers up to one year from the effective date of the final rule to come into compliance with the rule if the state's legislature has met in that year, otherwise 2 years.

Any medical supplies, equipment, and appliances provided under the home health benefit must meet the face-to-face requirement. If the state is providing supplies, equipment or appliances under a benefit category other than home health, such as the therapy services authorized at § 440.110, or prosthetics authorized under § 440.120, the state would need to adhere to the requirements of that particular benefit. In response to the concern that we clarify that the final rule will not apply to medical equipment under the Medicaid program until we have issued a final Medicare face-to-face rule, Medicare's DME face-to-face rule was effective on July 1, 2013. Our alignment of the scope of items requiring the face-to-face encounter with Medicare does not depend on Medicare regulation. The list of DME items subject to the face-to-face encounter can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/DME_List_of_Specified_Covered_Items_updated_March_26_2015.pdf.* States may decide to apply face-to-face requirements to a broader range of medical supplies, equipment, and appliances than those for which Medicare requires an encounter, but are not required to do so.

Comment: One commenter stated that with regards to the face-to-face requirement for DME, the regulation is vague as to which party is responsible for the face-to-face documentation for billing purposes and does not sufficiently define the items that will be subject to this requirement.

Response: The physician or the NPP who completed the face-to-face encounter is responsible for documenting the encounter. However, as previously stated, this rule does not replace the existing Medicaid regulatory requirements related to physician orders. In response to the comment that the regulation does not sufficiently define the items that will be subject to the face-to-face requirement, we intend to issue guidance to states indicating how they, and providers, can access the current Medicare list of specific DME items subject to the face-to-face requirement. Medical supplies, equipment and appliances for which a face-to-face encounter would not be required under the Medicare program as DME, would not require a face-to-face encounter before the ordering of items under the Medicaid program.

Comment: One commenter stated that it is a rare physician who is able to determine what DME is appropriate for a beneficiary without the advice of rehabilitation therapists. In addition, almost all DME requires training of beneficiaries and caregivers. The commenter encouraged reconsideration of state discretion in relation to rehabilitation when DME is required.

Response: We recognize that the recommendation and determination of appropriate medical equipment is often made by providers other than the physician and we encourage a collaborative approach to determining a beneficiary's needs. The statute sets forth the practitioners who are authorized to complete the face-to-face encounter for medical supplies, equipment, and appliances and maintains the role of the physician in the actual ordering of medical supplies, equipment, and appliances. However, as stated in the preamble, only items of DME specified by CMS under the Medicare program would be subject to a face-to-face encounter requirement.

Comment: Many commenters had suggestions pertaining to CMS's proposal of exceptions to the face-to-face encounter for certain DME as specified by under the Medicare program. Commenters suggested that the face-to-face exceptions for home health medical equipment should be expanded so that only those items that are most likely to be abused require a face-to-face visit. Another commenter believed that CMS can develop a suggested list of DME that requires face-to-face encounters, but state Medicaid programs should be able to make the final decision on which items will require the face-to-face encounter. Other commenters suggested that the requirement of face-to-face encounter should apply to all medical supplies and DME.

Response: We believe that by aligning with Medicare's implementation of this provision, we will ensure that beneficiaries are receiving needed items and provide clear and consistent guidance to states. Therefore, we will not be expanding the exceptions from the face-to-face requirement beyond the list used in Medicare. Based on the previously stated rationale, state Medicaid programs could require face-to-face encounters on more items than would be required under Medicare, but not fewer items. In response to the comments suggesting that the face-to-face encounter should apply to all medical supplies and DME, we disagree as we believe that this alignment and consistency will reduce the administrative burden on the provider community.

Comment: One commenter suggested that CMS look first to its Medicare national and local coverage determinations to determine what DME items require an in-person physician visit. Additionally, the commenter stated that CMS should adhere to already established Medicare coverage policies regarding the need for a beneficiary to see his or her physician for DME rather than expand the face-to-face requirements to more routine types of DME such as canes, walkers, and commodes. The commenter also recommended that CMS not require beneficiaries who need supplies, refills, repairs, or service of their equipment to have follow-up face-to-face physician visits. Another commenter indicated that DME and medical supplies items also include basic needs such as canes, crutches, walkers, diapers, applicator sticks, just to name a few. The commenter specified that to require a physician endorsement of each of the items for a population that is already under-served and receives care exclusively from NPs in a large number of states, is not only unreasonable, but

increases costs and causes delays in care.

Response: As previously stated, only items of DME specified by CMS under the Medicare program would be subject to a face-to-face encounter requirement for the Medicaid program. Additionally, to clarify, an additional face-to-face encounter would not be required for refills, repairs, or service of equipment. The face-to-face encounter is required for the initial ordering of medical supplies, equipment, and appliances. As this rule does not preclude existing regulations, the need for medical supplies, equipment, and appliances must be reviewed by a physician annually. We believe that the requirements may be met without causing undue hardship on beneficiaries or the provider community.

