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Presidential Documents

Title 3—

The President

Executive Order 13741 of September 29, 2016

Amending Executive Order 13467 To Establish the Roles and Responsibilities of the National Background Investigations Bureau and Related Matters

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Executive Order 13467 of June 30, 2008, is amended as follows:

(a) The preamble is replaced with the following: ''By the authority vested in me as President by the Constitution and the laws of the United States of America, including 5 U.S.C. 3301 and 7103(b), and in order to strengthen and ensure a secure, efficient, timely, reciprocal, and aligned system for investigating and determining suitability or fitness for Government employment, contractor employee fitness, eligibility for access to classified information or to hold a sensitive position, and authorization to be issued a Federal credential, while taking appropriate account of title III of Public Law 108–458, it is hereby ordered as follows:''

(b) Section 1.1 is amended to read as follows:

''Section 1.1. *Policy*: Executive branch policies and procedures relating to suitability, contractor or Federal employee fitness, eligibility to hold a sensitive position, authorization to be issued a Federal credential for access to federally controlled facilities and information systems, and eligibility for access to classified information shall be aligned using consistent standards to the extent possible, shall provide for reciprocal recognition, and shall ensure cost-effective, timely, and efficient protection of the national interest, while providing fair treatment to those upon whom the Federal Government relies to conduct the Nation's business and protect national security. Further, the Government's systems and processes for conducting these background investigations and managing sensitive investigative information must keep pace with technological advancements, regularly integrating current best practices, to better anticipate, detect, and counter malicious activities and threats posed by external or internal actors who may seek to do harm to the Government's personnel, property, or information. To help fulfill these responsibilities, there shall be a primary executive branch investigative service provider whose mission is to provide effective, efficient, and secure background investigations for the Federal Government.''

(c) Sections 1.3(k) and (l) are redesignated as sections 1.3(l) and (m).

(d) A new section 1.3(k) is added to read as follows: ''(k) ''National Background Investigations Bureau'' (NBIB) means the National Background Investigations Bureau, established within the Office of Personnel Management with responsibility for conducting effective, efficient, and secure personnel background investigations pursuant to law, rule, regulation, or Executive Order.''

(e) Section 2.2(b) is amended to read as follows:

''(b) The Deputy Director for Management, Office of Management and Budget, shall serve as Chair of the Council and shall have authority, direction, and control over the Council's functions. Membership on the Council shall include the Suitability Executive Agent, the Security Executive Agent, and the Under Secretary of Defense for Intelligence of the Department of Defense. These four officials collectively shall constitute ''the Suitability and Security Clearance Performance Accountability Council Principals.'' The Director of

the National Background Investigations Bureau shall also serve as a member of the Council. The Chair shall select a Vice Chair to act in the Chair's absence. The Chair shall have authority to designate officials from additional agencies who shall serve as members of the Council. Council membership shall be limited to Federal Government employees in leadership positions.''

(f) Section 2.4 is redesignated as section 2.5, and a new section 2.4 is added to read as follows:

''Sec. 2.4. *Roles and Responsibilities of the National Background Investigations Bureau and the Department of Defense.*

(a) The National Background Investigations Bureau shall:

''(1) serve as the primary executive branch service provider for background investigations for eligibility for access to classified information; eligibility to hold a sensitive position; suitability or, for employees in positions not subject to suitability, fitness for Government employment; fitness to perform work for or on behalf of the Government as a contractor employee; and authorization to be issued a Federal credential for logical and physical access to federally controlled facilities and information systems;

''(2) provide effective, efficient, and secure personnel background investigations for the Federal Government;

''(3) provide the Council information, to the extent permitted by law, on matters of performance, timeliness, capacity, information technology modernization, continuous performance improvement, and other relevant aspects of NBIB operations;

''(4) be headquartered in or near Washington, District of Columbia;

''(5) have dedicated resources, including but not limited to a senior privacy official;

''(6) institutionalize interagency collaboration and take advantage of expertise across the executive branch;

''(7) continuously improve investigative operations, emphasizing information accuracy and protection, and regularly integrate best practices, including those identified by subject matter experts from industry, academia, or other relevant sources;

''(8) conduct personnel background investigations in accordance with uniform and consistent policies, procedures, standards, and requirements established by the Security Executive Agent and the Suitability Executive Agent; and

''(9) conduct other personnel background investigations as authorized by law, rule, regulation, or Executive Order.

''(b) The Secretary of Defense shall design, develop, deploy, operate, secure, defend, and continuously update and modernize, as necessary, background investigation information technology systems that support all Federal background investigation processes conducted by the National Background Investigations Bureau. Design and operation of the information technology systems for the National Background Investigations Bureau shall comply with applicable information technology standards and, to the extent practicable, ensure security and interoperability with other Federal background investigation information technology systems. The Secretary of Defense shall operate the database in the information technology systems containing appropriate data relevant to the granting, denial, or revocation of a security clearance or access pertaining to military, civilian, or Government contractor personnel, see 50 U.S.C. 3341(e), consistent with and following an explicit delegation from the Director of the Office of Personnel Management pursuant to 5 U.S.C. 1104.

''(c) Delegations and designations of investigative authority in place on the date of establishment of the National Background Investigations Bureau shall remain in effect until amended or revoked. The National Background

Investigations Bureau, through the Director of the Office of Personnel Management, shall be subject to the oversight of the Security Executive Agent in the conduct of investigations for eligibility for access to classified information or to hold a sensitive national security position; and to the oversight of the Suitability Executive Agent in the conduct of investigations of suitability or fitness for Government employment and logical and physical access, as provided in section 2.3 of this order. The Council shall hold the National Background Investigations Bureau accountable for the fulfillment of the responsibilities set forth in section 2.4(a) of this order.''

Sec. 2. *Updating Governance, Authorities, Roles, and Responsibilities.* (a) Within 90 days of the date of this order, and building on the strength of the current Suitability and Security Clearance Performance Accountability Council and Executive Agent governance structure, the Council shall review and update executive-level authorities across the vetting enterprise to clarify and de-conflict existing authorities, to assign new responsibilities where gaps may exist, and to address necessary governance changes.

(b) Specifically, the Council shall submit to the President a recommendation to:

(i) update, clarify, or replace Executive Orders (such as Executive Order 10450 of April 27, 1953, as amended, or Executive Order 12968 of August 2, 1995, as amended) as necessary to accommodate adding new entities into the current governance structure, and to reflect changes to policies, governance, or operational structure; and

(ii) consolidate multiple authorities (such as Executive Order 10450 of April 27, 1953, as amended, or Executive Order 13467 of June 30, 2008) and reaffirm or clarify existing roles and responsibilities in new or existing Executive Orders.

(c) The Council's submission shall include, but will not be limited to, the appropriate means to:

(i) create a Credentialing Executive Agent with responsibility for policy and oversight of credentialing matters that parallels the respective authorities and responsibilities of the Security and Suitability Executive Agents, which will clarify, align, and consolidate credentialing authority under a single Executive Agent;

(ii) make explicit the Suitability Executive Agent's oversight role;

(iii) de-conflict Security Executive Agent and Suitability Executive Agent authorities;

(iv) establish a definition of ''vetting'' as the overarching construct for investigations and the decisions based on them, inclusive of security, suitability or fitness, and credentialing; and

(v) establish clear lanes of responsibility for new overarching enterprise-wide needs for example, acquisition, funding models, data security requirements, and contracting, and the respective roles of the Security, Suitability, and Credentialing Line of Business; and the Enterprise Investment Board.

Sec. 3. *Amendment to Executive Order 12171.* Executive Order 12171 of November 19, 1979, as amended, is further amended by striking ''The Federal Investigative Services Division'' in section 1–216 and inserting in lieu thereof:

''Agencies or subdivisions of the Office of Personnel Management:

(a) The Federal Investigative Services.

(b) The National Background Investigations Bureau.

(c) Units with a primary Suitability Executive Agent mission, including adjudicating suitability investigations and conducting related policy, advisory services, operations support, and agency oversight.

(d) Units with a primary mission of engineering, information technology, and cybersecurity support for personnel background investigations and adjudications.''

Sec. 4. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) If any provision of this order or the application of such provision is held to be invalid, the remainder of this order shall not be affected.

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

THE WHITE HOUSE,
September 29, 2016.

[FR Doc. 2016–24066
Filed 10–3–16; 8:45 am]
Billing code 3295–F7–P

Rules and Regulations

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2016–P–1026]

Medical Devices; Exemption From Premarket Notification: Method, Metallic Reduction, Glucose (Urinary, Nonquantitative) Test System in a Reagent Tablet Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order denying a petition requesting exemption from the premarket notification requirements for ''method, metallic reduction, glucose (urinary, nonquantitative)'' devices that are in a reagent tablet format and are classified as class II devices as urinary glucose (nonquantitative) test system (hereinafter referred to as ''copper reduction tablet test''). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This order is effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Sheila Connors, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4620, Silver Spring, MD 20993–0002, 301–796–6181, *Sheila.Connors@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of the safety and effectiveness of the device. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations (21 CFR part 807) require persons who intend to market a device intended for human use to submit a premarket notification (510(k)) to FDA containing information that allows FDA to determine whether the device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval (PMA).

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section, 510(m), to the FD&C. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a class II device on its own initiative or upon petition of an interested person if FDA determines that a 510(k) is not necessary to provide a reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

FDA classified the urinary glucose (nonquantitative) test system into class II effective July 30, 1987 (52 FR 16102 at 16122, May 1, 1987). The classification for urinary glucose (nonquantitative) test system is at § 862.1340 (21 CFR 862.1340). The urinary glucose (nonquantitative) test system is identified as a device that is intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia. Devices under this classification regulation require premarket notification under section 510(k) of the FD&C Act.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket

notification is necessary: (1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Petition

On March 18, 2016, FDA received a petition requesting an exemption from premarket notification requirements for copper reduction tablet tests that are classified as class II devices under § 862.1340, urinary glucose (nonquantitative) test system, from Martin O'Connor, Germaine Laboratories, Inc. (See Docket No. FDA–2016–P–1026).

On May 4, 2016 (81 FR 26802), FDA published a notice in the **Federal Register** announcing that this petition had been received in accordance with section 510(m)(2) of the FD&C Act. On June 20, 2016 (81 FR 39929), FDA republished a notice of the petition due to an inadvertent error in the docket number and provided an opportunity for interested persons to submit comments on the petition by July 20, 2016. FDA received no comments regarding this petition.

FDA has completed review of the referenced petition and assessed the need for 510(k) clearance for copper reduction tablet test against the criteria laid out in section II. For the reasons described in this document, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of the copper reduction tablet tests classified under § 862.1340 and assigned the classification product code JIM. Accordingly, FDA responded to the petition by letter dated September 6, 2016, denying the petition within the 180-day timeframe under section 510(m)(2) of the FD&C Act. (See Docket No. FDA–2016–P–1026).

IV. Order

After reviewing the petition, FDA has determined that the petition failed to provide information to demonstrate that premarket notification is not necessary to provide a reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is denying the referenced petition for exemption from the premarket notification requirements.

With regard to the first factor (see section II, Criteria for Exemption), although there have been no medical device reports reported to the Agency in recent years, there have been numerous reports to the Agency [1] and in medical literature of risks associated with the inherent characteristics of this device, including possible device-associated deaths, serious injuries, and malfunctions such as burns, explosions of the product bottle due to heat, and consumption of the device. For instance, there have been reports in the medical literature of patients consuming the tablets because of their similarity to pills, which has led to poisoning and one report of a death. Therefore, FDA does not agree with the petitioner that the device does not have a significant history of risks associated with inherent characteristics of the device.

Additionally, failure to observe the reaction at all times after the tablet has been added to the sample is another risk associated with the inherent characteristics of the device. This can lead to a false-negative result and result in improper patient management, which can lead to serious injury or possibly death. The petition does not address how the device's inherent risks can be mitigated or controlled without premarket notification to provide a reasonable assurance of the safety and effectiveness of the device.

With regard to the second factor, the petition stated that healthcare and laboratory professionals understand the appropriate use of a copper reduction tablet test and that a definitive diagnostic or therapeutic decision should not be based on the result of this method. However, a copper reduction tablet test can be used to evaluate pediatric patients for possible hereditary metabolic disorders through detection of reducing substances. For example, although all States require mandatory newborn screening for genetic metabolic defects, clinical laboratories may still use this device as a screening test on pediatric urine samples if there are any suspicions of metabolic disease prior to receiving newborn screening results or if the newborn screening results do not match the clinical state of the newborn. Although further diagnostic testing may be performed to confirm the result(s), physicians may immediately treat the newborn relying solely on the result of this test while awaiting the results for any followup diagnostic tests. False negative results also present a safety and effectiveness concern because followup diagnostic testing may not be performed, leading to the failure to start needed treatment for the newborn. The petition failed to demonstrate that a premarket submission is not necessary to provide a reasonable assurance of the safety and effectiveness of the device for such uses, and FDA does not agree that the characteristics of the device necessary for its safe and effective use are well established.

With regard to the third factor, FDA also does not agree that changes in the device that could affect safety and effectiveness will either be readily detectable or not materially increase risks. The petition claimed that users could employ positive or negative controls to validate the reagents performance. However, while available quality control materials may contain glucose, they do not contain other reducing sugars (*e.g.,* galactose, lactose). Therefore, such materials might not readily detect an issue with the device's safety or effectiveness in detecting other reducing sugars before causing harm. The petition argued that well-established protocols and methods could ensure there is no material increase in risk. The petition provided insufficient information to support this argument that changes in the device that could affect safety and effectiveness will either be readily detectable or not materially increase risks. Moreover, changes in the device that could affect safety and effectiveness might materially increase the risk of injury, incorrect diagnosis or ineffective treatment given the device type's intended uses. The petition also did not provide information to the contrary. The petition did not provide any relevant information regarding the fourth factor.

In addition to these four factors, FDA considers the ''limitations on exemption.'' Manufacturers of any commercially distributed device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA prior to marketing the device when any of the limitations of exemption are exceeded. The general limitations of exemption from premarket notification contained in § 862.9 (21 CFR 862.9) are broadly applicable to in vitro diagnostic (IVD) devices classified under part 862 (21 CFR part 862). Under § 862.9, the

[1] For more information, see Medical Device Reporting (MDR) database at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.*

exemption from the premarket notification requirements applies, in the case of IVD devices, only to those devices under part 862 for which misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA has previously assessed that this limitation is exceeded, and a premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of an IVD device, when such device is intended for use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism (§ 862.9(c)(2)) or intended for use in diabetes management (§ 862.9(c)(5)). The petition argued that the copper reduction tablet test is not intended for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism, or for use in diabetes management. However, as explained previously, FDA disagrees and believes that the copper reduction tablet test described in the petition is intended for such uses and would likely exceed the limitations previously mentioned.

Accordingly, for all of the foregoing reasons, the petition failed to demonstrate that a premarket submission is not necessary to provide a reasonable assurance of the safety and effectiveness of the device intended for such uses. Therefore, FDA is issuing this order denying the petition requesting exemption for a method, metallic reduction, glucose (urinary, nonquantitative) test system in a reagent tablet format that is intended to measure glucosuria (glucose in urine) from the premarket notification requirements. Manufacturers of this device type must continue to submit and receive FDA clearance of a 510(k) before marketing their device, as well as comply with all other applicable requirements under the FD&C Act.

V. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23899 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2016–P–0159]

Medical Devices; Exemption From Premarket Notification; Method, Metallic Reduction, Glucose (Urinary, Nonquantitative) Test System in a Reagent Tablet Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order denying a petition requesting exemption from the premarket notification requirements for method, metallic reduction, glucose (urinary, nonquantitative) devices that are in a reagent tablet format and are classified as class II devices as urinary glucose (nonquantitative) test system (hereinafter referred to as ''copper reduction tablet test''). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This order is effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Sheila Connors, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4620, Silver Spring, MD 20993–0002, 301–796–6181, *Sheila.Connors@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of the safety and effectiveness of the device. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations (21 CFR part 807) require persons who intend to market a device intended for human use to submit a premarket notification (510(k)) to FDA containing information that allows FDA to determine whether the device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added section 510(m) to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a class II device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

FDA classified the urinary glucose (nonquantitative) test system into class II effective July 30, 1987 (52 FR 16102 at 16122, May 1, 1987). The classification for urinary glucose (nonquantitative) test system is at § 862.1340 (21 CFR 862.1340). The urinary glucose (nonquantitative) test system is identified as a device that is intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia. Devices under this classification regulation require premarket notification under section 510(k) of the FD&C Act.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary: (1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Petition

On January 7, 2016, FDA received a petition requesting an exemption from premarket notification requirements for copper reduction tablet tests that are classified as class II devices under § 862.1340, urinary glucose (nonquantitative) test system, from Evelyn Mirza, Biorex Labs, LLC. (See Docket No. FDA–2016–P–0159).

On March 24, 2016 (81 FR 15728), FDA published a notice in the **Federal Register** announcing that this petition had been received and provided an opportunity for interested persons to submit comments on the petition by April 25, 2016, in accordance with section 510(m)(2) of the FD&C Act. FDA received no comments regarding this petition.

FDA has completed review of the previously referenced petition and assessed the need for 510(k) clearance for copper reduction tablet test against the criteria laid out in section II. For the reasons described in section IV, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of the copper reduction tablet tests classified under § 862.1340 and assigned the classification product code JIM. Accordingly, FDA responded to the petition by letter dated July 1, 2016, denying the petition within the 180-day timeframe under section 510(m)(2) of the FD&C Act. (See Docket No. FDA–2016–P–0159.)

IV. Order

After reviewing the petition, FDA has determined that the petition failed to provide information to demonstrate that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is denying the previously referenced petition for exemption from the premarket notification requirements.

With regard to the first factor (section II, Criteria for Exemption), although there have been no medical device reports reported to the Agency in recent years, there have been numerous reports to the Agency [1] and in medical literature of risks associated with the inherent characteristics of this device, including possible device-associated deaths, serious injuries, and malfunctions such as burns, explosions of the product bottle due to heat, and consumption of the device. For instance, there have been reports in the medical literature of patients consuming the tablets because of their similarity to pills, which has led to poisoning and one report of a death. Therefore, FDA does not agree with the petitioner that the use of the device is well established without any reports of patient or user injury, or that the device does not have a significant history of risks associated with inherent characteristics of the device.

Additionally, failure to observe the reaction at all times after the tablet has been added to the sample is another risk associated with the inherent characteristics of the device. This can lead to a false-negative result and result in improper patient management, which can lead to serious injury or possibly death. The petition failed to demonstrate how the device's inherent risks can be mitigated or controlled without premarket notification to provide a reasonable assurance of the safety and effectiveness of the device.

With regard to the second factor, the petition stated that a copper reduction tablet test can be used to evaluate pediatric patients for possible hereditary metabolic disorders through detection of reducing substances. For example, although all States require mandatory newborn screening for genetic metabolic defects, clinical laboratories may still use this device as a screening test on pediatric urine samples if there are any suspicions of metabolic disease prior to receiving newborn screening results or if the newborn screening results do not match the clinical state of the newborn. Although further diagnostic testing may be performed to confirm the result(s), physicians may immediately treat the newborn relying solely on the result of this test while awaiting the results for any followup diagnostic tests. False negative results also present a safety and effectiveness concern because followup diagnostic testing may not be performed, leading to the failure to start needed treatment for the newborn. The petition also stated that this device is used in the diagnosis, monitoring, and treatment of metabolic disorders such as diabetes mellitus. However, the petition failed to demonstrate that a premarket submission is not necessary to provide a reasonable assurance of the safety and effectiveness of the device for such uses, and FDA does not agree that the characteristics of the device necessary for its safe and effective use are well established.

With regard to the third factor, FDA also does not agree that changes in the device that could affect safety and effectiveness will either be readily detectable or not materially increase

[1] For more information, see Medical Device Reporting (MDR) database at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.*

risks. For example, available quality control materials may contain glucose but do not contain other reducing sugars (*e.g.,* galactose, lactose). Therefore, such materials might not readily detect an issue with the device's safety or effectiveness in detecting other reducing sugars, before causing harm. The petition provided insufficient information to support the position that changes in the device that could affect safety and effectiveness will either be readily detectable or not materially increase risks. Moreover, changes in the device that could affect safety and effectiveness might materially increase the risk of injury, incorrect diagnosis, or ineffective treatment given the device type's intended uses. The petition also did not provide information to the contrary. The petition did not provide any information regarding the fourth factor.