Comment: One commenter strongly recommended that there be an explicit prohibition on any ownership relationship between the physician ordering the equipment/supplies/appliances and the provider of those items.

Response: We thank the commenter for the recommendation, but this is beyond the scope of this regulation.

Comment: One commenter indicated that for beneficiaries participating in a section 1115 demonstration or section 1915(c) HCBS waiver, benefits such as DME and supplies requiring a physician encounter, or one by the proposed list of NPPs, may be problematic as the benefits are often determined by non-physician case managers and the physician requirement could add additional costs to strained state Medicaid budgets.

Response: We recognize the commenter's concern. However, statute mandates the face-to-face encounter for medical supplies, equipment, and appliances under the home health services benefit. We note that this rule applies to the home health benefit as implemented in the Medicaid state plan. To the extent that state plan service is provided through a waiver or demonstration, the requirements would continue to apply.

Comment: One commenter stated that PAs should be authorized to order medical supplies and equipment for Medicaid beneficiaries, consistent with DME supplies and equipment within the Medicare program. Another commenter urged CMS to allow NPs to continue to order durable medical supplies, equipment, and appliances, as they are able to do under current regulations. One commenter was concerned about the limits being placed on NPs regarding the ordering of DME. Other commenters urged CMS to allow other practitioners who may prescribe medical supplies and DME under state law, to do so under Medicaid as well. The commenters also suggested that audiologists and podiatrists be permitted to conduct the face-to-face encounter and then communicate the information to the physician who is responsible for documenting the face-to-face encounter.

Response: We appreciate the suggestions. As previously stated, this rule does not supplant existing regulatory requirements that provide that a physician must order an individual's services under the Medicaid home health benefit. The statute maintains the role of the physician in the actual ordering of medical supplies, equipment, and appliances. Additionally, the statute sets forth the NPPs who are authorized to conduct the face-to-face encounters before the start of home health services. It is beyond our authority to change statute.

Comment: One commenter stated that certified nurse-midwives should not be prohibited from ordering DME for their beneficiaries.

Response: The statute and current regulations maintains the role of the physician in the ordering of medical supplies, equipment, and appliances.

Comment: One commenter believed home health agencies should be permitted to include medical supplies in their plan of care and be separately paid for those medical supplies.

Response: If the home health agency is a Medicaid provider of medical supplies, equipment and appliances, then it can receive payment for medical supplies, equipment, and appliances based on the physician's order and plan of care.

Comment: Many commenters recommended that the requisite timeframe be extended to 6 months for medical equipment and appliances.

Response: As indicated above, we are revising the timeframe requirements to no more than 6 months prior to the start of services. We believe that this alignment will provide consistency among the programs and less fragmented services for beneficiaries who are dually eligible.

Comment: Several commenters recommended that when home health care is complicated (for example, certain medical equipment), CMS permit a greater period of time between the face-to-face visit and receipt of services.

Response: We believe that the 6 month timeframe for the face-to-face encounter will meet the needs of beneficiaries and permit sufficient time for providers to analyze beneficiary needs.

Comment: One commenter indicated that they are confident that the overwhelming majority of orders for medical equipment are already made in an appropriate medical context. The commenter believed that it would be unnecessary for CMS to create, or require a state to create, new in-person evaluation or documentation requirements for many categories of medical equipment. Additionally, the commenter stated that when medical equipment is ordered on discharge from an inpatient stay, it would be unnecessary for CMS to impose additional face-to-face physician visit or documentation requirements because the beneficiary's need for equipment would have been evaluated during their stay.

Response: The face-to-face requirement is mandated by statute regardless of whether the majority of orders for medical equipment are already made in an appropriate medical context. We allow for the face-to-face documentation to be part of the order or an addendum to it. As previously stated, we have clarified in this final rule that the inpatient physician can order home health services, which would include medical equipment, supplies, and appliances, in accordance with § 440.70. Therefore, if the inpatient physician orders the medical equipment following all of the face-to-face requirements, including documentation of the face-to-face encounter, there would be no need for an additional face-to-face visit upon discharge. However, if the inpatient physician was not the ordering physician, it would be acceptable for the community physician (or his or her support staff) to attach a communication from a physician who cared for the beneficiary in an acute or post-acute facility, who performed the encounter (such as a discharge summary), to the order as an addendum. If, for example, a discharge summary from a physician who cared for the beneficiary in an acute or post-acute facility contains all of the needed documentation content, the ordering physician would simply need to sign and date the discharge summary and ensure it is attached as an addendum to the order. We believe that this process will help to insure continuity of care between the hospital and the community physician.

Comment: One commenter stated that there may be times where a physician might order an item such as a walker based on self-reports from the beneficiary or his or her caregiver. For example, a beneficiary may report recent falls within the home and a

doctor might order a cane or a walker before he examines the beneficiary in person. Similarly, the beneficiary may have a progressive condition and the physician determines, based on the beneficiary's self-reports and clinical history, that he or she needs different equipment. When the physician orders DME in these situations, CMS should not require a face-to-face encounter because the physician prescription is based on the beneficiary's medical history and is made in response to predictable changes in the beneficiary's condition.

Response: We appreciate the comment, however, we do not have the authority to revise the requirements of the statute which requires a face-to-face encounter for home health services as they apply to medical supplies, equipment, and appliances under the home health services benefit. Since the encounter can be conducted up to 6 months prior to the ordering of equipment, this provision should not prevent the provision of timely care.

Comment: One commenter believed that CMS should not require an additional face-to-face visit for DME identified by the home health agency nurse or other skilled clinician and communicated to the physician overseeing the plan of care. The commenter also believed that CMS should not impose a physician visit requirement for prescription renewals, supplies, and/or accessories used with a particular device, and repairs or replacement of equipment. Additionally, CMS should not extend the face-to-face requirement to ongoing supplies or other items that are ancillary to the DME prescribed but nonetheless necessary to deliver appropriate therapy.

Response: The statute identifies the authorized NPPs who may conduct the face-to-face encounter. It is beyond our authority to expand this list to include the home health agency nurse or other skilled clinician not included as an authorized NPP. We clarify that an additional face-to-face requirement would only be required if a new medical equipment, supply or appliance is needed. Renewals, repairs and the need for ancillary equipment would not trigger the need for an encounter.

Comment: One commenter stated that the extension of a requirement for a physician order to provide DME to Medicaid enrollees is an additional barrier to beneficiaries receiving the medical supplies and equipment they need.

Response: We appreciate the commenter's concern. However, as previously stated, the statute mandated the face-to-face requirement for home health services, including medical equipment, supplies, and appliances. The purpose of this regulation is to implement that statutory directive.

After consideration of the public comments, this section is being finalized with revisions to the timeframes for the face-to-face encounter for DME. Specifically, we are adding § 440.70(f)(5)(ii) which indicates that for the initiation of DME, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur no more than 6 months prior to the start of services.

Additionally, as previously indicated, we are using this rule to conform with the Medicare Access and CHIP Reauthorization Act of 2015 and clarifying that for medical equipment, in addition to the physician, the allowed NPPs, as described in paragraph (f)(3)(ii) through (v) are authorized to document the face-to-face encounter.

IV. Provisions of the Final Regulation

For the most part, this final rule incorporates the July 12, 2011 provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- We are revising § 440.70(b) introductory text to state that coverage of home health services cannot be contingent upon the beneficiary needing a nursing or therapy services.
- We are amending § 440.70(b)(3)(ii) to include the term ''disability'' to the definition of equipment and appliances and to clarify that state Medicaid programs are not restricted to the items covered under DME in the Medicare program.
- We are adding § 440.70(b)(3)(v), to state that states can have a list of preapproved medical equipment supplies and appliances for administrative ease, but not as an absolute limit on coverage; states must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and individuals are informed of their right to a fair hearing.
- We are revising § 440.70(c)(1) to codify the homebound prohibition for Medicaid home health services; home health services may not be subject to a requirement that the individual be ''homebound.'' Additionally, we are clarifying the settings in which home health services may be provided. Specifically, we are adding the clarification that home health services may be provided in settings where normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.
- We are adding 440.70(f)(5)(i) and (ii) to specify that the ordering physician must document the face-to-face encounter which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services; must indicate the practitioner who conducted the encounter, and the date of the encounter.
- We are adding § 440.70(f)(2) which indicates that for the initiation of DME, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur no more than 6 months prior to the start of services.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

On July 12, 2011 (76 FR 41032), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). See below for a summary of the PRA-related comments along with our response.

Subsequent to the publication of the proposed rule, we have revised our cost estimates by using the most current U.S. Bureau of Labor Statistics' wage estimates along with our fringe benefit adjustment factor. An additional change is discussed in Collection of Information section V.B.2.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Family and General Practitioners	29–1062	89.58	89.58	179.16
Nurse Practitioners	29–1171	47.11	47.11	94.22
Physician Assistants	29–1071	46.77	46.77	93.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Carried Over From the July 12, 2011, Proposed Rule

1. ICRs Regarding Home Health Services: Physician Documentation of the Face-to-Face Encounter (§ 440.70(f) and (g))

Section 440.70(f) and (g) requires that physicians (or for medical equipment, authorized non-physician practitioners (NPPs) including nurse practitioners, clinical nurse specialists and physician assistants) document that there was a face-to-face encounter with the Medicaid beneficiary. The burden associated with this requirement is the time and effort to complete and maintain this documentation. The documentation must clearly demonstrate that the face-to-face encounter occurred within the required timeframes and indicate the practitioner who conducted the encounter along with the date of the encounter. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. In this regard, we estimate 10 minutes for each encounter. We also estimate that there are approximately 1,143,443 initial home health episodes in a given year (this estimate is based on our 2008 claims data which is also our most recent data). Due to the lack of data for each provider type, we are dividing our 1,143,443 episode estimate into 3 equal parts of 381,147.67 for each of the three respondent types (family and general practitioners, nurse practitioners, and physician assistants). Our estimated burden for documenting, signing, and dating the beneficiary's face-to-face encounter is 190,574 hours (this estimate is based on our CY 2011 data which is also our most recent data). We acknowledge that this figure is inflated by instances in which the physician conducted the face-to-face encounter with the beneficiary, making this second 10-minute documentation burden unnecessary.