In addition to these four factors, FDA considers the ''limitations on exemption.'' Manufacturers of any commercially distributed device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA prior to marketing the device when any of the limitations of exemption are exceeded. The general limitations of exemption from premarket notification contained in § 862.9 (21 CFR 862.9) are broadly applicable to in vitro diagnostic (IVD) devices classified under part 862 (21 CFR part 862). Under § 862.9, the exemption from the premarket notification requirements applies, in the case of IVD devices, only to those devices under part 862 for which misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA has previously assessed that this limitation is exceeded, and a premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of an IVD device, when such device is intended for use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism (§ 862.9(c)(2)) or intended for use in diabetes management (§ 862.9(c)(5)). The copper reduction tablet test described in the petition is intended for such uses and would likely exceed the limitations just described.

Accordingly, for all of the foregoing reasons, the petition failed to demonstrate that a premarket submission is not necessary to provide a reasonable assurance of the safety and effectiveness of the device intended for such uses. Therefore, FDA is issuing this order denying the petition requesting exemption for a method, metallic reduction, glucose (urinary, nonquantitative) test system in a reagent tablet format that is intended to measure glucosuria (glucose in urine) from the premarket notification requirements. Manufacturers of this device type must continue to submit and receive FDA clearance of a 510(k) before marketing their device, as well as comply with all other applicable requirements under the FD&C Act.

V. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23901 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 570

[Docket No. FR–5767–N–05]

RIN 2506–AC35

Section 108 Loan Guarantee Program: Announcement of Fee To Cover Credit Subsidy Costs

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Announcement of fee.

SUMMARY: This document announces the fee that HUD will collect from borrowers of loans guaranteed under HUD's Section 108 Loan Guarantee Program (Section 108 Program) to offset the credit subsidy costs of the guaranteed loans pursuant to commitments awarded in FY 2017.

DATES: *Effective Date:* November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Paul Webster, Director, Financial Management Division, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street, SW., Room 7180, Washington, DC 20410; telephone number 202–402–4563 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339. FAX inquiries (but not comments) may be sent to Mr. Webster at 202–708–1798 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113–235, approved December 16, 2014) (2015 Appropriations Act) provided that ''the Secretary shall collect fees from borrowers . . . to result in a credit subsidy cost of zero for guaranteeing'' Section 108 loans. The Continuing Appropriations Act, 2016 (Public Law 114–53, approved September 30, 2015) continued the 2015 provision. This continued funding act was followed by The Consolidated Appropriations Act, 2016, Public Law 114–133, approved December 18, 2015) (2016 Appropriations Act), which had identical language regarding Section 108 credit subsidy to the 2015 Appropriations Act. The fiscal year 2017 HUD appropriations bills under consideration in the House of Representatives (H.R. 5394), and the Senate (S. 2844) also have identical language regarding the credit subsidy for the Section 108 Program, and it is expected that, when enacted, the final fiscal year 2017 appropriations act will as well.

On November 3, 2015, HUD published a final rule (80 FR 67626) following a February 5, 2015 proposed rule (80 FR 6470) that amended the Section 108 Program regulations at 24 CFR part 570 to establish additional procedures, including procedures for determining the amount of the fee and for a 30-day public comment process when HUD adopts changes to the assumptions underlying the fee calculation or if the fee structure itself raises new considerations for borrowers.

HUD is required to collect fees from Section 108 borrowers when necessary to offset the credit subsidy costs to the Federal government to guarantee Section 108 loans. Following

consideration of the public comments submitted in response to HUD's February 5, 2015 proposed rule (80 FR 6469) that proposed the fee required to offset the credit subsidy costs, on November 3, 2015, HUD issued an announcement of fee (80 FR 67634) to set the fee for Section 108 loan disbursements under loan guarantee commitments awarded in FY 2016 at 2.58 percent of the principal amount of the loan.

II. FY 2017 Fee: 2.59 Percent of the Principal Amount of the Loan

This document sets the fee for Section 108 loan disbursements under loan guarantee commitments awarded in FY 2017 at 2.59 percent of the principal amount of the loan. This amount was proposed in the President's FY 2017 budget.[1] HUD will collect this fee from borrowers of loans guaranteed under the Section 108 Program to offset the credit subsidy costs of the guaranteed loans pursuant to commitments awarded in FY 2017, as authorized by the 2017 appropriations act.

For this fee document, HUD is not changing the underlying assumptions or creating new considerations for borrowers. The calculation of the FY 2017 fee uses the same fee calculation model as the FY 2016 announcement of fee, but incorporates updated information regarding the composition of the Section 108 portfolio and the timing of the estimated future cash flows for defaults and recoveries. The calculation of the fee is also affected by the discount rates required to be used by HUD when calculating the present value of the future cash flows as part of the Federal budget process.

As described in 24 CFR 570.712(b), HUD's credit subsidy calculation is based on the amount required to fully offset the credit subsidy cost to the Federal government associated with making a Section 108 loan guarantee. As a result, HUD's credit subsidy cost calculations incorporated assumptions based on: (i) data on default frequency for municipal debt where such debt is comparable to loans in the Section 108 loan portfolio; (ii) data on recovery rates on collateral security for comparable municipal debt; (iii) the expected composition of the Section 108 portfolio by end users of the guaranteed loan funds (*e.g.,* third party borrowers and public entities); and (iv) other factors that HUD determined were relevant to this calculation (*e.g.,* assumptions as to loan disbursement and repayment patterns).

Taking these factors into consideration, HUD determined that the fee for disbursements made under loan guarantee commitments awarded in FY 2017 will be 2.59 percent, which will be applied only at the time of loan disbursements. Note that future documents may provide for a combination of up-front and periodic fees for loan guarantee commitments awarded in future fiscal years but, if so, will provide the public an opportunity to comment if appropriate under 24 CFR 570.712(b)(2).

The expected cost of a Section 108 loan guarantee is difficult to estimate using historical program data because there have been no defaults in the history of the program that required HUD to invoke its full faith and credit guarantee or use the credit subsidy reserved each year for future losses.[2] This is due to a variety of factors, including the availability of Community Development Block Grant (CDBG) funds as security for HUD's guarantee as provided in 24 CFR 570.705(b). As authorized by Section 108 of the Housing and Community Development Act of 1974, as amended (42 U.S.C. 5308), borrowers may make payments on Section 108 loans using CDBG grant funds. Borrowers may also make Section 108 loan payments from other anticipated sources but continue to have CDBG funds available should they encounter shortfalls in the anticipated repayment source. Despite the program's history of no defaults, federal credit budgeting principles require that the availability of CDBG funds to repay the guaranteed loans cannot be assumed in the development of the credit subsidy cost estimate (see 80 FR 67629, November 3, 2015). Thus, the estimate must incorporate the risk that alternative sources are used to repay the guaranteed loan in lieu of CDBG funds, and that those sources may be insufficient. Based on the rate that CDBG funds are used annually for repayment of loan guarantees, HUD's calculation of the credit subsidy cost must take into account the possibility of future defaults if those CDBG funds were not available. The fee of 2.59 percent of the principal amount of the loan will offset the expected cost to the government due to default, financing costs, and other relevant factors. To arrive at this measure, HUD analyzed data on comparable municipal debt over an extended 16 to 23-year period. The estimated rate is based on the default and recovery rates for general purpose municipal debt and industrial development bonds. The cumulative default rates on industrial development bonds (14.62 percent) were higher than the default rates on general purpose municipal debt (0.25 percent) during the period from which the data were taken. (The recovery rates for industrial development bonds and general purpose debt were 74.76 and 90.27 percent, respectively.) These two subsectors of municipal debt were chosen because their purposes and loan terms most closely resemble those of Section 108 guaranteed loans. In this regard, Section 108 guaranteed loans can be broken down into two categories: (1) loans that finance public infrastructure and activities to support subsidized housing (other than financing new construction) and (2) other development projects (*e.g.,* retail, commercial, industrial). The 2.59 percent fee was derived by weighting the default and recovery data for general purpose municipal debt and the data for industrial development bonds according to the expected composition of the Section 108 portfolio by corresponding project type. Based on the dollar amount of Section 108 loan guarantee commitments awarded during the period from FY 2011 through FY 2015, HUD expects that 25 percent of the Section 108 portfolio will be similar to general purpose municipal debt and 75 percent of the portfolio will be similar to industrial development bonds. In setting the fee at 2.59 percent of the principal amount of the guaranteed loan, HUD expects that the amount generated will fully offset the cost to the Federal government associated with making guarantee commitments awarded in FY 2017. Note that the FY 2017 fee represents only a .01 percent increase over the FY 2016 fee of 2.58 percent. This is due primarily to updated loan repayment patterns and discount rates used in calculating the present value of cash flows. These are variable that ordinarily are modified in the credit subsidy calculation.

This document establishes a rate that does not constitute a development decision that affects the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this document is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

[1] The FY 2017 President's Budget for HUD is available at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/hud.pdf.* The fee is specified in table 6 of the Federal Credit Supplement to the 2017 budget and is available at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/cr_supp.pdf*

[2] U.S. Department of Housing and Urban Development, Study of HUD's Section 108 Loan Guarantee Program, (prepared by Econometrica, Inc. and The Urban Institute), September 2012.

Dated: September 28, 2016.

Harriet Tregoning,

Principal Deputy Assistant, Secretary for Community Planning and Development.

[FR Doc. 2016–23986 Filed 10–3–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9786]

RIN 1545–BC70

Credit for Increasing Research Activities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the application of the credit for increasing research activities. These final regulations provide guidance on software that is developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer (internal use software). These final regulations also include examples to illustrate the application of the process of experimentation requirement to software. These final regulations will affect taxpayers engaged in research activities involving software.

DATES: *Effective date:* These regulations are effective on October 4, 2016.

Applicability date: For date of applicability see § 1.41–4(e).

FOR FURTHER INFORMATION CONTACT: Martha Garcia or Jennifer Records of the IRS Office of the Associate Chief Counsel (Passthroughs and Special Industries) at (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations that amend the Income Tax Regulations (26 CFR part 1) relating to the credit for increasing research activities (research credit) under section 41 of the Internal Revenue Code (Code). Section 41(d)(4)(E) provides that, except to the extent provided by regulations, research with respect to software that is developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer is excluded from the definition of qualified research under section 41(d). Software that is developed for use in an activity that constitutes qualified research for purposes of section 41(d) and software that is developed for use in a production process with respect to which the general credit eligibility requirements under section 41 are satisfied are internal use software, but are not excluded under section 41(d)(4)(E) from the definition of qualified research and are not subject to these regulations.

On January 20, 2015, the Treasury Department and the IRS published in the **Federal Register** (80 FR 2624, January 20, 2015) a notice of proposed rulemaking (REG–153656–03, 2015–5 IRB 566) under section 41 (the proposed regulations) relating to the research credit. Comments responding to the proposed regulations were received and a public hearing was held on April 17, 2015. After consideration of all of the comments received, these final regulations adopt the proposed regulations as revised by this Treasury decision.

Summary of Comments and Explanation of Provisions

I. Definition of Internal Use Software

The proposed regulations provided that software is developed by (or for the benefit of) the taxpayer primarily for internal use if the software is developed by the taxpayer for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business. General and administrative functions, as defined in the proposed regulations, are limited to (1) financial management functions, (2) human resource management functions, and (3) support services functions. Financial management functions are functions that involve the financial management of the taxpayer and the supporting recordkeeping. Human resource management functions are functions that manage the taxpayer's workforce. Support services functions are functions that support the day-to-day operations of the taxpayer, such as data processing or facilities services.

Commenters expressed concern that the list of general and administrative functions in the proposed regulations was overly broad and included functions that do not represent ''back-office'' functions. In particular, the commenters noted that inventory management, marketing, legal services, and government compliance services can provide significant benefits to third parties and may be developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system. Specifically, one commenter noted that many inventory management software applications are an integral part of a taxpayer's supply chain management system and can be readily seen as part of the modern ''front office.'' This commenter noted that modern inventory management software usually requires interaction with a number of third party vendors to ensure the correct flow of raw materials and a corresponding flow of finished goods. Additionally, the commenter added that inventory management is inherently customer facing because it provides the proper amount of inventory to customers at the point of sale at the right time. Another commenter added that marketing is an external-facing function by nature, and software that supports marketing is necessarily intended to interact with third parties.

The Treasury Department and the IRS understand that many modern software systems perform more than back-office functions. These software systems commonly provide benefits to vendors and include functions that are customer facing. Additionally, software with functions such as marketing or inventory management may not provide solely back-office functions, but may also contain functions that enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system. Recognizing such situations, the proposed regulations provided rules under § 1.41–4(c)(6)(iv)(C) (dual function rules) to evaluate whether software that has both back-office and front-office functions is developed primarily for internal use. The Treasury Department and the IRS continue to believe that functions such as inventory management, marketing, legal services, and government compliance services provide support to day-to-day operations of a taxpayer in carrying on business regardless of the taxpayer's industry and that the benefits that such functions may provide to third parties are collateral and secondary. In addition, the Treasury Department and the IRS believe the dual function rules in these final regulations sufficiently address these comments by allowing taxpayers to identify subsets of elements of dual function software that only enable a taxpayer to interact with third parties or allow third parties to initiate functions or review data. Accordingly, the list of general and administrative functions provided in the proposed regulations remains unchanged in the final regulations.

Another commenter referred to the tax software example in the preamble to the proposed regulations which notes that tax software developed by a company engaged in providing tax services to its customers is not used by the taxpayer in general and administrative functions

even though tax is listed under § 1.41–4(c)(6)(iii)(B)(*1*) of the proposed regulations, as a general and administrative function. The commenter requested that we make this concept more explicit by revising § 1.41–4(c)(6)(iii)(A) of the proposed regulations and providing additional examples. As discussed in the preamble to the proposed regulations, the list of general and administrative functions is intended to target the back-office functions that most taxpayers would have regardless of the taxpayer's industry, although the characterization of a function as back office will vary depending on the facts and circumstances of the taxpayer. Because § 1.41–4(c)(6)(v) of these final regulations makes clear that the determination of whether software is developed primarily for internal use depends on the intent of the taxpayer and the facts and circumstances at the beginning of software development, the Treasury Department and the IRS believe that additional clarifying language and examples are unnecessary.

II. Definition of Software Not Developed Primarily for Internal Use

The proposed regulations provided that software is not developed primarily for internal use only if it is developed to be commercially sold, leased, licensed, or otherwise marketed to third parties, or if it is developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system. After consideration of the comments described herein, these final regulations clarify that (1) software is not developed primarily for the taxpayer's internal use if it is not developed for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business; and (2) software that is developed to be commercially sold, leased, licensed, or otherwise marketed to third parties and software that is developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system are examples of software that is not developed primarily for the taxpayer's internal use.

A. Software Developed To Be Commercially Sold, Leased, Licensed or Otherwise Marketed to Third Parties

A commenter requested that § 1.41–4(c)(6)(iv)(A)(*1*) of the proposed regulations be revised to state that software is not developed primarily for the taxpayer's internal use if the software is developed to be commercially sold, leased, licensed, *hosted,* or otherwise marketed to third parties. (Emphasis added.) The commenter also recommended additional language to further define ''otherwise marketed'' to include transactions where the taxpayer effectively provides the functionality of the software to a third party even if there is no transfer of a copy of the software itself to such third party. The Treasury Department and the IRS understand that a taxpayer may develop software where the full functionality of that software is provided to a third party even though there is no transfer of a copy of the software. The Treasury Department and the IRS believe the phrase ''software that is developed to be commercially sold, leased, licensed or otherwise marketed to third parties'' is sufficiently broad to encompass hosted software and other software where there is no transfer of a copy of the software. An example has been added to further illustrate this point (Example 9 of these final regulations).

B. Software Developed To Enable a Taxpayer To Interact With Third Parties or Allow Third Parties To Initiate Functions or Review Data on the Taxpayer's System

Several commenters requested clarification on the terms ''interact,'' ''initiate,'' or ''review,'' and recommended additional examples illustrating the terms. One commenter noted that a common example that should be clarified is whether a third party reviewing a Web site constitutes ''interaction,'' ''initiate functions,'' or ''review data.'' In response to these comments, the final regulations clarify that software that is developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system are examples of software that is not developed primarily for the taxpayer's internal use. In addition, these final regulations provide that the determination of whether software is internal use or developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system depends on the intent of the taxpayer and the facts and circumstances at the beginning of the software development. Accordingly, Example 3 of the proposed regulations, now designated as Example 4 in these final regulations, is revised to show that software developed with the intent of marketing via a Web site and not to allow third parties to review data on the taxpayer's system is developed for internal use because it was developed for use in a general and administrative function.

III. Connectivity Software

In the proposed regulations, the Treasury Department and the IRS requested comments on the appropriate definition and treatment of connectivity software that allows multiple processes running on one or more machines to interact across a network, sometimes referred to as bridging software, integration software, or middleware. The Treasury Department and the IRS received very few responses to this request for comments. One of the commenters noted that the treatment of such software is challenging because of its multi-faceted purposes; it could fall within a category in which it is not sold, does not interact with a third party, and does not perform a general and administrative function. The other commenter recommended that the regulations provide a general rule for connectivity software that is tied to the intent of the taxpayer and the facts and circumstances at the beginning of the software development and that the regulations provide examples demonstrating the rule. In addition, with respect to this category of software, the Treasury Department and the IRS understand that with wide use and availability of enterprise resource planning (ERP) software, few companies actually engage in developing connectivity software. Connectivity software is often purchased or the need for it has diminished due to the use of ERP software.

After further consideration of business practices and the limited comments received, the Treasury Department and the IRS believe that a special rule for connectivity software is not needed. The final regulations clarify that software is not developed by (or for the benefit of) the taxpayer primarily for the taxpayer's internal use if the software is not developed for use in general and administrative functions. Accordingly, any software that is not developed to be used in a general and administrative function will not be considered to be developed for internal use. This is the case even if the software is not developed to be commercially sold, leased, licensed, or otherwise marketed to third parties, or is not developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system.

Furthermore, connectivity software should not be specifically identified or categorized differently from other types of software. Whether certain software is developed to be used primarily for

internal use should be based on the function the software provides, rather than the type of software. For example, connectivity software that is developed to connect a taxpayer's existing payroll software with financial budgeting software to allow an exchange of data between the two software modules would be considered to be developed for the taxpayer's internal use because the connectivity software's function is to be used in human resources and financial management functions. Accordingly, the Treasury Department and the IRS believe that the general rule in the final regulations to determine whether or not software is developed primarily for internal use already provides sufficient guidance for connectivity software. Whether software, including connectivity software, is developed for use in general and administrative functions depends upon the intent of the taxpayer and the facts and circumstances at the beginning of the software development.

IV. Intent of the Taxpayer and the Facts and Circumstances at the Beginning of the Software Development

The proposed regulations provided that whether software is or is not developed primarily for internal use depends upon the intent of the taxpayer and the facts and circumstances at the beginning of the software development. If a taxpayer originally develops software primarily for internal use but later makes improvements to the software with the intent to hold the improved software for commercial sale, lease, or license or to allow third parties to initiate functions or review data on the taxpayer's system, the improvements will be considered separate from the existing software and will not be considered developed primarily for internal use. Likewise, if a taxpayer originally develops software for commercial sale, lease, or license or to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system, but later makes improvements to the software with the intent to use the software in general and administrative functions, the improvements will be considered separate from the existing software and will be considered developed primarily for internal use. After consideration of the comments described below, these final regulations retain these rules without modification.

A commenter explained that it is common for a taxpayer to initiate a software development project with one purpose in mind and to later discover that other purposes should be considered and pursued. Commenters also explained that it is common for a taxpayer to abandon its original intentions of how the software might be used. Commenters made several different recommendations, among them that the final regulations adopt a standard that allows facts at any point during the software development to be considered. Another suggested looking to the intended use of the software, and not just the improvements, as of the tax return filing date for the taxable year or the beginning of the taxable year in which the software development expenditures were incurred. One commenter further suggested that if the regulations require a determination at the beginning of the software development, the regulations should allow that determination to be rebutted with evidence about how the software is actually used when it is placed in service. Commenters also noted that taxpayers will likely have difficulty substantiating their intended use of the software at the beginning of the development process.

The Treasury Department and the IRS conclude that only a rule that generally requires that a determination be made at the beginning of software development is consistent with the intent and the purpose of section 41. Congress intended that the credit for increasing research activities would provide an incentive for greater private activity in research. That incentive nature of section 41 is promoted by taking into account a taxpayer's intent at the beginning of the software development; allowing any change in a taxpayer's intent throughout the development to support treatment as qualifying research of expenses incurred prior to that change would frustrate the purpose of the credit. Furthermore, allowing a taxpayer to redetermine the overall project's credit eligibility throughout the development which could span multiple years would provide uncertain and inconsistent treatment and impose an undue burden on both taxpayers and the IRS. Finally, the final regulations continue to provide a special rule for improvements to software that can be separately identified. This special rule would apply, for example, when a taxpayer completes a software development and then decides to improve that software by undertaking further development to the same software.

V. Dual Function Software and Safe Harbor

A. Presumption and Third Party Subset

The proposed regulations provided that software developed by (or for the benefit of) the taxpayer both for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business and to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data (dual function software) is presumed to be developed primarily for a taxpayer's internal use. However, this presumption is inapplicable to the extent that a taxpayer can identify a subset of elements of dual function software that only enables a taxpayer to interact with third parties or allows third parties to initiate functions or review data on the taxpayer's system (third party subset). The proposed regulations provided that if the taxpayer can identify a third party subset, the portion of qualified research expenditures allocable to such third party subset of the dual function software may be eligible for the research credit, provided all the other applicable requirements are met.

The Treasury Department and the IRS received several comments on dual function software rules. One commenter recommended changes to clarify that the dual function software rules do not apply to software developed to be commercially sold, leased, licensed, or otherwise marketed to third parties, even if such software was also developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system.

The Treasury Department and the IRS believe such clarification is unnecessary as § 1.41–4(c)(6)(iv)(C)(*1*) of the proposed regulations clearly defines dual function software as software that is developed by the taxpayer both for use in general and administrative functions and to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data. Software that is developed to be commercially sold, leased, licensed, or otherwise marketed to third parties is not dual function software, even if such software was also developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system.

One commenter suggested that the ''substantially all'' and ''shrink back'' rules found in § 1.41–4(b)(2) can be easily applied to evaluate dual function software. If substantially all of the software is non-internal use, then all of the software should be considered non-internal use under the substantially all rule. Similarly, if substantially all of the software is internal use, then the software should be considered internal use. In the case where the software as

a whole does not meet the substantially all rule, then the taxpayer would apply the shrink back rule and the software would be divided into subcomponents based on functionality until the non-internal use portion and the internal use portion were appropriately separated. That commenter noted that these two rules have worked for many years with little difficulty in other areas of the research credit rules and could be used equally well to address the issue of dual function software. Another commenter encouraged the addition of a rule to cover cases in which a taxpayer's dual function subset's third party use or interaction exceeds 80 percent. The commenter stated that in this circumstance, the remaining internal use is de minimis and should be disregarded and the entire development should be treated as not developed for internal use.

The shrink back rule provides that the requirements of section 41(d) and § 1.41–4(a) are to be applied first at the level of the discrete business component, that is, the product, process, computer software, technique, formula, or invention to be held for sale, lease, or license, or used by the taxpayer in a trade or business of the taxpayer. If these requirements are not met at that level, then they apply at the most significant subset of elements of the product, process, computer software, technique, formula, or invention to be held for sale, lease, or license. This shrinking back of the product is to continue until either a subset of elements of the product that satisfies the requirements is reached, or the most basic element of the product is reached and such element fails to satisfy the test.

The Treasury Department and the IRS believe that the proposed rules already apply principles similar to the shrink back rule to allow taxpayers to identify a subset of elements of dual function software that only enables a taxpayer to interact with third parties or allows third parties to initiate functions or review data on the taxpayer's system. The substantially all test referenced by the commenter is similar to the general credit eligibility requirement in section 41(d)(1)(C), which provides that in order for activities to constitute qualified research, substantially all of the activities must constitute elements of a process of experimentation that relates to a qualified purpose. Under § 1.41–4(a)(6), this substantially all requirement is satisfied only if 80 percent or more of a taxpayer's research activities, for the development or improvement of a business component, measured on a cost or other consistently applied reasonable basis, constitute elements of a process of experimentation. In contrast to the general requirement of section 41(d)(1) pertaining to qualifying research, section 41(d)(4)(E) does not apply the substantially all test when it excludes activities related to internal use software from qualifying research. Accordingly, the Treasury Department and the IRS believe the use of the substantially all test in these regulations is inappropriate, and the final regulations do not adopt the commenter's suggested approach.

Another commenter requested that the dual function rules be eliminated because the provisions are confusing and unnecessary and that trying to delineate elements of dual function software raises significant administrative issues. Similarly, another commenter noted that the concepts in the dual function rules can be confusing to taxpayers and will require additional recordkeeping by taxpayers. According to this commenter, most taxpayers do not differentiate their software applications by ''third party interactions'' or generally track such interactions. One commenter similarly stated that § 1.41–4(c)(6)(iv)(C) of the proposed regulations fails to take into account that software systems cannot always be broken into mutually exclusive subsets enabling only internal use or third party functionality.

Regarding the presumption that dual function software is developed for internal use, a commenter stated that such presumption is contrary to the intent of the statute. One commenter recommended that the presumption should be replaced with a primary purpose test, consistent with the statutory language that looks to whether software is developed ''primarily'' for internal use.

The Treasury Department and the IRS believe it is necessary to implement rules for dual function software as this type of software development is increasingly common in business practice. Rather than simply reiterating the ''primarily'' language in the statute, these regulations specifically identify the types of software functions that are considered to be primarily for internal use. A definition that specifically identifies the types of software functions that are considered to be primarily for internal use provides a clearer objective test that will provide consistency in application. The nature of software and its development has rapidly evolved over time, and the statute did not expressly address the treatment of dual function software. In conjunction with crafting a narrow definition of internal use, the Treasury Department and the IRS believe that the dual function software rules in the proposed regulations strike an appropriate balance between the administrative burdens and compliance concerns relating to claiming the research credit for activities relating to software. Thus, these final regulations retain the dual function rules. These final regulations are applicable to taxable years beginning on or after the date of their publication in the **Federal Register**. Taxpayers have been aware of the proposed rules and have had the opportunity to begin maintaining the necessary documentation to establish their entitlement to research credits under these rules.

B. Safe Harbor

The proposed regulations provided taxpayers with a safe harbor to apply to dual function software if there remains a subset of elements of dual function software (dual function subset) after the third party subset has been identified. The safe harbor allows a taxpayer to include 25 percent of the qualified research expenditures of the dual function subset in computing the amount of the taxpayer's credit, provided that the taxpayer's research activities related to the dual function subset constitute qualified research and the use of the dual function subset by third parties or by the taxpayer to interact with third parties is reasonably anticipated to constitute at least 10 percent of the dual function subset's use.

Some commenters requested that the safe harbor be removed from the regulations. Specifically, one commenter stated that the burdens associated with the safe harbor may be greater than its benefits and noted the multiple steps that a taxpayer must take to determine if it meets the safe harbor. Another commenter noted that the safe harbor complicates the administration of the credit for both taxpayers and the IRS.

Another commenter noted that the safe harbor potentially penalizes the taxpayer with the inequitable result of allowing only 25 percent of the qualified research expenditures. According to the commenter, given that a taxpayer must document anticipated use, it should then follow that the portion of software treated as third party facing should mirror this analysis. In other words, the proportion anticipated to be third party facing should be the proportion of software that is not developed primarily for internal use.

After careful consideration, the final regulations do not adopt these comments. However, the safe harbor has

been modified to clarify that the safe harbor can be applied to the dual function software or the dual function subset after the application of § 1.41–4(c)(6)(vi)(B) of the final regulations. The safe harbor is not a requirement but an option available for taxpayers who cannot identify a third party subset, or after identification of a third party subset, still have a dual function subset. Without the safe harbor, dual function software or a dual function subset would be presumed to be internal use and the taxpayer would have to demonstrate that the research with respect to the dual function software or dual function subset meets the high threshold of innovation test in addition to the general eligibility requirements under section 41(d)(1). The safe harbor provides a benefit, not a detriment, to taxpayers, provided the dual function software or dual function subset's use by third parties is anticipated to be at least 10 percent of the total use. Taxpayers who consider it too burdensome to comply with the requirements of the safe harbor can choose not to rely upon it.

C. Time of Determination

Several commenters noted concerns with the time of determination for the application of the safe harbor. A commenter noted that determining the percentage of third party use based upon an estimate made at the beginning of software development imposes an undue administrative burden and may not be an accurate reflection of the actual use once the software is released. This commenter requested that the rule be eliminated or amended to provide that a taxpayer must estimate third party use once the software is deployed. Similarly, another commenter noted that it has not been their experience that taxpayers plot out the future expected use of their software at the time the development begins with such specificity, especially given that software development is an iterative development process where functionality and expected uses rapidly evolve. Lastly, another commenter requested that, similar to the provisions for improvements to existing software, there should be a mechanism to recharacterize software over time.

While the Treasury Department and the IRS understand commenters' concerns, the final regulations do not change the requirement that the time of determination occur at the beginning of the software development. As discussed herein, the Treasury Department and the IRS continue to believe that the rule requiring that a determination be made at the beginning of the software development is most accurate and appropriate given Congress' intent that the research credit serve as an incentive to conduct qualifying research rather than an unanticipated reward for doing so.

D. Objective Reasonable Method

In the proposed regulations, the Treasury Department and the IRS invited comments on the administrability of measuring the reasonably anticipated use of software by taxpayers to interact with third parties and by third parties to initiate functions or review data based on reasonable methods (such as processing time, amount of data transfer, number of software user interface screens, number of third party initiated functions, and other objective, reasonable methods) and whether the regulations should include specific reasonable methods and examples.

A commenter recommended that due to the wide range of taxpayers that will be subject to these regulations, the final regulations should not provide overly detailed examples of ''reasonable methods.'' This commenter noted that it should be clear that any examples of reasonable methods are for illustrative purposes only and any reasonable method may be acceptable. Another commenter recommended the adoption of the phrase ''within each industry'' to ensure that the application of the objective, reasonable method takes into account unique aspects of all taxpayers within given industries.

The Treasury Department and the IRS agree that it is unrealistic to impose one specific method that will be used to measure reasonably anticipated use due to the variety of industries that are subject to the final regulations. Therefore, the final regulations provide that any objective, reasonable method within the taxpayer's industry may be used for purposes of the safe harbor.

VI. Third Party Definition

The proposed regulations provided that the term ''third party'' means any corporation, trade or business, or other person that is not treated as a single taxpayer with the taxpayer pursuant to section 41(f). A commenter raised concerns and requested that the Treasury Department and the IRS reconsider whether it is appropriate to apply the controlled group standard under section 41(f). The commenter contended that this third party definition would potentially deny a research credit to some software for artificial reasons. The commenter further noted that if the regulations do not modify the third party definition, taxpayers should at least have an opportunity to demonstrate that software provided to a member of the controlled group is not internal use software based on the facts and circumstances.

The Treasury Department and the IRS continue to believe that the use of the controlled group standard under section 41(f) is appropriate. A well established, objective standard is essential and using the standard in section 41(f) is consistent with the reference to section 41(f) in section 41(b)(2) relating to in-house research expenditures and in § 1.41–6(a)(3)(ii) relating to the definition of controlled group for purposes of aggregating expenditures.

The proposed regulations also provided that third parties do not include any persons that use the software to support the taxpayer's general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business, *e.g.,* the taxpayer's own vendors. A commenter contended that excluding any person that uses a taxpayer's software to support a general and administrative function from the definition of third party creates confusion and blurs a well-conceived, objective measurement. This commenter believes the term third party suggests a person who is external to the organization or a person who is not an employee. The Treasury Department and the IRS note that the statute provides a higher standard for internal use software, in part, because the benefits of such software are intended primarily for the taxpayer developing it. Where a taxpayer develops software for internal use, any benefit to others, such as vendors or those who provide support services to the taxpayer, is collateral and secondary. Accordingly, the final regulations do not adopt these comments requesting a change to the definition of third party.

VII. High Threshold of Innovation—Significant Economic Risk

The proposed regulations provided that certain internal use software is eligible for the research credit if the software satisfies the high threshold of innovation test, the three parts of which are (1) software is innovative in that the software would result in a reduction in cost or improvement in speed or other measurable improvement, that is substantial and economically significant, if the development is or would have been successful; (2) software development involves significant economic risk in that the taxpayer commits substantial resources to the development and there is a substantial uncertainty, because of

technical risk, that such resources would be recovered within a reasonable period; and (3) software is not commercially available for use by the taxpayer in that the software cannot be purchased, leased, or licensed and used for the intended purpose without modifications that would satisfy the innovation and significant economic risk requirements. The proposed regulations further provided that substantial uncertainty exists if, at the beginning of the taxpayer's activities, the information available to the taxpayer does not establish the capability or method for developing or improving the software.

A. Design Uncertainty

Several commenters requested that the final regulations include design uncertainty in the definition of technical risk for purposes of meeting the significant economic risk test. Commenters noted that both sections 174 and 41 have long included the concept of design uncertainty. Commenters also raised concerns that the statute and regulations do not define the concepts of capability, methodology, and design uncertainty. Commenters further explained that these three types of uncertainties are inherently related to each other, and it is often difficult for taxpayers to clearly state or describe which type of uncertainty they face.

The use of the word ''substantial'' before ''uncertainty'' in the significant economic risk test for internal use software indicates a higher threshold of uncertainty than that required for business components that are not internal use software. While there may be design uncertainty in the development of internal use software, substantial uncertainty generally exists only when there is also uncertainty in regard to the capability or method of achieving the intended result. However, the Treasury Department and the IRS understand that it is difficult to delineate the types of technical uncertainties and attempting to do so may lead to unnecessary burdens on both taxpayers and the IRS. Furthermore, the appropriate design uncertainty of internal use software may be inextricably linked to substantial uncertainty regarding capability or method. The focus of the significant economic risk test should be on the level of uncertainty that exists and not the types of uncertainty. For these reasons, the final regulations remove the reference to capability and method uncertainty. However, the Treasury Department and the IRS believe that internal use software research activities that involve only uncertainty related to appropriate design, and not capability or methodology, would rarely qualify as having substantial uncertainty for purposes of the high threshold of innovation test.

B. Substantial Resources/Reasonable Time Period

A commenter requested that the final regulations provide further explanation or examples on what constitutes ''substantial resources'' or a ''reasonable time period'' for purposes of meeting the significant economic risk test. The Treasury Department and the IRS believe that whether the amount of resources committed is substantial or whether substantial resources would be recovered within a reasonable time period are factual determinations to be resolved based on the taxpayer's facts and circumstances and, therefore, further explanation or examples would be too specific and not helpful. Accordingly, the final regulations do not adopt these comments.

C. Application of High Threshold of Innovation Test

Another commenter requested deletion of the statement, ''[i]t is not always necessary to have a revolutionary discovery or creation of new technologies such as a new programming language, operating system, architecture, or algorithm to satisfy the high threshold of innovation test.'' The commenter is concerned that the sentence can be read to imply that in some situations it will be necessary to have a revolutionary discovery to qualify internal use software for the research credit. The Treasury Department and the IRS did not intend the inclusion of this statement to have the interpretation suggested or taken by the commenter. Accordingly, the Treasury Department and the IRS agree that this statement should be removed from the final regulations because a revolutionary discovery is not required to meet the high threshold of innovation test.

Furthermore, the Treasury Department and the IRS are revising §§ 1.41–4(c)(6)(i) and (ii) of the proposed regulations to clarify that the internal use software rules under § 1.41–4(c)(6) do not apply to (1) software developed for use in an activity that constitutes qualified research, (2) software developed for use in a production process to which the requirements of section 41(d)(1) are met, and (3) a new or improved package of software and hardware developed together by the taxpayer as a single product. Accordingly, under the final regulations, the high threshold of innovation test applies only to the software developed for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business and to dual function software.

VIII. Examples

A. Process of Experimentation

Section 1.41–4(a)(8) of the proposed regulations provided six new examples illustrating the application of the process of experimentation requirement to software under section 41(d)(1)(C).

One commenter noted that the examples appear to suggest a presumption that activities related to developing web design or ERP software do not meet the process of experimentation requirement. This commenter requested that the final regulations clearly state the reasons for such presumption. The proposed regulations and these final regulations do not establish a presumption against a particular type of software; rather these examples focus on the facts and circumstances surrounding activities to determine whether they involve a process of experimentation.

Another commenter requested that the final regulations include additional examples demonstrating fact patterns that do not initially qualify as a process of experimentation but where a change in facts introduces technical uncertainty that requires a process of experimentation. The final regulations could provide examples describing a particular change in facts that would introduce technical uncertainty and require a process of experimentation; however, because the examples are very factual and would differ based on a taxpayer's business, we do not think more examples would provide the clarification that the commenter is seeking. Accordingly, the final regulations do not include additional examples to address this comment.

i. Example 6

Section 1.41–4(a)(8), Example 6, of the proposed regulations analyzed whether activities related to selecting a commercial software vendor with object-oriented functions and selecting and incorporating the specific functions into new software developed by X involved conducting a process of experimentation.

One commenter noted that the use of certain terms in Example 6, such as ''develop,'' ''evaluate,'' and ''determine'' suggest that the process of experimentation criteria may be met and recommended changes to clearly show that a purchase, installation, and

selection from pre-determined categories do not meet a process of experimentation. We disagree with the commenter because the use or nonuse of certain terms is not an implication that the process of experimentation criteria has or has not been met. This example is intended to show that the process of experimentation requirement is not met regardless of the terms used. Accordingly, the final regulations do not adopt this comment.

ii. Example 7

Section 1.41–4(a)(8), Example 7, of the proposed regulations analyzed whether when developing software, activities relating to X's decision to use a separate server to distribute the workload across each of the web servers and X's decision that a round robin workload distribution algorithm is appropriate for its needs involved conducting a process of experimentation.

Two commenters recommended removing Example 7. One commenter believed that the example did not provide any clarification. The other commenter stated that the example shows a failure to meet the technical uncertainty requirement under section 174, rather than a process of experimentation. While the Treasury Department and the IRS agree with the commenter that activities under section 174 must be for the purpose of discovering information that would eliminate uncertainties, Example 7 is intended to demonstrate the process of experimentation requirement under section 41(d). The example shows a taxpayer's failure to meet the process of experimentation requirement under section 41(d)(1) because the use of a technique or design, such as a round robin workload distribution algorithm, does not qualify where the taxpayer did not conduct a process of evaluating alternatives intended to eliminate uncertainty regarding the development of software. Accordingly, the final regulations do not adopt these comments.

iii. Example 8

Section 1.41–4(a)(8), Example 8, of the proposed regulations analyzed whether X's activities relating to design and systematic testing and evaluation of several different algorithms in the development of load balancing software involved conducting a process of experimentation.

One commenter recommended that all references to the terms ''dynamic'' and ''highly volatile'' be removed because the commenter believes the terms provide no additional value and that they suggest that the nature of X's business environment has some bearing on the performance of qualified research. The Treasury Department and the IRS disagree and the final regulations do not adopt the commenter's recommendation because we believe the nature of a taxpayer's business environment can be a valuable indicator of circumstances that may result in the necessary uncertainty required for a process of experimentation.

Another commenter requested that for both Example 8 and Example 10, the Treasury Department and the IRS provide clarification by applying the high threshold of innovation test once the software is determined to be internal use software. Additionally, this commenter requested that the final regulations provide an additional example addressing this process. The Treasury Department and the IRS note that the examples are added to illustrate only the application of a process of experimentation to software research. They are not meant to address the high threshold of innovation test; those examples were provided under § 1.41–4(c)(6)(vi) of the proposed regulations. Furthermore, a comprehensive example that applies the rules contained in § 1.41–4(c)(6) would require more developed facts and layers of analysis and would be better suited for a different type of published guidance than these final regulations. Accordingly, the final regulations do not adopt these comments.

iv. Example 9

Section 1.41–4(a)(8), Example 9, of the proposed regulations analyzed whether X's activities relating to the installation of an ERP system involved a process of experimentation.

Two commenters requested deletion of the phrase ''routine programming'' in Example 9 because the term is subjective, immeasurable, and inconsistent with *Suder* v. *Commissioner,* T.C. Memo 2014–201. One commenter also stated that taxpayers may confront uncertainty about the appropriate design of the configuration of an ERP system, and the example does not address this technical uncertainty. The Treasury Department and the IRS did not intend to illustrate in this example the types of uncertainty that must be eliminated to satisfy the process of experimentation requirement under section 41(d)(1). Rather, this example demonstrates a taxpayer's failure to meet the process of experimentation requirement under section 41(d)(1) because X did not conduct a process of evaluating alternatives in order to eliminate uncertainty regarding the development of the ERP software. Accordingly, the Treasury Department and the IRS believe further clarification of these examples is unnecessary. Furthermore, the Tax Court's decision in *Suder* is not inconsistent with Example 9 because in *Suder* the court did not address whether ''routine programming'' could meet the process of experimentation requirement.