The estimated cost to document the face-to-face encounter, which varies by practitioner, consists of $29.74 (0.167 hr × $179.16/hr) for a family and general practitioner, $15.64 (0.167 hr × $94.22/hr) for a nurse practitioner, and $15.52 (0.167 hr × $93.54/hr) for a physician assistant. We estimate an aggregated cost of $23,355,067 (see the burden table in section V.C. of this final rule). The requirements and burden will be submitted to OMB under control number: 0938–1188 (CMS–10434).

Upon consideration of the public comments received, we are finalizing this section as proposed.

Comment: Several commenters reported that the estimated burden does not accurately account for home health agency burden. One commenter further stated that 35 minutes per beneficiary should be added to home care agency time if the form is completed correctly the first time. If the form is not correct, 25 to 45 minutes should be added to 25 percent of the beneficiaries. Another commenter stated that in reality, the face-to-face is already taking up another 30 to 45 minutes on the home health agency side plus at least 15 minutes on the physician side. Another commenter stated that the estimate does not include the time that is required for home health agencies and medical equipment companies to ensure that the encounter occurred and that the documentation is received and in compliance with federal and state requirements. To ensure that the encounter has occurred and the required documentation is in place, the commenter reported that state home health agencies would need an additional 0.5 FTE in an agency with an average census of 100 to 120 beneficiaries. Another commenter stated that the estimates do not include the time and effort for the home health agency to contact and recontact the physicians to obtain the correct documentation. The commenter estimated that the burden on home health agencies is at least as much as it is on the physicians and requested that this burden be included in our estimate.

Response: We do not agree that the new requirements will add administrative requirements to home health agencies. Home health agencies are currently required to obtain the physician's order prior to implementing home health services. We do not believe that the additional documentation requirements as defined at § 440.70(f)(5) will add to the existing requirements.

Comment: One commenter stated that home health agencies do not typically cover costs through Medicaid reimbursement when serving Medicaid beneficiaries. Consequently, the additional administrative burden that would be placed on home health agencies because of the face-to-face requirement would further exacerbate this problem.

Response: We recognize the commenter's concern. This is a statutory requirement that is applicable across Medicare and Medicaid. We encourage home care agencies to communicate with their state Medicaid agencies to discuss the impact of the requirements on current Medicaid reimbursement rates. We also encourage home care agencies to share best practices for complying with the requirements in cost effective ways.

Comment: Many commenters provided feedback on additional items to include in our burden estimates. One commenter specified the following items: The education of each physician on how to complete the form (10 minutes); time for the home care agency to audit each form (10 minutes per form) and to notify the physician of the

missing or incomplete information (5 minutes per notification—and consider that 25 percent of the forms are inaccurate and must be returned to the physician for revision); time for home care intake to coordinate and access the form (10 minutes) and time for home care office personnel to track and log the form (10 minutes); time for home care agency staff to educate beneficiaries on the requirement (5 minutes); time for home care agency staff to track the appointment compliance if the encounter was not completed by the time the beneficiary was admitted to home care (10 minutes); if the physician did not complete the form correctly the first time, add physician office personnel time to communicate the issue to the physician and pull the medical records and physician time to review the medical record and redocument (10 minutes minimum); and add burden for the home care agency to obtain the encounter documentation from the community physician if it was performed in a hospital. These commenters indicated that this new interpretation could add up to 30 minutes to coordinate. Another commenter indicated that additional support personnel time is required in physicians' offices as staff field the telephone calls from home health beneficiaries and agencies to request documentation, schedule encounters, and secure the documentation in an acceptable and compliant condition.

Response: We would like to remind commenters that we do not have any standard form that we require to be completed. Rather, we defer to state Medicaid agencies to work with the provider community to develop a documentation form that will best meet the documentation requirement. Since this provision became effective in 2010, we believe that documentation forms should be already in place.

Comment: Many commenters indicated that CMS did not include components in its burden estimates. One commenter stated that no impact was estimated for the implementation of the requirement for medical equipment, supplies, and devices. The commenter also indicated that our estimate does not include the cost to both state and federal governments of the additional physician visits that will occur and have to be paid for in order to meet the requirements. Another commenter stated that the burden estimate does not account for the time it may take to collect and review pertinent test results, specialist reports or assessments performed by clinicians such as physical therapists and occupational therapists. Another commenter indicated that there is no time identified for getting the documentation from the NP to the physician for endorsement and back, nor the time and personnel to support such coordination.