B. Internal Use Software

The proposed regulations provided examples illustrating the provisions contained in § 1.41–4(c)(6) of the proposed regulations.

i. Example 3

Section 1.41–4(c)(6)(vi), Example 3, of the proposed regulations analyzed whether software that is developed for a Web site that provides general information about the taxpayer's business, and which does not enable a taxpayer to interact with third parties or allow third parties to initiate functions or review data, is internal use software.

One commenter disagreed with the characterization of the facts in Example 3 which illustrates a support services function. The commenter believes that the software is dual function software that is developed to allow a third party to review data and to be used in marketing. The Treasury Department and the IRS disagree with the commenter's characterization of Example 3. The example demonstrates that the software is intended to serve marketing purposes and thus is developed to be used in general and administrative functions. Changes were made to clarify this example which is designated as Example 4 of the final regulations.

ii. Example 6

Section 1.41–4(c)(6)(vi), Example 6, of the proposed regulations analyzed the definition of third parties, specifically whether software that is developed to allow its users to upload and modify photographs at no charge allows third parties to initiate functions on the taxpayer's system.

A commenter believed the example is an important example that comes to the correct conclusion, but the commenter believed it is not a particularly good fact pattern to illustrate the third party interaction exclusion. Specifically, the commenter requested changes to the conclusion of the example to show that the advertising software is developed for use in a marketing function to an unrelated third party.

The purpose of the example is to illustrate the third party definition and

to demonstrate whether the software is developed to allow third parties to initiate functions or review data. The example is not meant to address which, if any, general and administrative function applies to the software. Accordingly, the final regulations do not adopt this comment. However, other changes were made to clarify Example 6 of the proposed regulations, which is designated as Example 8 of the final regulations.

IX. Effective/Applicability Date

Some commenters requested that the final regulations apply retroactively back to 1986, while one commenter requested that the final regulations apply retroactively back to 2004 to give software development equal treatment with all other types of qualified research as defined under TD 9104 (69 FR 22). After further consideration, the effective date in the proposed regulations is generally retained with slight modifications. These final regulations are prospective and apply to taxable years beginning on or after the date of publication of this Treasury decision in the **Federal Register**.

Retroactive application of these final regulations may provide an unfair advantage to taxpayers whose prior taxable years are not closed by the statute of limitations. Furthermore, retroactively determining whether taxpayers engaged in research activities does not further the purpose of section 41 which is to encourage taxpayers to engage in qualifying research activities within the United States and would impose a significant administrative burden on the IRS.

Section 41(d)(4)(E) provides that, except to the extent provided by regulations, research with respect to computer software that is developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer is excluded from the definition of qualified research under section 41(d). The nature of software and its development has rapidly evolved over time. Recognizing the evolving nature of software technology and its role in business practices, these final regulations more narrowly define internal use software than the rules that apply for prior periods. These final regulations are not, and should not be viewed as, an interpretation of prior regulatory guidance. Software not developed for internal use under these final regulations, such as software developed to enable a taxpayer to interact with third parties, may or may not have been internal use software under prior law.

The proposed regulations provided that the 2004 ANPRM (published in the **Federal Register** (69 FR 43)) is withdrawn effective for taxable years beginning on or after January 20, 2015, the date the proposed regulations were published in the **Federal Register** (80 FR 2624). For taxable years ending before January 20, 2015, taxpayers may choose to follow either all of the internal use software provisions of § 1.41–4(c)(6) in the final regulations published on January 3, 2001 in the **Federal Register** (TD 8930; 66 FR 280) or all of the internal use software provisions of § 1.41–4(c)(6) contained in the proposed regulations (REG–112991–01) published on December 26, 2001 in the **Federal Register** (66 FR 66362). In addition, the IRS will not challenge return positions consistent with all of paragraph (c)(6) of these final regulations or all of paragraph (c)(6) of the proposed regulations for any taxable year that both ends on or after January 20, 2015, the date the proposed regulations were published in the **Federal Register** (80 FR 2624), and begins before October 4, 2016.

X. Duty of Consistency

Some commenters noted the administrative difficulties of applying the duty of consistency rule under section 41(c)(6)(A) and requested guidance on how to comply with the consistency rule.

The duty of consistency is a statutory requirement and existing regulations under §§ 1.41–3(d) and 1.41–9(c) provide sufficient guidance for taxpayers to follow. In computing the research credit, qualified research expenses and gross receipts must be determined on a basis consistent with the definition of qualified research expenses and gross receipts for the credit year. These final regulations do not modify this existing law. Section 1.41–3(d) provides that in computing the credit for increasing research activities, qualified research expenses and gross receipts taken into account in computing a taxpayer's fixed-base percentage and a taxpayer's base amount must be determined on a basis consistent with the definition of qualified research expenses and gross receipts for the credit year, without regard to the law in effect for the taxable years taken into account in computing the fixed-base percentage or the base amount. Section 1.41–3(d) also provides examples illustrating the requirement. Current section 1.41–9(c) contains similar rules. Accordingly, the final regulations do not adopt the commenters' suggestions concerning the duty of consistency.

Special Analyses

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

Drafting Information

The principal author of these regulations is Martha M. Garcia, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.41–4 also issued under 26 U.S.C. 41(d)(4)(E).

* * * * *

■ **Par. 2.** Section 1.41–0 is amended by:
■ 1. Revising the entry in the table of contents for § 1.41–4(c)(6).
■ 2. Adding entries in the table of contents for § 1.41–4(c)(6)(i) through (viii).

The revision and additions read as follows:

§ 1.41–0. Table of contents.

* * * * *

§ 1.41–4. Qualified research for expenditures paid or incurred in taxable years ending on or after December 31, 2003.

* * * * *

(c) * * *

(6) Internal use software.
(i) General rule.
(ii) Inapplicability of the high threshold of innovation test.
(iii) Software developed primarily for internal use.
(iv) Software not developed primarily for internal use.
(v) Time and manner of determination.
(vi) Software developed for both internal use and to enable interaction with third parties (dual function software).
(vii) High threshold of innovation test.
(viii) Illustrations.

* * * * *

■ **Par. 3.** Section 1.41–4 is amended by:
■ 1. Adding *Example 5* through *Example 10* at the end of paragraph (a)(8).
■ 2. Revising paragraphs (c)(6) and (e).

The additions and revisions read as follows:

§ 1.41–4 Qualified research for expenditures paid or incurred in taxable years ending on or after December 31, 2003.

(a) * * *
(8) * * *

Example 5. (i) *Facts.* X, a retail and distribution company, wants to upgrade its warehouse management software. X evaluates several of the alternative warehouse management software products available from vendors in the marketplace to determine which product will best serve X's technical requirements. X selects vendor V's software.

(ii) *Conclusion.* X's activities to select the software are not qualified research under section 41(d)(1) and paragraph (a)(5) of this section. X did not conduct a process of evaluating alternatives in order to eliminate uncertainty regarding the development of a business component. X's evaluation of products available from vendors is not a process of experimentation.

Example 6. (i) *Facts.* X wants to develop a new web application to allow customers to purchase its products online. X, after reviewing commercial software offered by various vendors, purchases a commercial software package of object-oriented functions from vendor Z that X can use in its web application (for example, a shopping cart). X evaluates the various object-oriented functions included in vendor Z's software package to determine which functions it can use. X then incorporates the selected software functions in its new web application software.

(ii) *Conclusion.* X's activities related to selecting the commercial software vendor with the object-oriented functions it wanted, and then selecting which functions to use, are not qualified research under section 41(d)(1) and paragraph (a)(5) of this section. In addition, incorporating the selected object-oriented functions into the new web application software being developed by X did not involve conducting a process of evaluating alternatives in order to eliminate uncertainty regarding the development of software. X's evaluation of products available from vendors and selection of software functions are not a process of experimentation.

Example 7. (i) *Facts.* In order to be more responsive to user online requests, X wants to develop software to balance the incoming processing requests across multiple web servers that run the same set of software applications. Without evaluating or testing any alternatives, X decides that a separate server will be used to distribute the workload across each of the web servers and that a round robin workload distribution algorithm is appropriate for its needs.

(ii) *Conclusion.* X's activities to develop the software are activities relating to the development of a separate business component under section 41(d)(2)(A). X's activities to develop the load distribution function are not qualified research under section 41(d)(1) and paragraph (a)(5) of this section. X did not conduct a process of evaluating different load distribution alternatives in order to eliminate uncertainty regarding the development of software. X's selection of a separate server and a round robin distribution algorithm is not a process of experimentation.

Example 8. (i) *Facts.* X must develop load balancing software across a server cluster supporting multiple web applications. X's web applications have high concurrency demands because of a dynamic, highly volatile environment. X is uncertain of the appropriate design of the load balancing algorithm, given that the existing evolutionary algorithms did not meet the demands of their highly volatile web environment. Therefore, X designs and systematically tests and evaluates several different algorithms that perform the load distribution functions.

(ii) *Conclusion.* X's activities to develop software are activities to develop a separate business component under section 41(d)(2)(A). X's activities involving the design, evaluation, and systematic testing of several new load balancing algorithms meet the requirements as set forth in paragraph (a)(5) of this section. X's activities constitute elements of a process of experimentation because X identified uncertainties related to the development of a business component, identified alternatives intended to eliminate those uncertainties, and evaluated one or more alternatives to achieve a result where the appropriate design was uncertain at the beginning of X's research activities.

Example 9. (i) *Facts.* X, a multinational manufacturer, wants to install an enterprise resource planning (ERP) system that runs off a single database so that X can track orders more easily, and coordinate manufacturing, inventory, and shipping among many different locations at the same time. In order to successfully install and implement ERP software, X evaluates its business needs and the technical requirements of the software, such as processing power, memory, storage, and network resources. X devotes the majority of its resources in implementing the ERP system to evaluating the available templates, reports, and other standard programs and choosing among these alternatives in configuring the system to match its business process and reengineering its business process to match the available alternatives in the ERP system. X also performs some data transfer from its old system, involving routine programming and one-to-one mapping of data to be exchanged between each system.

(ii) *Conclusion.* X's activities related to the ERP software including the data transfer are not qualified research under section 41(d)(1) and paragraph (a)(5) of this section. X did not conduct a process of evaluating alternatives in order to eliminate uncertainty regarding the development of software. X's activities in choosing between available templates, reports, and other standard programs and conducting data transfer are not elements of a process of experimentation.

Example 10. (i) *Facts.* Same facts as *Example 9* except that X determines that it must interface part of its legacy software with the new ERP software because the ERP software does not provide a particular function that X requires for its business. As a result, X must develop an interface between its legacy software and the ERP software, and X evaluates several data exchange software applications and chooses one of the available alternatives. X is uncertain as to how to keep the data synchronized between the legacy and ERP systems. Thus, X engages in systematic trial and error testing of several newly designed data caching algorithms to eliminate synchronization problems.

(ii) *Conclusion.* Substantially all of X's activities with respect to this ERP project do not satisfy the requirements for a process of experimentation. However, when the shrinking-back rule is applied, a subset of X's activities do satisfy the requirements for a process of experimentation. X's activities to develop the data caching software and keeping the data on the legacy and ERP systems synchronized meet the requirements of qualified research as set forth in paragraph (a)(2) of this section. Substantially all of X's activities to develop the specialized data caching and synchronization software constitute elements of a process of experimentation because X identified uncertainties related to the development of a business component, identified alternatives intended to eliminate those uncertainties, and evaluated alternatives to achieve a result where the appropriate design of that result was uncertain as of the beginning of the taxpayer's research activities.

* * * * *

(c) * * *

(6) *Internal use software*—(i) *General rule.* Research with respect to software that is developed by (or for the benefit of) the taxpayer primarily for the taxpayer's internal use is eligible for the research credit only if—

(A) The research with respect to the software satisfies the requirements of section 41(d)(1);

(B) The research with respect to the software is not otherwise excluded under section 41(d)(4) (other than section 41(d)(4)(E)); and

(C) The software satisfies the high threshold of innovation test of paragraph (c)(6)(vii) of this section.

(ii) *Inapplicability of the high threshold of innovation test.* This paragraph (c)(6) does not apply to the following:

(A) Software developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer for use in an activity that constitutes qualified research (other than the development of the internal use software itself);

(B) Software developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer for use in a production process to which the requirements of section 41(d)(1) are met; and

(C) A new or improved package of software and hardware developed together by the taxpayer as a single product (or to the costs to modify an acquired software and hardware package), of which the software is an integral part, that is used directly by the taxpayer in providing services in its trade or business. In these cases, eligibility for the research credit is to be determined by examining the combined hardware-software product as a single product.

(iii) *Software developed primarily for internal use*—(A) *In general.* Except as otherwise provided in paragraph (c)(6)(vi) of this section, software is developed by (or for the benefit of) the taxpayer primarily for the taxpayer's internal use if the software is developed for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business. Software that the taxpayer develops primarily for a related party's internal use will be considered internal use software. A related party is any corporation, trade or business, or other person that is treated as a single taxpayer with the taxpayer pursuant to section 41(f).

(B) *General and administrative functions.* General and administrative functions are:

(*1*) *Financial management.* Financial management functions are functions that involve the financial management of the taxpayer and the supporting recordkeeping. Financial management functions include, but are not limited to, functions such as accounts payable, accounts receivable, inventory management, budgeting, cash management, cost accounting, disbursements, economic analysis and forecasting, financial reporting, finance, fixed asset accounting, general ledger bookkeeping, internal audit, management accounting, risk management, strategic business planning, and tax.

(*2*) *Human resources management.* Human resources management functions are functions that manage the taxpayer's workforce. Human resources management functions include, but are not limited to, functions such as recruiting, hiring, training, assigning personnel, and maintaining personnel records, payroll, and benefits.

(*3*) *Support services.* Support services are other functions that support the day-to-day operations of the taxpayer. Support services include, but are not limited to, functions such as data processing, facility services (for example, grounds keeping, housekeeping, janitorial, and logistics), graphic services, marketing, legal services, government compliance services, printing and publication services, and security services (for example, video surveillance and physical asset protection from fire and theft).

(iv) *Software not developed primarily for internal use.* Software is not developed primarily for the taxpayer's internal use if it is not developed for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business, such as—

(A) Software developed to be commercially sold, leased, licensed, or otherwise marketed to third parties; or

(B) Software developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system.

(v) *Time and manner of determination.* For purposes of paragraphs (c)(6)(iii) and (iv) of this section, whether software is developed primarily for internal use or not developed primarily for internal use depends on the intent of the taxpayer and the facts and circumstances at the beginning of the software development. For example, software will not be considered internal use software solely because it is used internally for purposes of testing prior to commercial sale, lease, or license. If a taxpayer originally develops software primarily for internal use, but later makes improvements to the software with the intent to hold the improved software to be sold, leased, licensed, or otherwise marketed to third parties, or to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system using the improved software, the improvements will be considered separate from the existing software and will not be considered developed primarily for internal use. Alternatively, if a taxpayer originally develops software to be sold, leased, licensed, or otherwise marketed to third parties, or to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system, but later makes improvements to the software with the intent to use the software in general and administrative functions, the improvements will be considered separate from the existing software and will be considered developed primarily for internal use.

(vi) *Software developed for both internal use and to enable interaction with third parties (dual function software)*—(A) *Presumption of development primarily for internal use.* Unless paragraph (c)(6)(vi)(B) or (C) of this section applies, software developed by (or for the benefit of) the taxpayer both for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business and to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system (dual function software) is presumed to be developed primarily for a taxpayer's internal use.

(B) *Identification of a subset of elements of software that only enables interaction with third parties.* To the extent that a taxpayer can identify a subset of elements of dual function software that only enables a taxpayer to interact with third parties or allows third parties to initiate functions or review data (third party subset), the presumption under paragraph (c)(6)(vi)(A) of this section does not apply to such third party subset, and such third party subset is not developed primarily for internal use as described under paragraph (c)(6)(iv)(B) of this section.

(C) *Safe harbor for expenditures related to software developed for both internal use and to enable interaction with third parties.* If, after the application of paragraph (c)(6)(vi)(B) of this section, there remains dual function software or a subset of elements of dual function software (dual function subset), a taxpayer may include 25 percent of the qualified research expenditures of such dual function software or dual function subset in computing the amount of the taxpayer's credit. This paragraph (c)(6)(vi)(C) applies only if the taxpayer's research activities related to the development or improvement of the dual function software or dual function subset constitute qualified research under section 41(d), without regard to section 41(d)(4)(E), and the dual function software or dual function

subset's use by third parties or by the taxpayer to interact with third parties is reasonably anticipated to constitute at least 10 percent of the dual function software or the dual function subset's use. An objective, reasonable method within the taxpayer's industry must be used to estimate the dual function software or dual function subset's use by third parties or by the taxpayer to interact with third parties. An objective, reasonable method may include, but is not limited to, processing time, amount of data transfer, and number of software user interface screens.

(D) *Time and manner of determination.* A taxpayer must apply this paragraph (c)(6)(vi) based on the intent of the taxpayer and the facts and circumstances at the beginning of the software development.

(E) *Third party.* For purposes of paragraphs (c)(6)(iv), (v), and (vi) of this section, the term *third party* means any corporation, trade or business, or other person that is not treated as a single taxpayer with the taxpayer pursuant to section 41(f). Additionally, for purposes of paragraph (c)(6)(iv)(B) of this section, third parties do not include any persons that use the software to support the general and administrative functions of the taxpayer.

(vii) *High threshold of innovation test*—(A) *In general.* Software satisfies this paragraph (c)(6)(vii) only if the taxpayer can establish that—

(*1*) The software is innovative;

(*2*) The software development involves significant economic risk; and

(*3*) The software is not commercially available for use by the taxpayer in that the software cannot be purchased, leased, or licensed and used for the intended purpose without modifications that would satisfy the requirements of paragraphs (c)(6)(vii)(A)(*1*) and (*2*) of this section.

(B) *Innovative.* Software is innovative if the software would result in a reduction in cost or improvement in speed or other measurable improvement, that is substantial and economically significant, if the development is or would have been successful. This is a measurable objective standard, not a determination of the unique or novel nature of the software or the software development process.

(C) *Significant economic risk.* The software development involves significant economic risk if the taxpayer commits substantial resources to the development and if there is substantial uncertainty, because of technical risk, that such resources would be recovered within a reasonable period. The term ''substantial uncertainty'' requires a higher level of uncertainty and technical risk than that required for business components that are not internal use software. This standard does not require technical uncertainty regarding whether the final result can ever be achieved, but rather whether the final result can be achieved within a timeframe that will allow the substantial resources committed to the development to be recovered within a reasonable period. Technical risk arises from uncertainty that is technological in nature, as defined in paragraph (a)(4) of this section, and substantial uncertainty must exist at the beginning of the taxpayer's activities.

(D) *Application of high threshold of innovation test.* The high threshold of innovation test of paragraph (c)(6)(vii) of this section takes into account only the results anticipated to be attributable to the development of new or improved software at the beginning of the software development independent of the effect of any modifications to related hardware or other software. The implementation of existing technology by itself is not evidence of innovation, but the use of existing technology in new ways could be evidence of a high threshold of innovation if it resolves substantial uncertainty as defined in paragraph (c)(6)(vii)(C) of this section.

(viii) *Illustrations.* The following examples illustrate provisions contained in this paragraph (c)(6). No inference should be drawn from these examples concerning the application of section 41(d)(1) and paragraph (a) of this section to these facts.

Example 1. Computer hardware and software developed as a single product—(i) *Facts.* X is a telecommunications company that developed high technology telephone switching hardware. In addition, X developed software that interfaces directly with the hardware to initiate and terminate a call, along with other functions. X designed and developed the hardware and software together.

(ii) *Conclusion.* The telecommunications software that interfaces directly with the hardware is part of a package of software and hardware developed together by the taxpayer that is used by the taxpayer in providing services in its trade or business. Accordingly, this paragraph (c)(6) does not apply to the software that interfaces directly with the hardware as described in paragraph (c)(6)(ii)(C) of this section, and eligibility for the research credit is determined by examining the combined software-hardware product as a single product.

Example 2. Internal use software; financial management—(i) *Facts.* X, a manufacturer, self-insures its liabilities for employee health benefits. X develops its own software to administer its self-insurance reserves related to employee health benefits. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The software is developed for use in a general and administrative function because reserve valuation is a financial management function under paragraph (c)(6)(iii)(B)(*1*) of this section. Accordingly, the software is internal use software because it is developed for use in a general and administrative function.

Example 3. Internal use software; human resources management—(i) *Facts.* X, a manufacturer, develops a software module that interacts with X's existing payroll software to allow X's employees to print pay stubs and make certain changes related to payroll deductions over the internet. At the beginning of the development, X does not intend to develop the software module for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The employee access software module is developed for use in a general and administrative function because employee access software is a human resources management function under paragraph (c)(6)(iii)(B)(*2*) of this section. Accordingly, the software module is internal use software because it is developed for use in a general and administrative function.

Example 4. Internal use software; support services—(i) *Facts.* X, a restaurant, develops software for a Web site that provides information, such as items served, price, location, phone number, and hours of operation for purposes of advertising. At the beginning of the development, X does not intend to develop the Web site software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system. X intends to use the software for marketing by allowing third parties to review general information on X's Web site.

(ii) *Conclusion.* The software is developed for use in a general and administrative function because the software was developed to be used by X for marketing which is a support services function under paragraph (c)(6)(iii)(B)(*3*) of this section. Accordingly, the software is internal use software because it is developed for use in a general and administrative function.

Example 5. Internal use software—(i) *Facts.* X, a multinational manufacturer with different business and financial systems in each of its divisions, undertakes a software development project aimed at integrating the majority of the functional areas of its major software systems (Existing Software) into a single enterprise resource management system supporting centralized financial systems, human resources, inventory, and sales. X purchases software (New Software) upon which to base its enterprise-wide system. X has to develop software (Developed Software) that transfers data from

X's legacy financial, human resources, inventory, and sales systems to the New Software. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The financial systems, human resource systems, inventory and sales systems are general and administrative functions under paragraph (c)(6)(iii)(B) of this section. Accordingly, the Developed Software is internal use software because it is developed for use in general and administrative functions.

Example 6. Internal use software; definition of third party—(i) *Facts.* X develops software to interact electronically with its vendors to improve X's inventory management. X develops the software to enable X to interact with vendors and to allow vendors to initiate functions or review data on the taxpayer's system. X defines the electronic messages that will be exchanged between X and the vendors. X's software allows a vendor to request X's current inventory of the vendor's product, and allows a vendor to send a message to X which informs X that the vendor has just made a new shipment of the vendor's product to replenish X's inventory. At the beginning of development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties.

(ii) *Conclusion.* Under paragraph (c)(6)(vi)(E) of this section, X's vendors are not third parties for purposes of paragraph (c)(6)(iv) of this section. While X's software was developed to allow vendors to initiate functions or review data on the taxpayer's system, the software is not excluded from internal use software as set forth in paragraph (c)(6)(iv)(B) of this section because the software was developed to allow vendors to use the software to support X's inventory management, which is a general and administrative function of X.

Example 7. Not internal use software; third party interaction—(i) *Facts.* X, a manufacturer of various products, develops software for a Web site with the intent to allow third parties to access data on X's database, to order X's products and track the status of their orders online. At the beginning of the development, X does not intend to develop the Web site software for commercial sale, lease, license, or to be otherwise marketed to third parties.

(ii) *Conclusion.* The software is not developed primarily for internal use because it is not developed for use in a general and administrative function. X developed the software to allow third parties to initiate functions or review data on the taxpayer's system as provided under paragraph (c)(6)(iv)(B) of this section.

Example 8. Not internal use software; third party interaction—(i) *Facts.* X developed software that allows its users to upload and modify photographs at no charge. X earns revenue by selling advertisements that are displayed while users enjoy the software that X offers for free. X also developed software that has interfaces through which advertisers can bid for the best position in placing their ads, set prices for the ads, or develop advertisement campaign budgets. At the beginning of the development, X intended to develop the software to enable X to interact with third parties or to allow third parties to initiate functions on X's system.

(ii) *Conclusion.* The software for uploading and modifying photographs is not developed primarily for internal use because it is not developed for use in X's general and administrative functions under paragraph (c)(6)(iii)(A) of this section. The users and the advertisers are third parties for purposes of paragraph (c)(6)(iv) of this section. Furthermore, both the software for uploading and modifying photographs and the advertising software are not internal use software under paragraph (c)(6)(iv)(B) of this section because at the beginning of the development X developed the software with the intention of enabling X to interact with third parties or to allow third parties to initiate functions on X's system.

Example 9. Not internal use software; commercially sold, leased, licensed, or otherwise marketed—(i) *Facts.* X is a provider of cloud-based software. X develops enterprise application software (including customer relationship management, sales automation, and accounting software) to be accessed online and used by X's customers. At the beginning of development, X intended to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties.

(ii) *Conclusion.* The software is not developed primarily for internal use because it is not developed for use in a general and administrative function. X developed the software to be commercially sold, leased, licensed, or otherwise marketed to third parties under paragraph (c)(6)(iv)(A) of this section.

Example 10. Improvements to existing internal use software—(i) *Facts.* X has branches throughout the country and develops its own facilities services software to coordinate moves and to track maintenance requests for all locations. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system. Several years after completing the development and using the software, X consults its business development department, which assesses the market for the software. X determines that the software could be sold at a profit if certain technical and functional enhancements are made. X develops the improvements to the software, and sells the improved software to third parties.

(ii) *Conclusion.* Support services, which include facility services, are general and administrative functions under paragraph (c)(6)(iii)(B) of this section. Accordingly, the original software is developed for use in general and administrative functions and is, therefore, developed primarily for internal use. However, the improvements to the software are not developed primarily for internal use because the improved software was not developed for use in a general and administrative function. X developed the improved software to be commercially sold, leased, licensed, or otherwise marketed to third parties under paragraphs (c)(6)(iv)(A) and (c)(6)(v) of this section.

Example 11. Dual function software; identification of a third party subset—(i) *Facts.* X develops software for use in general and administrative functions that facilitate or support the conduct of X's trade or business and to allow third parties to initiate functions. X is able to identify a third party subset. X incurs $50,000 of research expenditures for the software, 50% of which is allocable to the third party subset.

(ii) *Conclusion.* The software developed by X is dual function software. Because X is able to identify a third party subset, the third party subset is not presumed to be internal use software under paragraph (c)(6)(vi)(A) of this section. If X's research activities related to the third party subset constitute qualified research under section 41(d), and the allocable expenditures are qualified research expenditures under section 41(b), $25,000 of the software research expenditures allocable to the third party subset may be included in computing the amount of X's credit, pursuant to paragraph (c)(6)(vi)(B) of this section. If, after the application of paragraph (c)(6)(vi)(B) of this section, there remains a dual function subset, X may determine whether paragraph (c)(6)(vi)(C) of this section applies.

Example 12. Dual function software; application of the safe harbor—(i) *Facts.* The facts are the same as in *Example 11,* except that X is unable to identify a third party subset. X uses an objective, reasonable method at the beginning of the software development to determine that the dual function software's use by third parties to initiate functions is reasonably anticipated to constitute 15% of the dual function software's use.

(ii) *Conclusion.* The software developed by X is dual function software. The software is presumed to be developed primarily for internal use under paragraph (c)(6)(vi)(A) of this section. Although X is unable to identify a third party subset, X reasonably anticipates that the dual function software's use by third parties will be at least 10% of the dual function software's use. If X's research activities related to the development or improvement of the dual function software constitute qualified research under section 41(d), without regard to section 41(d)(4)(E), and the allocable expenditures are qualified research expenditures under section 41(b), X may include $12,500 (25% of $50,000) of the software research expenditures of the dual function software in computing the amount of X's credit pursuant to paragraph (c)(6)(vi)(C) of this section.

Example 13. Dual function software; safe harbor inapplicable—(i) *Facts.* The facts are the same as in *Example 11,* except X is unable to identify a third party subset. X uses an objective, reasonable method at the beginning of the software development to determine that the dual function software's use by third parties to initiate functions is reasonably anticipated to constitute 5% of the dual function software's use.

(ii) *Conclusion.* The software developed by X is dual function software. The software is presumed to be developed primarily for X's internal use under paragraph (c)(6)(vi)(A) of this section. X is unable to identify a third party subset, and X reasonably anticipates that the dual function software's use by third parties will be less than 10% of the dual function software's use. X may only include the software research expenditures of the dual function software in computing the amount of X's credit if the software satisfies the high threshold of innovation test of paragraph (c)(6)(vii) of this section and X's research activities related to the development or improvement of the dual function software constitute qualified research under section 41(d), without regard to section 41(d)(4)(E), and the allocable expenditures are qualified research expenditures under section 41(b).

Example 14. Dual function software; identification of a third party subset and the safe harbor—(i) *Facts.* X develops software for use in general and administrative functions that facilitate or support the conduct of X's trade or business and to allow third parties to initiate functions and review data. X is able to identify a third party subset (Subset A). The remaining dual function subset of the software (Subset B) allows third parties to review data and provides X with data used in its general and administrative functions. X is unable to identify a third party subset of Subset B. X incurs $50,000 of research expenditures for the software, 50% of which is allocable to Subset A and 50% of which is allocable to Subset B. X determines, at the beginning of the software development, that the processing time of the third party use of Subset B is reasonably anticipated to account for 15% of the total processing time of Subset B.

(ii) *Conclusion.* The software developed by X is dual function software. Because X is able to identify a third party subset, such third party subset (Subset A) is not presumed to be internal use software under paragraph (c)(6)(vi)(A) of this section. If X's research activities related to the development or improvement of Subset A constitute qualified research under section 41(d), and the allocable expenditures are qualified research expenditures under section 41(b), the $25,000 of the software research expenditures allocable to Subset A may be included in computing the amount of X's credit pursuant to paragraph (c)(6)(vi)(B) of this section. Although X is unable to identify a third party subset of Subset B, 15% of Subset B's use is reasonably anticipated to be attributable to the use of Subset B by third parties. If X's research activities related to the development or improvement of Subset B constitute qualified research under section 41(d), without regard to section 41(d)(4)(E), and the allocable expenditures are qualified research expenditures under 41(b), X may include $6,250 (25% x $25,000) of the software research expenditures of Subset B in computing the amount of X's credit, pursuant to paragraph (c)(6)(vi)(C) of this section.

Example 15. Internal use software; application of the high threshold of innovation test—(i) *Facts.* X maintained separate software applications for tracking a variety of human resource (HR) functions, including employee reviews, salary information, location within the hierarchy and physical location of employees, 401(k) plans, and insurance coverage information. X determined that improved HR efficiency could be achieved by redesigning its disparate software applications into one employee-centric system, and worked to develop that system. X also determined that commercially available database management systems did not meet all of the requirements of the proposed system. Rather than waiting several years for vendor offerings to mature and become viable for its purpose, X embarked upon the project utilizing older technology that was severely challenged with respect to data modeling capabilities. The improvements, if successful, would provide a reduction in cost and improvement in speed that is substantial and economically significant. For example, having one employee-centric system would remove the duplicative time and cost of manually entering basic employee information separately in each application because the information would only have to be entered once to be available across all applications. The limitations of the technology X was attempting to utilize required that X attempt to develop a new database architecture. X committed substantial resources to the project, but could not predict, because of technical risk, whether it could develop the database software in the timeframe necessary so that X could recover its resources in a reasonable period. Specifically, X was uncertain regarding the capability of developing, within a reasonable period, a new database architecture using the old technology that would resolve its technological issues regarding the data modeling capabilities and the integration of the disparate systems into one system. At the beginning of the development, X did not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The software is internal use software because it is developed for use in a general and administrative function. However, the software satisfies the high threshold of innovation test set forth in paragraph (c)(6)(vii) of this section. The software was intended to be innovative in that it would provide a reduction in cost or improvement in speed that is substantial and economically significant. In addition, X's development activities involved significant economic risk in that X committed substantial resources to the development and there was substantial uncertainty, because of technical risk, that the resources would be recovered within a reasonable period. Finally, at the time X undertook the development of the system, software meeting X's requirements was not commercially available for use by X.

Example 16. Internal use software; application of the high threshold of innovation test—(i) *Facts.* X undertook a software project to rewrite a legacy mainframe application using an object-oriented programming language, and to move the new application off the mainframe to a client/server environment. Both the object-oriented language and client/server technologies were new to X. This project was undertaken to develop a more maintainable application, which X expected would significantly reduce the cost of maintenance, and implement new features more quickly, which X expected would provide both significant improvements in speed and reduction in cost. Thus, the improvements, if successful, would provide a reduction in cost and improvement in speed that is substantial and economically significant. X also determined that commercially available systems did not meet the requirements of the proposed system. X was certain that it would be able to overcome any technological uncertainties and implement the improvements within a reasonable period. However, X was unsure of the appropriate methodology to achieve the improvements. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The software is internal use software because it is developed for use in a general and administrative function. X's activities do not satisfy the high threshold of innovation test of paragraph (c)(6)(vii) of this section. Although the software meets the requirements of paragraphs (c)(6)(vii)(A)(*1*) and (*3*) of this section, X's development activities did not involve significant economic risk under paragraph (c)(6)(vii)(A)(*2*) of this section. X did not have substantial uncertainty, because of technical risk, that the resources committed to the project would be recovered within a reasonable period.

Example 17. Internal use software; application of the high threshold of innovation test—(i) *Facts.* X wants to expand its internal computing power, and is aware that its PCs and workstations are idle at night, on the weekends, and for a significant part of any business day. Because the general and administrative computations that X needs to make could be done on workstations as well as PCs, X develops a screen-saver-like application that runs on employee computers. When employees' computers have been idle for an amount of time set by each employee, X's application goes back to a central server to get a new job to execute. This job will execute on the idle employee's computer until it has either finished, or the employee resumes working on his computer. The ability to use the idle employee's computers would save X significant costs because X would not have to buy new hardware to expand the computing power. The improvements, if successful, would provide a reduction in cost that is substantial and economically significant. At the time X undertook the software development project, there was no commercial application available with such a capability. In addition, at the time X undertook the software development project, X was uncertain regarding the capability of developing a server application that could schedule and

distribute the jobs across thousands of PCs and workstations, as well as handle all the error conditions that occur on a user's machine. X commits substantial resources to the project. X undertakes a process of experimentation to attempt to eliminate its uncertainty. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The software is internal use software because it is developed for use in a general and administrative function. However, the software satisfies the high threshold of innovation test as set forth in paragraph (c)(6)(vii) of this section. The software was intended to be innovative because it would provide a reduction in cost or improvement in speed that is substantial and economically significant. In addition, X's development activities involved significant economic risk in that X committed substantial resources to the development and there was substantial uncertainty that because of technical risk, such resources would be recovered within a reasonable period. Finally, at the time X undertook the development of the system, software meeting X's requirements was not commercially available for use by X.

Example 18. Internal use software; application of the high threshold of innovation test—(i) *Facts.* X, a multinational manufacturer, wants to install an enterprise resource planning (ERP) system that runs off a single database. However, to implement the ERP system, X determines that it must integrate part of its old system with the new because the ERP system does not have a particular function that X requires for its business. The two systems are general and administrative software systems. The systems have mutual incompatibilities. The integration, if successful, would provide a reduction in cost and improvement in speed that is substantial and economically significant. At the time X undertook this project, there was no commercial application available with such a capability. X is uncertain regarding the appropriate design of the interface software. However, X knows that given a reasonable period of time to experiment with various designs, X would be able to determine the appropriate design necessary to meet X's technical requirements and would recover the substantial resources that X commits to the development of the system within a reasonable period. At the beginning of the development, X does not intend to develop the software for commercial sale, lease, license, or to be otherwise marketed to third parties or to enable X to interact with third parties or to allow third parties to initiate functions or review data on X's system.

(ii) *Conclusion.* The software is internal use software because it is developed for use in a general and administrative function. X's activities do not satisfy the high threshold of innovation test of paragraph (c)(6)(vii) of this section. Although the software meets the requirements of paragraphs (c)(6)(vii)(A)(*1*) and (*3*) of this section, X's development activities did not involve significant economic risk under paragraph (c)(6)(vii)(A)(*2*) of this section. X did not have substantial uncertainty, because of technical risk, that the resources committed to the project would be recovered within a reasonable period.

* * * * *

(e) *Effective/applicability dates.* Other than paragraph (c)(6) of this section, this section is applicable for taxable years ending on or after December 31, 2003. Paragraph (c)(6) of this section is applicable for taxable years beginning on or after October 4, 2016. For any taxable year that both ends on or after January 20, 2015 and begins before October 4, 2016, the IRS will not challenge return positions consistent with all of paragraph (c)(6) of this section or all of paragraph (c)(6) of this section as contained in the Internal Revenue Bulletin (IRB) 2015–5 (see *www.irs.gov/pub/irs-irbs/irb15-05.pdf*). For taxable years ending before January 20, 2015, taxpayers may choose to follow either all of § 1.41–4(c)(6) as contained in 26 CFR part 1 (revised as of April 1, 2003) and IRB 2001–5 (see *www.irs.gov/pub/irs-irbs/irb01-05.pdf*) or all of § 1.41–4(c)(6) as contained in IRB 2002–4 (see *www.irs.gov/pub/irs-irbs/irb02-04.pdf*).

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: August 22, 2016.

Mark J. Mazur

Assistant Secretary of the Treasury (Tax Policy).

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 236

[DOD–2014–OS–0097/RIN 0790–AJ29]

Department of Defense (DoD)'s Defense Industrial Base (DIB) Cybersecurity (CS) Activities

AGENCY: Office of the DoD Chief Information Officer, DoD.

ACTION: Final rule.

SUMMARY: This final rule responds to public comments and updates DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities. This rule implements mandatory cyber incident reporting requirements for DoD contractors and subcontractors who have agreements with DoD. In addition, the rule modifies eligibility criteria to permit greater participation in the voluntary DIB CS information sharing program.

DATES: *Effective Date:* This rule is effective on November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Vicki Michetti, DoD's DIB Cybersecurity Program Office: (703) 604–3167, toll free (855) 363–4227, or *OSD.DIBCSIA@mail.mil.*

SUPPLEMENTARY INFORMATION:

Purpose: This final rule responds to public comments to the interim final rule published on October 2, 2015. This rule implements statutory requirements for DoD contractors and subcontractors to report cyber incidents that result in an actual or potentially adverse effect on a covered contractor information system or covered defense information residing therein, or on a contractor's ability to provide operationally critical support. The mandatory reporting applies to all forms of agreements between DoD and DIB companies (contracts, grants, cooperative agreements, other transaction agreements, technology investment agreements, and any other type of legal instrument or agreement). The revisions provided are part of DoD's efforts to establish a single reporting mechanism for such cyber incidents on unclassified DoD contractor networks or information systems. Reporting under this rule does not abrogate the contractor's responsibility for any other applicable cyber incident reporting requirement. Cyber incident reporting involving classified information on classified contractor systems will be in accordance with the National Industrial Security Program Operating Manual (DoD–M 5220.22 (*http://dtic.mil/whs/directives/corres/pdf/522022M.pdf*)).

The rule also addresses the voluntary DIB CS information sharing program that is outside the scope of the mandatory reporting requirements. By modifying the eligibility criteria for the DIB CS program, the rule enables greater participation in the voluntary program. Expanding participation in the DIB CS program is part of DoD's comprehensive approach to counter cyber threats through information sharing between the Government and DIB participants.

Benefits: The DIB CS program allows eligible DIB participants to receive Government furnished information and cyber threat information from other DIB participants, thereby providing greater insights into adversarial activity targeting the DIB. The program builds trust between DoD and DIB and provides a collaborative environment for participating companies and DoD to share actionable unclassified cyber threat information that may be used to

bolster cybersecurity posture. The program also offers access to government classified cyber threat information to better understand the threat, as well as providing technical assistance from the DoD Cyber Crime Center (DC3) including analyst-to-analyst exchanges, mitigation and remediation strategies, and best practices. Through cyber incident reporting and voluntary cyber threat information sharing, both DoD and the DIB have a better understanding of adversary actions and the impact on DoD information and warfighting capabilities.

Related Regulations: The definitions in the rule are consistent with Controlled Unclassified Information as used by the National Archives and Records Administration pursuant to Executive Order (E.O.) 13556 ''Controlled Unclassified Information'' (November 4, 2010) and 32 Code of Federal Regulations (CFR) 2002, ''Controlled Unclassified Information'' (September 14, 2016). The rule is also harmonized with Defense Federal Acquisition Regulation Supplement (DFARS) Case 2013–D018, ''Network Penetration Reporting and Contracting for Cloud Services'' and FAR Case 2011–020, ''Basic Safeguarding of Contractor Information Systems.''