Response: We believe that our estimates accurately reflect new burdens. In response to the comment pertaining to the services performed by physical therapists and occupational therapists, we did not account for additional time for physical therapy and occupational therapy services as the services are presumed covered in existing regulatory language. We do not believe that the burden for the situations described would be significant. We view administrative functions such as the transmission of information between NPs and physicians as an existing part of the duties of administrative personnel and do not need to be quantified as additional burden.

Comment: One commenter requested that CMS clarify its plans to collect the additional documentation from physicians about the face-to-face encounters and what role states and health plans may have in the process.

Response: The intention of the comment is not clear. We defer operational procedures for implementing this provision to the states and therefore, the state will communicate to fee-for-service providers and managed care plans the details of how it will be implemented. We will not be collecting documentation from physicians.

Comment: One commenter reported that physicians complain that they receive different forms from agencies and suggested that there be one universal form for everyone. Additionally, the commenter reported that the forms are returned incomplete and not timely and the education of how to complete the documentation is lengthy.

Response: We defer to state Medicaid agencies for operational details. We encourage states to use universal forms where appropriate. As previously indicated, the statutory provision became effective in 2010 and therefore, states should have appropriate forms in place.

2. ICRs Regarding Home Health Services: Communication of Clinical Findings (§ 440.70(f)(4))

Section 440.70(f)(4) requires that NPPs and attending acute or post-acute physicians communicate the clinical findings of the face-to-face encounter to the ordering physician. The clinical findings must be incorporated into a written or electronic document that is included in the beneficiary's medical record. While we set out burden in the proposed rule, we believe the requirement and burden are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). Specifically, we believe that the time, effort, and financial resources to communicate the findings of the encounter would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

Comment: Several commenters indicated that the proposed burden is underestimated. One commenter further stated that the proposal significantly underestimates the burden to both FFS providers and to managed care plans. Another commenter stated that not all face-to-face encounters will be limited to 10 minutes, depending on the health state of the beneficiary being examined. Another commenter indicated that 10 minutes for NPPs and attending acute or post-acute physicians to communicate the findings of the face-to-face encounter to the ordering physician does not account for the time required for each face-to-face encounter nor for the time for staff to send endorsements back and forth between the involved parties.

Response: We are not attempting to be overly burdensome. We are requiring a general description of beneficiary's health condition. We believe that 10 minutes on average is an appropriate amount of time as this should be a routine provision of care. We note that the time required to conduct the actual encounter with the beneficiary could vary widely. The 10 minute estimate had referred to the time it would take for the health status to be communicated to the ordering physician. Although we set out burden in the proposed rule, we believe that that the requirement is a usual and customary business practice and the burden is therefore exempt from formal OMB approval under the authority of the PRA.

Comment: One commenter recommended that we work to streamline the requirements for documenting the in-person visit.

Response: We believe that providing states with the flexibility to determine their own documentation requirements will best meet the unique needs of the beneficiaries served, states, and providers. We would like to reiterate that we are not prescribing the specific types of information that has to be documented, but rather we are requiring an overall description of the linkage of the health status and the services ordered.

C. Summary of Annual Burden Estimates

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) in Title 42 of the CFR	OMB Control No. (CMS ID No.)	Respondents	Total responses	Time per response	Total annual burden (hr)	Labor rate ($/hr)	Total capital/ maintenance costs ($)	Total cost ($)
440.70(f) and (g) ..	0938–1188 (CMS–10434).	381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	179.16	0	11,403,831.41
		381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	94.22	0	5,997,259.41
		381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	93.54	0	5,953,976.28
Total	.....	1,143,443.01	1,143,443.01	10 min (0.167 hr)	190,954.98	n/a	0	23,355,067.10

D. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please identify the rule (CMS–2348–F) the ICR's CFR citation, CMS ID number and OMB control number, and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer;

Fax Number: (202) 395–5806 or

Email: OIRA_submission@omb.eop.gov.

ICR-related comments are due March 3, 2016.

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

Section 6407(a) of the Affordable Care Act (as amended by section 10605) added new requirements to section 1814(a)(2)(C) of the Act under Part A of the Medicare program, and section 1835(a)(2)(A) of the Act, under Part B of the Medicare program, that the physician, or certain allowed NPPs, document a face-to-face encounter with the beneficiary (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act), before making a certification that home health services are required under the Medicare home health benefit. Section 1814(a)(2)(C) of the Act indicates that in addition to a physician, a NP or CNS (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by state law), or a PA (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters before the start of home health services.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act to require documentation of a similar face-to-face encounter with a physician or specific NPPs by a physician ordering DME. The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for this provision as for the provision described above, with one exception. Certified nurse-midwives are not permitted to conduct the face-to-face encounter before the physician ordering DME. The timing of this face-to-face encounter is specified as being within the 6-month period preceding the written order for DME, or other reasonable timeframe specified by the Secretary. This provision also maintains the role of the physician in the actual ordering of DME.