Authorities: The mandatory cyber incident reporting requirements support implementation of sections 391, 393, and 2224 of Title 10, United States Code (U.S.C); the Federal Information Security Modernization Act (FISMA), codified at 44 U.S.C. 3551 *et seq.;* and 50 U.S.C. 3330(e), and the Intelligence Authorization Act for Fiscal Year 2014. Cyber threat information sharing activities under this rule fulfill important elements of DoD's critical infrastructure protection responsibilities, as the sector specific agency for the DIB (see Presidential Policy Directive 21 (PPD–21), ''Critical Infrastructure Security and Resilience,'' available at *https://www.whitehouse.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil*).

Associated Costs: Under this rule, contractors will incur costs associated with identifying and analyzing cyber incidents and their impact on covered defense information, or a contractor's ability to provide operationally critical support, and reporting those incidents to DoD. Contractors must obtain DoD-approved medium assurance certificates to ensure authentication and identification when reporting cyber incidents to DoD. Medium assurance certificates are individually issued digital identity credentials used to ensure the identity of the user in online environments. Certificates typically cost about $175 each. If a contractor submits five cyber incident reports and participates in the voluntary DIB CS program, the annual cost to the contractor is estimated at $1,045. If the contractor elects to receive classified information electronically, the cost to establish the capability is approximately $4,500. The Government incurs cost to collect and analyze cyber incident information and develop trends and other analysis products, analyze malicious software, analyze media, onboard new companies into the voluntary DIB CS information sharing program, and facilitate collaboration activities related to the cyber threat information sharing.

Cybersecurity and Privacy: A foundational element of the mandatory reporting requirements, as well as the voluntary DIB CS program, is the recognition that the information being shared between the parties includes extremely sensitive information that requires protection. For additional information regarding the Government's safeguarding of information received from the contractors that require protection, see the Privacy Impact Assessment (PIA) for DoD's DIB Cybersecurity Activities located at *http://dodcio.defense.gov/IntheNews/PrivacyImpactAssessments.aspx.* The PIA provides detailed procedures for handling personally identifiable information (PII), attributional information about the strengths or vulnerabilities of specific covered contractor information systems, information providing a perceived or real competitive advantage on future procurement action, and contractor information marked as proprietary or commercial or financial information.

Public Comments

DoD published an interim final rule on October 2, 2015 (80 FR 59581). Twenty-eight comments were received and reviewed by DoD in the development of this final rule. A discussion of the comments received and changes made to the rule as a result of those comments follows:

Comment: One respondent recommended that the rule be clarified to confirm the requirements in the rule are prospective to be implemented in new agreements or in modifying an existing agreement.

Response: There should be no confusion regarding the prospective effect and effective date of the rule, nor is there basis to infer or interpret the rule as being intended to apply retroactively or otherwise to mandate the modification of pre-existing agreements; however, DoD agrees that the rule enables the option to modify such pre-existing agreements where deemed appropriate. No change is made to the rule.

Comment: One respondent expressed concern about being unable to locate the text of Section 941 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 in the U.S. Code.

Response: Section 941 of NDAA for FY13 has been codified at 10 U.S.C. 393 and all citations to this law have been updated accordingly.

Comment: One respondent recommended regularly conducting and releasing PIAs.

Response: DoD updates PIAs in accordance with DoD regulations and policy. DoD revised the PIA and published it in October 2015 (see *http://dodcio.defense.gov/IntheNews/PrivacyImpactAssessments.aspx*). No change is made to the rule.

Comment: Two respondents recommended publishing a report on the program's privacy implications and addressing personal information in internal contractor systems and that DoD address special procedures and protections for personal information.

Response: DIB CS program activities are in compliance with DoD and national policies for collecting, handling, safeguarding, and sharing sensitive information in accordance with DoD Directive 5400.11, ''DoD Privacy Program'' and 5400.11-Regulation, ''Department of Defense Privacy Program,'' which prescribes uniform procedures for implementation of and compliance with the DoD Privacy Program. Also, as noted in the immediately preceding response, the PIA for this program is also publicly available at *http://dodcio.defense.gov/IntheNews/PrivacyImpactAssessments.aspx.* In addition, DoD submits a privacy and civil liberties assessment of the DIB CS voluntary program for the annual Privacy and Civil Liberties Assessment Report required by E.O. 13636. No change is made to the rule.

Comment: One respondent stated that contractors are faced with multiple and sometimes conflicting reporting requirements for reporting cyber incidents from across the Government and even within DoD, and asserts that these reporting requirements should be clearly set forth in agreements with the Government. The respondent did not specifically identify any other cyber incident reporting requirements that might conflict with this rule.

Response: This rule consolidates and streamlines mandatory cyber incident reporting requirements and procedures originating from multiple separate statutory bases (*e.g.,* 10 U.S.C. 391 and 393, and 50 U.S.C. 3330(e))—however, reporting under these procedures in no way abrogates the contractor's responsibility to meet other cyber incident reporting requirements that may be applicable based on other contract requirements, or other U.S. Government statutory or regulatory requirements (see § 236.4(p)). DoD is working to streamline reporting procedures within the Department, including by designating the DoD Cyber Crime Center (DC3) as the single DoD focal point for receiving cyber incident reporting affecting unclassified networks of DoD contractors. No change is made to the rule.

Comment: One respondent recommended that Congress repeal the requirement to establish procedures for mandatory cyber incident reporting.

Response: This rule implements mandatory statutory requirements for mandatory cyber incident reporting set forth in 10 U.S.C. 391 and 393 (§ 236.4(b)–(d)). No change is made to the rule.

Comment: Two respondents questioned the Department's use of specific terms and definitions in the rule. One respondent stated that ''a violation of security policy of a system'' that is a subset of the definition of ''compromise'' is very broad and could result in over reporting and overwhelming DoD's resources. Another respondent recommended that the scope of the rule should be narrowed to only information that relates to a ''successful penetration.''

Response: The rule leverages established definitions from the Committee on National Security Systems Instruction No. 4009, ''National Information (IA) Assurance Glossary,'' (*https://www.ncsc.gov/nittf/docs/CNSSI-4009_National_Information_Assurance.pdf*). The term ''successful penetration'' is not in the CNSS glossary. However, the rule uses the established terms ''cyber incident'' and ''compromise'' from the CNSS glossary, which are widely accepted and understood Government definitions. Adhering to this definition will not overwhelm DoD resources. No change is made to the rule.

Comment: One respondent stated that the four categories of covered defense information are unclear and will hamper timely reporting.

Response: The definition of covered defense information has been clarified to more closely align with, and leverage, the Controlled Unclassified Information (CUI) Registry at *http://www.archives.gov/cui/registry/category-list.html* (§ 236.2).

Comment: One respondent stated the scope of a cyber incident ''affecting the contractor's ability to provide operationally critical support'' is so vague that it may result in over reporting.

Response: DoD designates the supplies or services that qualify as operationally critical support, and is developing procedures to ensure that contractors are notified when they are providing supplies or services designated as operationally critical support. If the contractor is unclear as to what specific supplies or services being provided have been designated as operationally critical, the contractor should request clarification from the DoD point of contact (*e.g.,* contracting officer or agreements officer) for the agreement(s) governing the activity in question. No change is made to the rule.

Comment: One respondent stated that it is not clear why the rule now distinguishes information ''created by or for DoD'' from information ''not created by DoD.''

Response: The distinction regarding whether information has been created by or for DoD originates from that distinction being an element of the underlying statutes that are implemented in this rule (*e.g.,* 10 U.S.C. 391 and 393). The distinction is made in a variety of contexts—generally to reinforce the underlying reason for requiring the contractor to share information with DoD (*e.g.,* as it relates to a potential compromise of information created by or for DoD in support of a DoD program), and to minimize the requirement to share or provide access to information that is not related to DoD programs or activities (*e.g.,* except as necessary for forensics analysis regarding an incident in which DoD information may have been compromised). No change is made to the rule.

Comment: One respondent requested clarification of the purpose of, ''Applicability and Order of Precedence,'' and the meaning of the phrase ''applicable laws and regulations'' in § 236.4 of this rule.

Response: Section 236.4(a) mandates that the cyber incident reporting requirements of this rule be incorporated into all relevant types of agreements between DoD, but recognizes that in some cases an individual agreement may have terms or conditions that may be inconsistent with this rule, and allows the terms of the agreement to take precedence over the requirements of this rule only when the terms of the agreement ''are authorized to have been included in the agreement in accordance with applicable laws and regulations.'' The laws and regulations that are applicable to any individual agreement will depend on the nature and context of the agreement. For example, in the context of procurement contracts, the requirements of this rule are implemented through Defense Federal Acquisition Regulation Supplement (DFARS) Subpart 204.73, ''Safeguarding Covered Defense Information and Cyber Incident Reporting,'' and its associated clauses (*e.g.,* DFARS 252.204–7009, and –7012). However, the FAR and DFARS also permit deviations from otherwise prescribed contract requirements under certain conditions, but not including cases when the deviation would be ''precluded by law, executive order, or regulation'' (see FAR 1.402). No change is made to the rule.

Comment: One respondent recommended that the phrase ''all applicable agreements'' in § 236.4(a) be clarified to identify the agreements that DoD intends to be covered by the rule.

Response: Section 236.4(a) has been revised to clarify that the rule applies to ''all forms of agreements (*e.g.,* contracts, grants, cooperative agreements, other transaction agreements, technology investment agreements, and any other type of legal instrument or agreement).'' For example, these requirements are implemented for DoD procurement contracts through DFARS Subpart 204.73 and its associated clauses (*e.g.,* DFARS 252.204–7009, and –7012).

Comment: One respondent raised issue about the practicality of the 72 hour reporting requirement.

Response: Timeliness in reporting cyber incidents is a key element in cybersecurity and provides the clearest understanding of the cyber threat targeting DoD information and the ability of companies to provide operationally critical support. The 72 hour reporting standard has been a part of the DIB CS program since it was first established as a pilot activity in 2008, and throughout its evolution into a permanent program and ultimate codification in the CFR in 2012. Based on this history, the 72 hour period has proven to be an effective balance of the need for timely reporting while recognizing the challenges inherent in the initial phases of investigating a cyber incident. Contractors should report available information within the 72 hour period and provide updates if more information becomes available. No change is made to the rule.

Comment: One respondent questioned the reporting by subcontractors and how DoD intends to enforce flow down of the clause and does DoD consider Internet Service Providers (ISPs) to fall in the category of subcontractors.

Response: Section 236.4(d) of the rule has been revised to clarify that contractors must flow down the reporting requirements to ''subcontractors that are providing operationally critical support or for which subcontract performance will involve a covered contractor information system.'' Whether these requirements would be required to flow down to an ISP would depend on whether the particular service(s) being provided would meet the flowdown criteria, and the implementation of these requirements for any specific type of agreement (*e.g.,* for procurement contracts governed by the DFARS) may provide additional guidance regarding flowdown. The contractor should consult with the DoD point of contact for the relevant agreement (*e.g.,* contracting officer or agreements officer) when it is uncertain if the requirements should flow down. Section 236.4(d) has been revised.

Comment: One respondent recommended that the rule establish what information a contractor must share with the Government under mandatory reporting.

Response: Contractors are required to report in accordance with § 236.4(b). A list of the reporting fields can be found at *http://dibnet.dod.mil.* These reporting fields include the statutory requirements set forth in 10 U.S.C. 391 and 393, including but not limited to an assessment of the impact of the cyber incident, description of the technique or method used, summary of information compromised. No change is made to the rule.

Comment: One respondent commented that the rule does not provide any mechanism for a contractor to raise concerns about, object to, or limit the data being provided due to its sensitivity.

Response: This rule implements mandatory information sharing requirements of 10 U.S.C. 391 and 393 by requiring DoD contractors to report key information regarding cyber incidents, and to provide access to equipment or information enabling DoD to conduct forensic analysis to determine if or how DoD information was impacted in a cyber incident. The rule's implementation of these requirements is tailored to minimize the sharing of unnecessary information (whether sensitive or not), including by carefully tailoring the information required in the initial incident reports (§ 236.4(c)), by expressly limiting the scope of the requirement to provide DoD with access to additional information to only such information that is ''necessary to conduct a forensic analysis,'' and by affirmatively requiring the Government to safeguard any contractor attributional/proprietary information that has been shared (or derived from information that has been shared) against any unauthorized access or use. In the event that the contractor believes that there is information that meets the criteria for mandatory reporting, but the contractor desires not to share that information due to its sensitivity, then the contractor should immediately raise that issue to the DoD point of contact (*e.g.,* contracting officer or agreements officer) for the agreement(s) governing the activity in question, and if necessary, follow the dispute resolution procedures that are applicable to the agreement(s). No change is made to the rule.

Comment: One respondent asked how DoD will safeguard any contractor data provided as part of media once in DoD's possession, and what are the recourses for contractors in the event of a breach of those safeguards.

Response: DoD uses a wide variety of mechanisms to safeguard all forms of sensitive information, including information received from contractors, to ensure that information is accessed, used, and shared only with authorized persons for authorized purposes. For example, the DIB CS PIA addresses how PII and other sensitive information will be protected. No change is made to the rule.

Comment: One respondent stated that the rule lacks sufficient protections for contractor sensitive information that is provided to government support contractors, and the rule should provide such protections consistent with 10 U.S.C. 2320(f)(2) and DFARS 252.227–7025, ''Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.''

Response: Responsibilities of government support contractors to protect sensitive information received from other contractors under this rule are addressed in § 236.4(m)(5) and are largely consistent with, although not identical to, the statutory provision and DFARS Clause cited by the commenter. In addition, the support contractor providing support for DoD's activities under this rule may also qualify as a ''covered Government support contractor'' under the cited DFARS clause, and thereby would already be subject to the cited DFARS clause. No change is made to the rule.

Comment: One respondent stated the information shared with the Government should only be used for cybersecurity purposes.

Response: 10 U.S.C. 391 and 393 provide specific authorization for sharing information received in cyber incident reports for a range of important activities that include, but are not limited to, cybersecurity activities (see § 236.4(m)(1)–(5)). Limiting the sharing of information to cybersecurity purposes only would be inconsistent with the statutory framework and would unnecessarily limit the use of information for critical activities such as law enforcement, counterintelligence, and national security. No change is made to the rule.

Comment: One respondent stated the rule provides no limitations on DoD's ability to share information with third-party contractors. It also imposes a confidentiality obligation upon receiving contractors but does not address measures needed to mitigate any potential conflicts of interest stemming from third-party access.

Response: Section 236.4(m)(5) authorizes sharing with government support contractors that are ''directly supporting'' Government activities under this rule, and applies a comprehensive set of use and non-disclosure restrictions and responsibilities for those government support contractors to safeguard the information they receive, including prohibiting the support contractor from using the information for any other purpose, making the reporting contractor a third-party beneficiary of the non-disclosure agreement with direct remedies for any breach of the restrictions by the support contractor. No change is made to the rule.

Comment: One respondent recommended the proposed rule should establish requirements for companies to remove PII before sharing with the Government and for the Government to remove upon receipt.

Response: The DIB CS program has implemented procedures to minimize the collection and sharing of PII. Companies are always asked to remove unnecessary PII, and only share information if it is relevant to a cyber incident (*e.g.,* for forensics or cyber intrusion damage assessment). The PIA for DoD's DIB CS Activities provides procedures on how the Government handles PII, as well as other forms of sensitive contractor information (*e.g.,* contractor attributional/proprietary). The PIA was updated and published in October 2015 (*http://*

dodcio.defense.gov/IntheNews/PrivacyImpactAssessments.aspx). No change is made to the rule.

Comment: One respondent stated the rule places burden on the contractor to mark information as, ''contractor attributional/proprietary,'' but if it is not marked and subsequently submitted in response to request for images at the time of the cyber incident, Government must ensure, in absence of marking, obligation to protect information as contractor/attributional/proprietary.

Response: The rule requires that, to the maximum extent practicable, the contractor shall identify and mark attributional/proprietary information, but it does not condition the Government's safeguarding of such information on that identification or marking. The Government has established procedures for receiving, evaluating, anonymizing, safeguarding and sharing of such reported information in connection with cyber incidents involving contractor information and information systems. The DIB CS PIA provides more details regarding processes for handling PII and other sensitive information. No change is made to the rule.

Comment: One respondent stated that the rule should include provisions for liability protection.

Response: Liability protections established by 10 U.S.C. 391 and 393 became effective after the publication of the interim rule. The regulatory implementation of these new statutory elements will be addressed through future rulemaking activities to ensure the opportunity for public comment.

Comment: One respondent recommended expanding the number of commercial service providers under the Enhanced Cybersecurity Service (ECS) program, as part of the DIB CS program.

Response: The ECS program is managed by the Department of Homeland Security (DHS). Recommendations regarding ECS should be forwarded to DHS at *ECS_Program@hq.dhs.gov.* No change is made to the rule.

Comment: One respondent cautioned against expanding the types of companies eligible for the DIB CS program until addressing all relevant operational, privacy, and security concerns. This expansion could encompass companies who provide services and products to the general public and current defense contractors who are not currently eligible to participate in the program.

Response: DoD has established eligibility requirements (§ 236.7) for participation in the DIB CS program and thus any future expansion or revision of this eligibility criteria will be accomplished in accordance with federal rulemaking requirements to allow for public review and comment. No change is made to the rule.

Comment: One respondent expressed concern about the burden of cost due to increased participation in the DIB CS program.

Response: The burden of cost for companies participating in the DIB CS program has been reduced. Under the revised rule, DoD removed the requirement for DIB CS participants to obtain access to DoD's secure voice and transmission systems supporting the program. All companies participating in the DIB CS program are still required to have a DoD-approved medium assurance certificate to enable encrypted unclassified information sharing between the Government and DIB CS participants. The cost of a DoD-approved medium assurance certificate has not changed and is approximately $175. No change is made to the rule.

Regulatory Procedures

Executive Orders 12866, ''Regulatory Planning and Review'' and 13563, ''Improving Regulation and Regulatory Review''

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, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Public Law 104–121, ''Congressional Review Act'' (5 U.S.C. 801)

It has been determined that this rule is not a ''major'' rule under 5 U.S.C. 801, enacted by Public Law 104–121, because it will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local Government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

2 U.S.C. Ch. 25, ''Unfunded Mandates Reform Act''

It has been determined that this rule does not contain a Federal mandate that may result in expenditure by State, local and tribal Governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. Ch. 6)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. Ch. 6) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This rule does contain reporting requirements under the Paperwork Reduction Act (PRA) of 1995. The collection requirements were published in the preamble of the interim final rule that was published on October 2, 2015 (80 FR 59581) for public comment. No comments were received for these collections. The Office of Management and Budget (OMB) Control Numbers are: 0704–0489, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Activities Cyber Incident Reporting,'' and 0704–0490, ''DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Program Points of Contact (POC) Information.''

Executive Order 13132, ''Federalism''

It has been determined that this rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(a) The States;

(b) The relationship between the National Government and the States; or

(c) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 236

Government contracts, Security measures.

Accordingly, the interim final rule published at 80 FR 59581 on October 2, 2015, is adopted as a final rule with the following changes:

PART 236—DEPARTMENT OF DEFENSE (DoD)'s DEFENSE INDUSTRIAL BASE (DIB) CYBERSECURITY (CS) ACTIVITIES

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

Authority: 10 U.S.C. 391, 393, and 2224; 44 U.S.C. 3506 and 3544; 50 U.S.C. 3330.

■ 2. Amend § 236.1 by revising the last two sentences in the section to read as follows:

§ 236.1 Purpose.

* * * The part also permits eligible DIB participants to participate in the voluntary DIB CS program to share cyber threat information and cybersecurity best practices with DIB CS participants. The DIB CS program enhances and supplements DIB participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems.

■ 3. Amend § 236.2 by:
■ a. Revising the definition of ''Covered contractor information system''.
■ b. Revising the definition of ''Covered defense information''.
■ c. Revising the definition of ''Cyber incident''.
■ d. Revising the definition of ''DIB participant''.
■ e. Removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program'' in the definition of ''Government furnished information''.
■ f. Removing ''Contractor'' and adding in its place ''contractor'' in the definition of ''Media''.

The revisions read as follows:

§ 236.2 Definitions.

* * * * *

Covered contractor information system means an unclassified information system that is owned or operated by or for a contractor and that processes, stores, or transmits covered defense information.