The Affordable Care Act applied both of the provisions to the Medicaid program.

B. Public Comments on the Regulatory Impact Analysis

Comment: We received many comments pertaining to the fiscal impact of this regulation. One commenter stated that the regulation needs to look further into the overall cost of changing the common practice for in-home care providers and make sure the quoted $100 million is on target. One commenter stated that the need for frequent documented encounters outlined in the rule will result in a duplication of effort and result in unnecessary costs. Increased costs will result from both the increase in encounters and from additional administrative oversight to monitor compliance with encounter and documentation requirements. Another commenter stated that the expansion of services that will result from the proposed regulations will come at considerable and untenable cost to the states. Another commenter reported that the fiscal impact of the face-to-face requirement for the commenter's state would be an increase of over $3 million per year in additional expenditures. The commenter stated that the regulation specifies that home health care services are a mandatory service to all categorically needy Medicaid beneficiaries, as well as mandatory to all medically needy if the state makes this population eligible for nursing home care. The fiscal impact of this change is estimated to be an additional $5 million per year for the state. Another commenter reported that states will incur costs and administrative burdens regarding the following: (1) Providing notice to providers through Medicaid bulletins, billing guides and provider handbooks about the face-to-face encounter requirement; (2) examining medical records by program integrity staff to ensure the face-to-face requirement has been met; and (3) providing notice to providers of the updated list of DME items that require a face-to-face encounter, as periodically updated by CMS. Another commenter stated that the proposed regulation would vastly expand the program. If the changes are made, a state and its taxpayers would be obligated to pay for a seemingly limitless benefit. One commenter recommended that CMS estimate the additional costs associated with the proposed expansion of home health services.

Response: While we recognize that states may have initial increases in costs, we do not believe that the potential increases outweigh the possible offsetting benefits to both beneficiaries and state budgets. The face-to-face encounter provision promotes program integrity and an effectively implemented home health benefit will enable beneficiaries to receive high quality care in the community, rather than rely on care in more expensive institutional settings. However, to allow states time for

budgetary planning and operational changes, we are allowing states up to one year to come into compliance with this rule if the state's legislature has met in that year, otherwise 2 years.

Comment: A few commenters reported on the regulatory impact with regard to health care providers. One commenter stated that an increased cost will be imposed on every order to accommodate the endorsement of a physician for the order. Another commenter reported that they expect that practitioners and physicians will ask for an increase in their fees. Another commenter stated that managed care plans and fee-for-service providers would also suffer from reduced physician productivity, which would increase the cost of treatment authorization. Another commenter stated that state Medicaid payment rates for physicians are significantly below Medicare rates and additional requirements are not likely to encourage practitioners and providers to serve the Medicaid population at the current depressed reimbursement rates.

Response: In response to the concerns that an increased cost will be imposed on every order to accommodate the endorsement of a physician for the order, we do not view implementation of section 6407 of the Affordable Care Act as supplanting the existing Medicaid regulatory requirements related to current practice for physician orders but is consistent with those practices. We do not agree that this rule will reduce physician productivity or have an impact on current cost structure. We encourage the provider community to collaborate with their State Medicaid Agencies to ensure continued dialogue on rate structures and reimbursement methodologies.

Comment: One commenter stated that the additional documentation would also impose a burden on the managed care plans and vendors under contract to perform billing services. The vendors would have to create protocols to ensure review of the appropriate documentation, which may include software development and system changes. The commenter indicated that the placement of face-to-face documentation into a beneficiary's medical record under the proposed rule would require new software development. This would occur at significant cost to managed care plans, fee-for-service providers, and/or software companies. The commenter also stated that the increased cost of treatment authorization for managed care plans would have to be incorporated into the capitation rates and if face-to-face visits are not billable, plans and fee-for-service providers would bear increased costs for treatment authorization due to higher transportation expenses and/or costs of telehealth equipment, facilities, and transmission. The commenter also believed that his state would incur significant costs in staff time and system changes to enact the proposed rule, including: (1) Drafting an analysis and possible state plan amendment; (2) preparing a regulation package; (3) providing training and education materials to providers; (4) developing changes to billing systems; (5) revising health plan contracts and recalculating capitation rates; and (6) performing periodic audits and investigations to ensure compliance. Additionally, the commenter stated that the increased cost of treatment authorization for managed care plans would have to be incorporated into the capitation rates. Another commenter reported that the current level of payment for home health agencies does not begin to cover the costs of providing services. The commenter stated that adding an additional documentation requirement to every admission further diminishes the impact of this substandard payment.