Covered defense information means unclassified controlled technical information or other information (as described in the Controlled Unclassified Information (CUI) Registry at *http://www.archives.gov/cui/registry/category-list.html*) that requires safeguarding or dissemination controls pursuant to and consistent with law, regulations, and Government wide policies, and is:

(1) Marked or otherwise identified in an agreement and provided to the contractor by or on behalf of the DoD in support of the performance of the agreement; or

(2) Collected, developed, received, transmitted, used, or stored by or on behalf of the contractor in support of the performance of the agreement.

* * * * *

DIB participant means a contractor that has met all of the eligibility requirements to participate in the voluntary DIB CS program as set forth in this part (see § 236.7).

* * * * *

§ 236.3 [Amended]

■ 4. Amend § 236.3 by:
■ a. In paragraph (b)(1), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ b. In paragraph (c), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''

§ 236.4 [Amended]

■ 5. Amend § 236.4 by:
■ a. In paragraph (a), removing ''applicable agreements'' and adding in its place ''forms of agreements (*e.g.,* contracts, grants, cooperative agreements, other transaction agreements, technology investment agreements, and any other type of legal instrument or agreement).''
■ b. In paragraph (d), removing '', as appropriate'' and adding in its place ''that are providing operationally critical support or for which subcontract performance will involve a covered contractor information system.''
■ c. In paragraph (e), removing ''*http://iase.disa.mil/pki/eca/certificate.html*'' and adding in its place ''*http://iase.disa.mil/pki/eca/Pages/index.aspx.*''
■ d. In paragraph (m)(4), adding ''non-attributional cyber threat information'' after ''sharing.''
■ e. Redesignating paragraphs (n) through (p) as paragraphs (o) through (q).
■ f. Redesignating paragraph (m)(6) as paragraph (n).
■ 6. Amend § 236.5 by:
■ a. Revising the section heading.
■ b. In paragraph (a), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ c. In paragraph (b), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ d. Revising paragraph (d).
■ e. In paragraph (g), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''

The revisions read as follows:

§ 236.5 DoD's DIB CS program.

* * * * *

(d) DoD's DIB CS Program Office is the overall point of contact for the program. The DC3 managed DoD DIB Collaborative Information Sharing Environment (DCISE) is the operational focal point for cyber threat information sharing and incident reporting under the DIB CS program.

* * * * *

■ 7. Amend § 236.6 by:
■ a. Revising the section heading.
■ b. In paragraph (a):
■ i. Removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program'' in the first sentence.
■ ii. Removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program'' in the second sentence.
■ c. In paragraph (c), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ d. In paragraph (d), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ e. In paragraph (e), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ f. In paragraph (g), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''

The revisions read as follows:

§ 236.6 General provisions of DoD's DIB CS program.

* * * * *

■ 8. Amend § 236.7 by:
■ a. Revising the section heading.
■ b. In paragraph (a) introductory text, removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ c. In paragraph (a)(1), adding ''to at least the Secret level'' after ''FCL.''
■ d. In paragraph (a)(2), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''
■ e. In paragraph (a)(3)(iii), removing ''DoD–DIB CS information sharing program'' and adding in its place ''DIB CS program.''

The revisions read as follows:

§ 236.7 DoD's DIB CS program requirements.

* * * * *

Dated: September 29, 2016.

Patricia L. Toppings,

OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2016–23968 Filed 10–3–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0666]

RIN 1625–AA08

Special Local Regulation; Ouachita River, Monroe, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation controlling movement of vessels for certain waters of the Ouachita River. This rule is necessary to provide for the safety of life on navigable waters during a paddle boat race on October 15, 2016. This regulation requires commercial vessels to notify the Captain of the Port Memphis before entering the event area and require all vessels transiting the area to maintain a minimum speed for safe navigation.

DATES: This rule is effective on October 15, 2016, from 10 a.m. until 2 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0666 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Petty Officer Todd Manow, Waterways Management, Sector Lower Mississippi River, U.S. Coast Guard; telephone 901–521–4813, email *Todd.M.Manow@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On May 23, 2016, Louisiana Delta Adventures notified the Coast Guard that it will be conducting a paddle boat race from 10 a.m. to 2 p.m. on October 15, 2016. The paddle boats are to be launched from a boat ramp near mile marker 173.0 at D'Arbonne cutoff in the Ouachita River northwest of West Monroe, LA, and will proceed approximately 7.5 miles downriver to mile maker 166.5 near the Red River Market, Monroe, LA.

The Coast Guard has established special local regulations for similar events and determined that conducting paddle boat races in this portion of navigable waterway, paired with other activities and waterways usage in the area, presents potential safety hazards requiring this regulatory action.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. Although the event sponsor submitted an initial application for a marine event on May 23, 2016, final details of the event were not known to the Captain of the Port Memphis (COTP) until late August of 2016. This action is necessary to provide for the safety of life on navigable waters during the marine event. It is impracticable to publish an NPRM because we must establish this safety zone by October 15, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable.

III. Legal Authority and Need for a Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The COTP has determined that potential hazards posed to participants of a paddle boat race in this section of river would be a safety concern for anyone transiting the river from mile marker 173 to 166.5. The purpose of this rulemaking is to ensure the safety of event participants and other waterway users in U.S. navigable waters within mile marker 173 to 166.5 before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a special local regulation from 10 a.m. until 2 p.m. on October 15, 2016. In light of the aforementioned hazards, the COTP has determined that a special local regulation is necessary to protect spectators, vessels, and participants. The special local regulation will encompass the following waterway: All waters of the Ouachita River between mile markers 173 and 166.5 in the vicinity of Monroe, LA.

The COTP or a designated on-scene representative will permit vessels to transit the area on a case-by-case basis. Commercial vessel operators desiring to transit through the regulated area must contact the COTP before doing so. The COTP or a designated on-scene representative may be contacted via VHF Channel 16 or by telephone at 1–866–777–2784. During enforcement, all vessels are to proceed at slowest speed for safe navigation while transiting the regulated area.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The Coast Guard's use of this special local regulation will be only four hours in duration on a Saturday, and it is designed to minimize the impact on navigation. Moreover, vessels may transit through the area affected by this special local regulation at a minimum speed for safe navigation as approved by the COTP on a case-by-case basis. Overall, the Coast Guard expects minimal impact to vessel movement from the enforcement of this special local regulation.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small

businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in this portion of the Ouachita River in the vicinity of Monroe, LA between 10 a.m. and 2 p.m. on October 15, 2016.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a special local regulation lasting four hours. Such actions are categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233

■ 2. Add § 100.35T08–0666 to read as follows:

§ 100.35T08–0666 Special Local Regulation; Ouachita River; Monroe, LA.

(a) *Regulated area.* A regulated area is established to encompass the following waterway: all waters of the Ouachita River mile 173 through mile 166.5.

(b) *Effective period.* This section is effective and will be enforced from 10 a.m. until 2 p.m. on October 15, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801 of this part, commercial vessel operators desiring to operate in the regulated area must contact the Captain of the Port Memphis (COTP) to before doing so. The COTP or a designated representative may be contacted via VHF Channel 16 or by telephone at 1–866–777–2784.

(2) During enforcement, all vessels are to proceed at slowest speed for safe navigation while transiting the regulated area.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the regulated area as well as any changes in the dates and times of enforcement.

Dated: September 27, 2016.

T.J. Wendt,

Captain, U.S. Coast Guard, Captain of the Port, Memphis, Tennessee.

[FR Doc. 2016–23973 Filed 10–3–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0189; FRL–9952–03–Region 6]

Promulgation of Air Quality Implementation Plans; State of Arkansas; Regional Haze and Interstate Visibility Transport Federal Implementation Plan

Correction

In rule document 2016–22508 beginning on page 66331 in the issue of Tuesday, September 27, 2016, make the following correction:

1. On page 66332, in the first column, after the **DATES** heading, the second line, ''October 27, 2017'' should read ''October 27, 2016.''

[FR Doc. C1–2016–22508 Filed 10–3–16; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0291; FRL–9952–13–Region 9]

Approval of California Air Plan Revisions, Sacramento Metropolitan Air Quality Management District and San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD) and the San Diego County Air Pollution Control District (SDCAPCD) portions of the California State Implementation Plan (SIP). These revisions concern emissions of volatile organic compounds (VOCs) from architectural coatings. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on December 5, 2016 without further notice, unless the EPA receives adverse comments by November 3, 2016. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0291 at *http://www.regulations.gov,* or via email to *Steckel.Andrew@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972–3024, *lazarus.arnold@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this action with the dates that they were adopted by the local air agencies and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule number	Rule title	Adopted/ amended	Repealed/ rescinded	Submitted
SDCAPCD	67.0	Architectural Coatings	12/12/01	6/24/15	11/13/15
SDCAPCD	67.0.1	Architectural Coatings	6/24/15		11/13/15
SMAQMD	442	Architectural Coatings	9/24/15		3/11/16

On April 19, 2016, the EPA determined that the submittal for SMAQMD Rule 442 met the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review. On January 19, 2016, the EPA determined that the submittals for SDCAPCD Rules 67.0 and 67.0.1 met the completeness criteria.

B. Are there other versions of these rules?

There are no previous versions of Rule 67.0.1 in the SIP. We approved earlier versions of Rule 442 into the SIP on November 9, 1998 (63 FR 60214) and Rule 67.0 on June 20, 2013 (78 FR 37130).

C. What is the purpose of the submitted rules and rule rescission?

VOCs help produce ground-level ozone, smog and particulate matter (PM), which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. Architectural coatings are applied to stationary structures and their accessories. They include house paints, stains, industrial maintenance coatings, traffic coatings, and many other products. VOCs are emitted from the coatings during application and curing, and from the associated solvents used for thinning and clean-up. SMAQMD Rule 442 controls VOC emissions from architectural coatings by establishing VOC limits on any architectural coating supplied, sold, offered for sale or manufactured for use within the SMAQMD. Rule 442 was revised to align SMAQMD's architectural coatings practices and VOC limits with those contained in CARB's ''2007 Suggested Control Measures for Architectural Coatings'' (SCM),[1] which are more stringent and make use of newer coating categories than the previous version of Rule 442.

Similarly, SDCAPCD Rule 67.0.1 was adopted to align SDCAPCD's architectural coatings practices and VOC limits with those contained in CARB's SCM. Rule 67.0.1 replaces SDCAPCD Rule 67.0, which was rescinded. SDCAPCD elected to make these changes in a new rule, rather than in revisions to Rule 67.0, ''due to the large number of revisions to existing Rule 67.0 that would be necessary to reflect the 2007 SCM.'' [2]

[1] *http://www.arb.ca.gov/coatings/arch/docs.htm.*

[2] Letter from Robert J. Kard, Air Pollution Control Officer of the SDCAPCD to the San Diego Air Pollution Control Board, June 24, 2015, p3.

The EPA's technical support documents (TSDs) have more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Generally, SIP rules must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major stationary source of VOCs in ozone nonattainment areas classified as moderate or above (see CAA sections 182(b)(2)). The SMAQMD has been designated as severe nonattainment for the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS). The SDCAPCD regulates an ozone nonattainment area classified as moderate for the 2008 8-Hour Ozone NAAQS (40 CFR 81.305). As addressed further in the TSDs, because there are no relevant EPA CTG documents and because architectural coatings are considered area sources, architectural coating sources are not subject to RACT requirements. However, architectural coating sources are subject to other VOC content limits and control measures described in the TSDs.

Guidance and policy documents that we use to evaluate enforceability, SIP revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' (57 FR 13498, April 16, 1992 and 57 FR 18070, April 28, 1992).

2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations'' (''the Bluebook,'' U.S. EPA, May 25, 1988; revised January 11, 1990).

3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies'' (''the Little Bluebook'', EPA Region 9, August 21, 2001).

4. ''Suggested Control Measure for Architectural Coatings,'' CARB, October 2007.

5. Code of Federal Regulations (CFR), title 40, part 59, subpart D—National Volatile Organic Compound Emission Standards for Architectural Coatings (40 CFR 59.400 *et seq.*).

B. Do the rules meet the evaluation criteria?

We believe these rules and rule rescission are consistent with the relevant policy and guidance regarding enforceability, RACT and SIP relaxations. The TSDs have more information on our evaluation.

C. EPA Recommendations To Further Improve the Rules

The TSDs describe additional rule revisions that we recommend for the next time the local agency modifies the rules but which are not currently the basis for rule disapproval.

D. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, the EPA is fully approving the submitted rules and rule rescission because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules and rule rescission. If we receive adverse comments by November 3, 2016, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on December 5, 2016. This will incorporate these rules and this rule rescission into the federally enforceable SIP.

Please note that if the EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SMAQMD and SDCAPCD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or

an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 24, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(255)(i)(A)(*7*), (c)(354)(i)(F)(*4*), (c)(472)(i)(C), and (c)(474)(i)(B) to read as follows:

§ 52.220 Identification of plan.

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(c) * * *

(255) * * *

(i) * * *

(A) * * *

(*7*) Previously approved on November 9, 1998, in paragraph (c)(255)(i)(A)(*2*) of this section and now deleted with replacement in paragraph (c)(474)(i)(B)(*1*) of this section, Rule 442, adopted on September 5, 1996.

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(354) * * *

(i) * * *

(F) * * *

(*4*) Previously approved on June 20, 2013, in paragraph (c)(354)(i)(F)(*3*) of this section and now deleted without replacement, Rule 67.0, ''Architectural Coatings,'' adopted on December 12, 2001.

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(472) * * *

(i) * * *

(C) San Diego Air Pollution Control District.

(*1*) Rule 67.0.1, ''Architectural Coatings,'' adopted on June 24, 2015.

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(474) * * *

(i) * * *

(B) Sacramento Metropolitan Air Quality Management District.

(*1*) Rule 442, ''Architectural Coatings,'' amended on September 24, 2015.

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[FR Doc. 2016–23837 Filed 10–3–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2013–0465; FRL–9952–82-Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Louisiana; Infrastructure State Implementation Plan Requirements for the National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of State Implementation Plan (SIP) submittals from Louisiana which address the requirements of Clean Air Act (CAA) sections 110(a)(1) and (2) regarding the infrastructure requirements for the 2006 fine particulate matter ($PM_{2.5}$), 2008 Lead (Pb), 2008 Ozone (O_3), 2010 Nitrogen Dioxide (NO_2), 2010 Sulfur Dioxide (SO_2) and 2012 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities as defined by the CAA. These infrastructure SIP (i-SIP) submittals address how the existing SIP provides for implementation, maintenance, and enforcement of the NAAQS.

DATES: This rule is effective on November 3, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2013–0465. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Sherry Fuerst 214–665–6454, *fuerst.sherry@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

The background for this action is discussed in detail in our June 3, 2016 proposal (81 FR 35674). In that rulemaking action, we proposed to approve portions of Louisiana's SIP submittals pertaining to requirements of CAA sections 110(a)(1) and 110(a)(2) of the 2006 $PM_{2.5}$, 2008 Pb, 2008 O_3, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS. CAA Section 110(a)(1) requires states to submit a revised i-SIP within three years after the promulgation of a new or revised NAAQS. The submission must provide for the ''implementation, maintenance, and enforcement'' of the NAAQS. We received substantive comments from the Sierra Club during the comment period on our Notice of Proposed Rulemaking (NPR). A synopsis of the comments and our responses are provided below.

II. Response to Comments

A. Background Comments

1. The Plain Language of the CAA

Comment 1: Sierra Club states that the plain language of section 110(a)(2)(A) of the CAA, legislative history of the CAA, case law, EPA regulations, and legislative and regulatory interpretations made previously by EPA in rulemakings require the inclusion of enforceable emission limits in an i-SIP to prevent NAAQS exceedances in areas not designated nonattainment. Sierra Club asserts that EPA must disapprove Louisiana's proposed i-SIP because it is in violation of CAA section 110(a)(2)(A) in that the i-SIP fails to include enforceable emission limitations necessary to ensure attainment and maintenance of the NAAQS. The Commenter also states that the Louisiana i-SIP revision fails to comport with CAA requirements for SIPs to establish enforceable emission limits that are adequate to prohibit NAAQS exceedances in areas not designated nonattainment.

The Commenter also states that, on its face, the CAA requires i-SIPs ''to be adequate to prevent exceedances of the NAAQS.'' In support, the Commenter quotes the language in section 110(a)(1) which requires states to adopt a plan for implementation, maintenance, and enforcement of the NAAQS and the language in section 110(a)(2)(A) which the Commenter interprets to require i-SIPs to include enforceable emissions limitations that are sufficient to ensure maintenance of the NAAQS. Sierra Club notes the CAA definition of emission limit and reads these provisions together to require ''enforceable emission limits on source emissions sufficient to ensure maintenance of the NAAQS.''

Response 1: EPA disagrees that section 110 is clear ''on its face'' and must be read in the manner suggested by Sierra Club in the context of i-SIP submissions. As we have previously explained in response to Sierra Club's similar comments in our previous actions on Virginia's 2008 ozone NAAQS i-SIP (*see,* 79 FR 17043, 17047 March 27, 2014), Virginia's 2010 SO_2 NAAQS i-SIP (*see,* 80 FR 11557 March 4, 2015), West Virginia's 2010 SO_2 i-SIP (*see,* 79 FR 62022 October 16, 2014), Pennsylvania's 2008 Ozone and 2010 SO_2 NAAQS i-SIP (*see,* 80 FR 46494 August 5, 2015), and New Hampshire's SO_2 NAAQS i-SIP (*see,* 81 FR 44542 July 8, 2016), CAA Section 110 is only one provision that is part of the multi-faceted structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and it must be read in the context of not only that structure, but also of the historical evolution of that structure.

Infrastructure SIPs are general planning SIPs, consistent with the CAA as understood in light of its history and structure. When Congress enacted the CAA in 1970, it did not include provisions requiring states and the EPA to label areas as attainment or nonattainment. Rather, states were required to include all areas of the state in ''air quality control regions'' (AQCRs) and section 110 set forth the core substantive planning provisions for these AQCRs. At that time, Congress anticipated that states would be able to address air pollution quickly by complying with the very general planning provisions in section 110 and bring all areas into compliance with a new NAAQS within five years. Moreover, at that time, section 110(a)(2)(A)(i) specified that the section 110 plan provide for ''attainment'' of the NAAQS and section 110(a)(2)(B) specified that the plan must include ''emission limitations, schedules, and timetables for compliance with such limitations, and such other measures as may be necessary to insure attainment and maintenance [of the NAAQS].''

In 1977, Congress recognized that the existing structure was not sufficient and many areas were still violating the NAAQS. At that time, Congress for the first time added provisions requiring that states and EPA identify whether areas of a state were violating the NAAQS (*i.e.,* were nonattainment) or were meeting the NAAQS (*i.e.,* were attainment/unclassifiable) and established specific planning requirements in section 172 for areas not meeting the NAAQS. In 1990, many areas still had air quality not meeting the NAAQS and Congress again amended the CAA and added yet another layer of more prescriptive planning requirements for each of the NAAQS. At that same time, Congress modified section 110 to remove references to the section 110 SIP providing for attainment, including removing pre-existing section 110(a)(2)(A) in its entirety and renumbering subparagraph (B) as section 110(a)(2)(A). Additionally, Congress replaced the clause ''as may be necessary to insure attainment and maintenance [of the NAAQS]'' with ''as may be necessary or appropriate to meet the applicable requirements of this chapter.'' Thus, the CAA has significantly evolved in the more than 40 years since it was originally enacted. While at one time section 110 of the CAA did provide the only detailed SIP planning provisions for states and specified that such plans must provide for attainment of the NAAQS, under the structure of the current CAA, section 110 is only the initial stepping-stone in the planning process for a specific NAAQS. More detailed, later-enacted provisions govern the substantive planning process, including planning for attainment of the NAAQS. CAA section 110 is only one provision that is part of the multi-faceted structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and it must be read in the context of that structure and the historical evolution of that structure. In light of the revisions to section 110 since 1970 and the later-promulgated and more specific planning requirements of the CAA, the requirement in section 110(a)(2)(A) of the CAA that the plan provide for ''implementation, maintenance and enforcement'' means that the state must demonstrate that it has the necessary tools to implement and enforce a NAAQS, such as adequate state personnel and the legal authority for an enforcement program. It is Part D of title I of the CAA that contains numerous requirements for the NAAQS attainment planning process, including the requirement for enforceable emissions limitations, and such other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for the attainment of the NAAQS. After a nonattainment designation is made, the Administrator establishes a plan submission schedule with which the state must comply. The schedule may include submission dates up to three

years after the nonattainment designation has been made. The state must, within the schedule provided by the Administrator, submit a plan that meets Part D's requirements. The general requirements of CAA section 110(a)(1) and the listing of elements in CAA section 110(a)(2) require review of each and every provision of a state's existing SIP against all requirements in the CAA and the EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. The requirement for emission limitations in section 110 means that the state may rely on measures already in place to address the pollutant at issue or any new control measures that the state may choose to submit to meet the requirements in section 110. Finally, as EPA has stated in the 2013 Infrastructure SIP Guidance [1] which specifically provides guidance to states in addressing the 2010 SO_2 NAAQS, ''[t]he conceptual purpose of an i-SIP submission is to assure that the air agency's SIP contains the necessary structural requirements for the new or revised NAAQS, whether by establishing that the SIP already contains the necessary provisions, by making a substantive SIP revision to update the SIP, or both.'' Infrastructure SIP Guidance at p. 1–2.[2] Infrastructure SIP submissions are not required to include enforceable emissions limitations and schedules for compliance with the NAAQS, as suggested by the Commenter. Louisiana appropriately demonstrated that it has the ''structural requirements'' to implement the NAAQS for the pollutants addressed in this rule in its infrastructure SIP submission.