Response: As previously stated, this rule does not require states to apply the face-to-face requirement to Medicaid managed care. We defer to states to determine the application of the face-to-face requirement in managed care plans to best meet the needs of their beneficiaries. We are requiring that if states direct their managed care plans to comply with face-to-face encounter requirements, the plans report on this in a manner similar to fee-for-service. We do agree that when states choose to require their managed care plans to meet these requirements they should take this into consideration while setting actuarially sound rates. While the rates may increase, this is not a certainty as managed care prior authorization requirements and/or existing reporting structures may already be in place within capitation rates to adequately cover the costs. We reiterate that the face-to-face encounter is an appropriate activity for which to be reimbursed under the Medicaid physician benefit, or, if a NPP is the practitioner performing the encounter, under the appropriate benefit established to reimburse those providers under the state plan. This reimbursement is provided for the face-to-face encounter. If a NPP performs the face-to-face encounter, there is no additional reimbursement available for the physician to document that the face-to-face encounter occurred. Managed care plans, providers, and State Medicaid Agencies are encouraged to collaborate to determine appropriate reimbursement structures and once those are determined, the state's actuary should be informed in order to consider those assumptions during the capitation rate development.

Comment: One commenter stated that the face-to-face encounter increases the burden on home care agencies by placing the onus on the providers to ensure that the encounter takes place in the manner prescribed by the final rule. Additionally, the commenter stated that the proposed rule did not address or consider the financial and operational burdens imposed on agencies and that it is home care agencies and not physicians that risk non-payment for services rendered if discrepancies regarding the face-to-face encounter arise. The commenter further stated that much of the Medicare face-to-face education was done by home care providers, resulting in even greater burden on agencies. Another commenter stated that the entirety of the face-to-face requirement is extraordinarily burdensome on small home health agencies and unnecessary for quality care outcomes and cost savings. Additionally, the commenter indicated that the face-to-face requirement penalizes home health agencies that are unable, due to size or geographic location, to secure the services of an independent physician.

Response: We do not view the implementation of the face-to-face requirement as replacing existing regulatory requirements, but rather enhancing existing regulatory language. We believe that aligning with Medicare's implementation of this requirement will allow for consistency and reduce the burden on providers. Additionally, the rule expands the providers who may complete the face-to-face encounter to include NPPs and allows for the use of telehealth, which we believe will reduce the burden on home health agencies securing the services of an independent physician.

Comment: One commenter stated that they believe that the existing Medicare face-to-face requirement has proven in many ways to be an ineffective and burdensome requirement on physicians, home health agencies, and patients, with little positive impact on program integrity, which should not be replicated for Medicaid cases.

Response: The face-to-face requirement for both the Medicare and the Medicaid programs is required by statute, and we anticipate that Medicaid agencies will work with providers to

effectively and efficiently implement the provision.

Comment: Some commenters reported that many providers have needed to devote full-time staff to the task of tracking down paperwork and following up with the physicians' offices on face-to-face documentation that is already duplicative of long-established service authorization records and standards.

Response: We appreciate the commenters' concerns. We believe that providers have established administrative procedures in place, and therefore, do not believe that the additional face-to-face requirements will be overly burdensome or result in significant costs.

After consideration of the public comments, this section is being finalized without revisions. However, as previously indicated, to allow time for budgetary planning and operational changes, we are allowing states up to one year to come into compliance with this rule if the state's legislature has met in that year, otherwise 2 years.

C. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and, therefore, is a major rule under the Congressional Review Act. Accordingly, we have prepared a final Regulatory Impact Analysis which to the best of our ability presents the costs and benefits of the rulemaking.

According to the CMS Actuarial estimates, section 6407 of the Affordable Care Act would bring an estimated $920 million in savings to the Medicare program from 2010–2014 and $2.29 billion in savings from 2010–2019. Although this provision applies to Medicaid in the same manner and to the same extent as the Medicare program, there were no estimates (costs or savings) generated for the Medicaid program as data to determine these estimates is unavailable.

The certification of the need for home health care by a physician would be a covered physician service or, at state option, could be covered as a component part of home health care services. States have substantial flexibility to design payment methodologies for covered services. These payment methodologies can be tailored by benefit and/or provider type. Therefore, there may be an increase in costs, but the scope of these increases are not measurable due to state flexibilities.

Although there is no quantitative data to arrive at a specific dollar figure to attribute to the additional medical supplies, equipment, and appliances that may now be authorized in accordance with § 440.70(b)(3), we acknowledge the potential for this provision to surpass the threshold for economic significance. We wish to note however, that this provision may result in offsetting benefits to both beneficiaries and state budgets, including the ability for beneficiaries to return to or enter the workforce, thereby increasing the pool of taxpayers, and decreasing reliance on other Medicaid benefits, including institutional care. Although there is no specific estimate regarding the benefits, they nonetheless should be taken into account. In the proposed rule, we specifically solicited comment regarding the potential increased costs and benefits associated with this provision, as well as the various sections throughout the RIA. After consideration of public comments, we are finalizing the burden costs estimates associated with the provisions in this regulation with no revision.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.5 million to $38.5 million in any 1 year. For details, see the Small Business Administration's final rule that set forth size standards for health care industries, (65 FR 69432, November 17, 2000). Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. Entities affected by this rule should already be administering these changes for Medicare purposes as the statutory change was effective in 2010. Entities should already have systems in place to accommodate this change for the Medicaid population.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is $144 million. This final rule will not result in an impact of $144 million or more on state, local, or tribal governments, in the aggregate, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

D. Conclusion

We estimate that this final rule will be ''economically significant'' as measured by the $100 million threshold as set forth by Executive Order 12866, as well

as the Congressional Review Act. The analysis above provides our final Regulatory Impact Analysis. We have not prepared an analysis for the RFA, section 1102(b) of the Act, section 202 of the UMRA, and Executive Order 13132 because the provisions are not impacted by this rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 440

Grant programs-health, Medicaid.

The Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 440—SERVICES: GENERAL PROVISIONS

■ 1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 440.70 is amended by—
■ a. Revising paragraph (b) introductory text.
■ b. Revising paragraph (b)(3) introductory text.
■ c. Redesignating paragraphs (b)(3)(i) and (ii) as paragraphs (b)(3)(iii) and (iv), respectively.
■ d. Adding new paragraphs (b)(3)(i) and (ii) and paragraph (b)(3)(v).
■ e. Adding paragraphs (c)(1) and (2).
■ f. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 440.70 Home health services.

* * * * *

(b) Home health services include the following services and items. Paragraphs (b)(1), (2) and (3) of this section are required services and items that must be covered according to the home health coverage parameters. Services in paragraph (b)(4) of this section are optional. Coverage of home health services cannot be contingent upon the beneficiary needing nursing or therapy services.

* * * * *

(3) Medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place, as defined at § 440.70(c)(1).

(i) Supplies are health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

(ii) Equipment and appliances are items that are primarily and customarily used to serve a medical purpose, generally are not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable. State Medicaid coverage of equipment and appliances is not restricted to the items covered as durable medical equipment in the Medicare program.

* * * * *

(v) States can have a list of preapproved medical equipment supplies and appliances for administrative ease but States are prohibited from having absolute exclusions of coverage on medical equipment, supplies, or appliances. States must have processes and criteria for requesting medical equipment that is made available to individuals to request items not on the State's list. The procedure must use reasonable and specific criteria to assess items for coverage. When denying a request, a State must inform the beneficiary of the right to a fair hearing.

(c) * * *

(1) Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Home health services cannot be limited to services furnished to beneficiaries who are homebound.

(2) Additional services or service hours may, at the State's option, be authorized to account for medical needs that arise in the settings home health services are provided.

* * * * *

(f) No payment may be made for services referenced in paragraphs (b)(1) through (4) of this section, unless the physician referenced in paragraph (a)(2) of this section or for medical equipment, the allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v), with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) documents that there was a face-to-face encounter with the beneficiary that meets the following requirements:

(1) For the initiation of home health services, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur within the 90 days before or within the 30 days after the start of the services.

(2) For the initiation of medical equipment, the face-to-face encounter must be related to the primary reason the beneficiary requires medical equipment and must occur no more than 6 months prior to the start of services.

(3) The face-to-face encounter may be conducted by one of the following practitioners:

(i) The physician referenced in paragraph (a)(2) of this section;

(ii) A nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician referenced in paragraph (a) of this section, in accordance with State law;

(iii) A certified nurse midwife, as defined in section 1861(gg) of the Act, as authorized by State law;

(iv) A physician assistant, as defined in section 1861(aa)(5) of the Act, under the supervision of the physician referenced in paragraph (a) of this section; or

(v) For beneficiaries admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

(4) The allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v) of this section, performing the face-to-face encounter must communicate the clinical findings of that face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record.

(5) To assure clinical correlation between the face-to-face encounter and the associated home health services, the physician responsible for ordering the services must:

(i) Document the face-to-face encounter which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services.

(ii) Must indicate the practitioner who conducted the encounter, and the date of the encounter.

(6) The face-to-face encounter may occur through telehealth, as implemented by the State.

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment (DME) under the Medicare program, unless the physician referenced in paragraph (a)(2) of this section or allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v) of this section documents a face-to-face encounter with

the beneficiary consistent with the requirements of paragraph (f) of this section except as indicated in paragraph (g)(2) of this section.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(3) of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) of this section.

Dated: July 28, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 21, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–01585 Filed 1–27–16; 4:15 pm]

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Part III

The President

Memorandum of January 29, 2016—Delegation of Certain Authority and Assignment of Certain Functions Under Section 103(a)(1)(A) and Section 103(b)(1) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015

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Title 3—

The President

Memorandum of January 29, 2016

Delegation of Certain Authority and Assignment of Certain Functions Under Section 103(a)(1)(A) and Section 103(b)(1) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015

Memorandum for the United States Trade Representative

In addition to the authorities and functions delegated and assigned to you by Executive Order 13701 of July 17, 2015, by the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to you the authority to enter into trade agreements, reserved to the President in Executive Order 13701, under section 103(a)(1)(A) and section 103(b)(1) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (Public Law 114–26, title I), and assign to you that function.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, January 29, 2016

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