2. The Legislative History of the CAA

Comment 2: Sierra Club cites two excerpts from the legislative history of the 1970 CAA claiming they support an interpretation that SIP revisions under CAA Section 110 must include emissions limitations sufficient to show maintenance of the NAAQS in all areas of Louisiana. Sierra Club also contends that the legislative history of the CAA supports the interpretation that i-SIPs under section 110(a)(2) must include enforceable emission limitations, citing the Senate Committee Report and the subsequent Senate Conference Report accompanying the 1970 CAA.

Response 2: As noted above, the CAA, as enacted in 1970, including its legislative history, cannot be read in isolation from the later amendments that refined that structure and deleted relevant language from CAA Section 110 concerning demonstrating attainment. *See also,* 79 FR at 17043, 80 FR 11557, 79 FR 62022, 80 FR 46494 (responding to comments on various other i-SIPs). In any event, the two excerpts of legislative history the Sierra Club cites merely provide that states should include enforceable emission limits in their SIPs and they do not mention or otherwise address whether states are required to impose additional emission limitations or control measures as part of the i-SIP submission, as opposed to requirements for other types of SIP submissions such as attainment plans required under section 110(a)(2)(I). The proposed rule and the Technical Support Document (TSD) for it explain why the Louisiana SIP includes sufficient enforceable emissions limitations for the purposes of the infrastructure SIP submission.

3. Case Law

Comment 3: Sierra Club also cites to several cases which have interpreted various parts of the CAA. Sierra Club claims these cases support their contention that section 110(a)(2)(A) requires i-SIPs submissions to contain enforceable emissions limits in order to prevent exceedances of the NAAQS in areas not designated nonattainment. Sierra Club first cites to language in *Train* v. *NRDC,* 421 U.S. 60, 78 (1975), addressing the requirement for ''emission limitations'' and stating that emission limitations ''are specific rules to which operators of pollution sources are subject, and which, if enforced, should result in ambient air which meet the national standards.'' Sierra Club also cites to *Pennsylvania Dept. of Envtl. Resources* v. *EPA,* 932 F.2d 269, 272 (3d Cir. 1991) for the proposition that the CAA directs EPA to withhold approval of a SIP where it does not ensure maintenance of the NAAQS, and to *Mision Industrial, Inc.* v. *EPA,* 547 F.2d 123, 129 (1st Cir. 1976), which quoted section 110(a)(2)(B) of the CAA of 1970. The commenter states that the 1990 Amendments do not alter how courts have interpreted the requirements of section 110, quoting *Alaska Dept. of Envtl. Conservation* v. *EPA,* 540 U.S. 461, 470 (2004) which in turn quoted section 110(a)(2)(A) of the CAA and also stated that ''SIPs must include certain measures Congress specified'' to ensure attainment of the NAAQS. The Commenter also quotes several additional opinions in this vein. *Mont. Sulphur & Chem. Co.* v. *EPA,* 666 F.3d 1174, 1180 (9th Cir. 2012) (''The Clean Air Act directs states to develop implementation plans—SIPs—that 'assure' attainment and maintenance of [NAAQS] through enforceable emissions limitations''); *Hall* v. *EPA* 273 F.3d 1146, 1153 (9th Cir. 2001) (''Each State must submit a [SIP] that specif[ies] the manner in which [NAAQS] will be achieved and maintained within each air quality control region in the State''); *Conn. Fund for Env't, Inc.* v. *EPA,* 696 F.2d 169, 172 (D.C. Cir. 1982) (CAA requires SIPs to contain ''measures necessary to ensure attainment and maintenance of NAAQS''). Finally, Sierra Club cites *Mich. Dept. of Envtl. Quality* v. *Browner,* 230 F.3d 181 (6th Cir. 2000) for the proposition that EPA may not approve a SIP revision that does not demonstrate how the rules would not interfere with attainment and maintenance of the NAAQS.

Response 3: None of the cases Sierra Club cites support its contention that section 110(a)(2)(A) requires i-SIP submissions to include detailed plans providing for attainment *and* maintenance of the NAAQS in all areas of the state, nor do they shed light on the present day requirements of section 110(a)(2)(A). With the exception of *Train,* none of the cases the Commenter cites specifically concerned the interpretation of CAA section 110(a)(2)(A) (or section 110(a)(2)(B) of the pre-1990 Act). Rather, the courts reference section 110(a)(2)(A) (or section 110(a)(2)(B) of the pre-1990 CAA) in the background sections of decisions in the context of a challenge to an EPA action on revisions to a SIP that were required and approved as meeting other provisions of the CAA or in the context of an enforcement action.

In *Train,* the Court was addressing a state revision to an attainment plan submission made pursuant to section 110 of the CAA, the sole statutory provision at that time addressing such submissions. The issue in that case concerned whether changes to requirements that would occur before attainment was required were variances that should be addressed pursuant to the provision governing SIP revisions or were ''postponements'' that must be addressed under section 110(f) of the CAA of 1970, which contained prescriptive criteria. The Court

[1] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act sections 110(a)(1) and 110(a)(2),'' Memorandum from Stephen D. Page, September 13, 2013.

[2] Thus, EPA disagrees with Sierra Club's general assertion that the main objective of infrastructure SIPs is to ensure all areas of the country meet the NAAQS, as the infrastructure SIP process is the opportunity to review the structural requirements of a state's air program. EPA, however, does agree with Sierra Club that the NAAQS are the foundation upon which emission limitations are set, as explained in responses to subsequent comments, these emission limitations are generally set in the attainment planning process envisioned by part D of title I of the CAA, including, but not limited to, CAA sections 172 and 191–192.

concluded that EPA reasonably interpreted section 110(f) not to restrict a state's choice of the mix of control measures needed to attain the NAAQS, so long as the state met other applicable requirements of the CAA, and that revisions to SIPs that would not impact attainment of the NAAQS by the attainment date were not subject to the limits of section 110(f). Thus the issue was not whether the specific SIP at issue needs to provide for attainment or whether emissions limits are needed as part of the SIP; rather the issue was which statutory provision governed when the state wanted to revise the emission limits in its SIP if such revision would not impact attainment or maintenance of the NAAQS.

Pennsylvania Dept. of Envtl. Resources was also decided based on the pre-1990 provision of the CAA. At issue was whether EPA properly rejected a revision to an approved SIP where the inventories relied on by the state for the updated submission had gaps. The Court quoted section 110(a)(2)(B) of the pre-1990 CAA in support of EPA's disapproval, but did not provide any interpretation of that provision. This decision did not address the question at issue in this action, *i.e.,* what a state must include in an i-SIP submission for the purposes of section 110(a)(2)(A).Yet, even if the Court had interpreted that provision, EPA notes that it was modified by Congress in 1990; thus, this decision has little bearing on the present issue here.

At issue in *Mision Industrial,* was the definition of ''emissions limitation'', not whether section 110 requires the State to demonstrate how all areas of the State will attain and maintain the NAAQS as part of the State's i-SIP submission. The language from the opinion the Commenter quotes does not interpret but rather merely describes section 110(a)(2)(A). Sierra Club does not raise any concerns about whether the measures relied on by the State in the i-SIP submission are ''emissions limitations'' within the definition provided by the Act and the decision in this case has no bearing here.[3]

In *Mont. Sulphur & Chem. Co.,* 666 F.3d 1174, the Court was reviewing a federal implementation plan (FIP) that EPA promulgated after a long history of the State failing to submit an adequate SIP in response to EPA's finding under section 110(k)(5) that the previously approved SIP was substantially inadequate to attain or maintain the NAAQS, which triggered the State's duty to submit a new SIP detailing how it would remedy that deficiency and the measures that would be put in place to attain the NAAQS. The Court cited generally to sections 107 and 110(a)(2)(A) of the CAA for the proposition that SIPs should assure attainment and maintenance of NAAQS through emission limitations, but this language was not part of the Court's holding in the case. The holding in *Mont. Sulphur* focused on whether EPA's finding of SIP inadequacy, disapproval of the State's responsive attainment demonstration, and adoption of a remedial FIP were lawful.

The Commenter suggests that *Alaska Dept. of Envtl. Conservation,* 540 U.S. 461, stands for the proposition that the 1990 CAA Amendments do not alter how courts interpret section 110. This claim is inaccurate. Rather, the Court quoted section 110(a)(2)(A), which, as noted previously, differs from the pre-1990 version of that provision and the court makes no mention of the changed language. Furthermore, Sierra Club also quotes the Court's statement that ''SIPs must include certain measures Congress specified,'' but that statement specifically referenced the requirement in section 110(a)(2)(C), which requires an enforcement program and a program for the regulation of the modification and construction of any stationary sources. Notably, at issue in that case was the State's ''new source'' permitting program, not what is required for an i-SIP submission for purposes of CAA section 110(a)(2)(A).

Two of the cases Sierra Club cites, *Mich. Dept. of Envtl. Quality,* 230 F.3d 181, 183, 185 and *Hall,* 273 F.3d 1146, 1153 interpret CAA section 110(l), the provision governing ''revisions'' to plans, and not the initial plan submission requirement under section 110(a)(2) for a new or revised NAAQS, such as the i-SIP submissions at issue in this instance. Neither case, however, addressed the question at issue here, *i.e.,* what states are required to address for purposes of an infrastructure SIP submission for purposes of section 110(a)(2)(A).

Finally, in *Conn. Fund for Env't, Inc.* v. *EPA,* the D.C. Circuit was reviewing EPA action on a control measure SIP provision which adjusted the percent of sulfur permissible in fuel oil. 696 F.2d 169 (D.C. Cir. 1982). The D.C. Circuit focused on whether EPA needed to evaluate effects of the SIP revision on one pollutant or effects of changes on all possible pollutants; therefore, the D.C. Circuit did not address required measures for i-SIPs and nothing in the opinion addressed whether i-SIP submissions need to contain measures to ensure attainment and maintenance of the NAAQS.

EPA's position is that none of these court cases addressed required measures for i-SIP submission and therefore nothing in the opinions addressed whether the state's i-SIP submission must contain measures to ensure attainment and maintenance of the NAAQS.

4. EPA Regulations, Such as 40 CFR 51.112(a)

Comment 4: Sierra Club cites to 40 CFR 51.112(a), which provides that ''[e]ach plan must demonstrate that the measures, rules and regulations contained in it are adequate to provide for the timely attainment and maintenance of the [NAAQS].'' Sierra Club asserts that this regulation requires all SIPs to include emissions limits necessary to ensure attainment of the NAAQS. Sierra Club states that ''[a]lthough these regulations were developed before the Clean Air Act separated i-SIPs from nonattainment SIPs—a process that began with the 1977 amendments and was completed by the 1990 amendments—the regulations apply to [i]-SIPs.'' Sierra Club relies on a statement in the preamble to the 1986 action restructuring and consolidating provisions in part 51, in which EPA stated that ''[i]t is beyond the scope of th[is] rulemaking to address the provisions of Part D of the Act . . .'' 51 FR 40656, 40656 (November 7, 1986).

Response 4: Sierra Club's reliance on 40 CFR 51.112 to support its argument that i-SIPs must contain emission limits ''adequate to prohibit NAAQS exceedances'' and adequate or sufficient to ensure the maintenance of the NAAQS is incorrect. As an initial matter, EPA notes and the Sierra Club recognizes this regulatory provision was initially promulgated and ''restructured and consolidated'' prior to the CAA Amendments of 1990, in which Congress removed all references to ''attainment'' in section 110(a)(2)(A). And, it is clear that 40 CFR 51.112 directly applies to state SIP submissions that are specifically required to attain the NAAQS in nonattainment areas. These regulatory requirements apply when states are developing ''control strategy'' SIPs under other provisions of the CAA, such as attainment plans required for various NAAQS in Part D and maintenance plans required in section 175A. Sierra Club's suggestion that these provisions must apply to section 110 i-SIPs because in the preamble to EPA's action ''restructuring

[3] While Sierra Club does contend that the State shouldn't be allowed to rely on emission reductions that were developed for the prior SO_2 standards (which we address herein), it does not claim that any of the measures are not ''emissions limitations'' within the definition of the CAA.

and consolidating'' provisions in part 51, we stated that the new attainment demonstration provisions in the 1977 Amendments to the CAA were ''beyond the scope'' of the rulemaking.[4]

Although EPA was explicit that it was not establishing requirements interpreting the provisions of new ''Part D'' of the CAA, it is clear that the regulations being restructured and consolidated were intended to address control strategy plans. In the preamble, EPA clearly stated that 40 CFR 51.112 was replacing 40 CFR 51.13 (''Control strategy: SO_X and PM (portion)''), 51.14 (''Control strategy: CO, HC, O_X and NO_2 (portion)''), 51.80 (''Demonstration of attainment: Pb (portion)''), and 51.82 (''Air quality data (portion)''). *Id.* at 40660. Thus, the present-day 40 CFR 51.112 contains consolidated provisions that are focused on control strategy SIPs, and the i-SIP is not such a plan.

5. EPA Interpretations in Other Rulemakings

Comment 5: Sierra Club also references two prior EPA rulemaking actions where EPA disapproved or proposed to disapprove SIPs and claimed these were actions in which EPA relied on section 110(a)(2)(A) and 40 CFR 51.112 to reject i-SIPs. The Sierra Club first points to a 2006 partial approval and partial disapproval of revisions to Missouri's existing plan addressing the SO_2 NAAQS. In that action, EPA cited section 110(a)(2)(A) as the basis disapproving a revision to the state plan on the basis that the State failed to demonstrate the SIP was sufficient to ensure maintenance of the SO_2 NAAQS after revision of an emission limit. EPA also cited to 40 CFR 51.112, stating it requires that a plan demonstrates the rules in a SIP are adequate to attain the NAAQS. Second, Sierra Club cites a 2013 disapproval of a revision to the SO_2 SIP for Indiana, where the revision removed an emission limit that applied to a specific emissions source at a facility in the State. *See,* 78 FR 17157, 17158 (March 20, 2013) (proposed rule on Indiana SO_2 SIP) and 78 FR 78720, 78721 (December 27, 2013) (final rule on Indiana SO_2 SIP). In its proposed disapproval, EPA relied on 40 CFR 51.112(a) in proposing to reject the revision, stating that the State had not demonstrated that the emission limit was ''redundant, unnecessary, or that its removal would not result in or allow an increase in actual SO_2 emissions.'' EPA further stated in that proposed disapproval that the State had not demonstrated that removal of the limit would not ''affect the validity of the emission rates used in the existing attainment demonstration.''

Response 5: EPA does not agree that the two prior actions referenced by Sierra Club establish how EPA reviews i-SIP submissions. It is clear from both the final Missouri rule and the proposed and final Indiana rule that EPA was not reviewing initial i-SIP submissions under section 110 of the CAA, but rather reviewing revisions that would make an *already approved* SIP designed to demonstrate attainment of the NAAQS less stringent. EPA's partial approval and partial disapproval of revisions to restrictions on emissions of sulfur compounds for the Missouri SIP in 71 FR 12623 addressed a control strategy SIP submission, and not an i-SIP submission. The Indiana action provides even less support for the Sierra Club's position since the EPA was reviewing a completely different requirement than that listed in CAA section 110(a)(2)(A). Rather, in that case, the State had an approved SO_2 attainment plan which already included a specific emissions limitation for sources and was seeking to remove provisions from the SIP that it relied on as part of the modeled attainment demonstration. *See,* 78 FR 78720. EPA proposed that the State had failed to demonstrate under section 110(l) of the CAA that the SIP revision would not result in increased SO_2 emissions and thus would interfere with attainment of the NAAQS. *See,* 78 FR 17157. Nothing in that proposed or final rulemaking addresses the necessary content of the initial i-SIP submission for a new or revised NAAQS. Rather, it is simply applying the clear statutory requirement that a state must demonstrate why a revision to an approved attainment plan will not interfere with attainment of the NAAQS.

As discussed in detail in the TSD and proposed rule, EPA finds the Louisiana SIP meets the appropriate and relevant structural requirements of section 110(a)(2) of the CAA, that it will aid in attaining and/or maintaining the NAAQS, and that the State demonstrated that it has the necessary tools to implement and enforce the NAAQS.

Comments on Louisiana SIP Emission Limits

Comment 6: Citing section 110(a)(2)(A) of the CAA, Sierra Club contends that EPA may not approve Louisiana's proposed i-SIP because it does not include enforceable NAAQS, including a 1-hour SO_2 emission limit, for sources that they claim are currently allowed to cause ''NAAQS exceedances.'' Sierra Club also asserts the proposed i-SIP fails to include other required measures to ensure attainment and maintenance of the NAAQS in areas not designated nonattainment as Sierra Club claims is required by section 110(a)(2)(A). Sierra Club argues that an i-SIP must ensure, through state-wide regulations or source specific requirements, proper mass limitations and short term averaging on specific large sources of pollutants such as power plants. Sierra Club states that emission limits are especially important for meeting the 1-hour SO_2 NAAQS because SO_2 impacts are strongly source-oriented. Sierra Club states coal-fired electric generating units (EGUs) are large contributors to SO_2 emissions, but contends Louisiana did not demonstrate that emissions allowed by the proposed i-SIP from such large sources of SO_2 will ensure compliance with the 2010 1-hour SO_2 NAAQS. They stated that the proposed i-SIP would allow major sources to continue operating with present emission limits. Sierra Club then refers to air dispersion modeling it conducted for two coal-fired EGUs in Louisiana, Cleco Power's Dolet Hills Power Station and Entergy's Big Cajun II Generating Station. Further, Sierra Club claims that the results of the air dispersion modeling it conducted employing EPA's AERMOD program for modeling used the plants' allowable and maximum emissions and showed the plants could cause exceedances of the 2010 SO_2 NAAQS with either allowable or maximum emissions.[5] Based on the modeling, Sierra Club claims the Louisiana's SO_2 i-SIP submittal authorizes the two EGUs to cause exceedances of the NAAQS with allowable and maximum emission rates and therefore the i-SIP fails to include adequate enforceable emission limitations or other required measures for sources of SO_2 sufficient to ensure attainment and maintenance of the 2010 SO_2 NAAQS. Sierra Club therefore asserts EPA must disapprove Louisiana's proposed SIP revision. In addition, Sierra Club asserts ''EPA must impose additional emission limits on the plants that ensure attainment and

[4] It is important to note, however, that EPA's action in 1986 was not to establish new substantive planning requirements, but rather was meant merely to consolidate and restructure provisions that had previously been promulgated. EPA noted that it had already issued guidance addressing the new ''Part D'' nonattainment planning obligations. Also, as to maintenance regulations, EPA expressly stated that it was not making any revisions other than to re-number those provisions. 51 FR at 40657.

[5] Sierra Club asserts its modeling followed protocols pursuant to 40 CFR part 50, Appendix W and EPA's 2011 Guideline on implementing the one-hour SO_2 NAAQS.

maintenance of the NAAQS at all times.''

Response 6: As explained in previous responses above, section 110(a)(2)(A) of the CAA requires states to submit i-SIPs that reflect the first step in their planning for attainment and maintenance of a new or revised NAAQS. These i-SIP revisions should contain a demonstration that the state has the available tools and authority to develop and implement plans to attain and maintain the NAAQS and show that the SIP has enforceable control measures. In light of the structure of the CAA, EPA's long-standing position regarding i-SIPs is that they are general planning SIPs to ensure that the state has adequate resources and authority to implement a NAAQS in general throughout the state. These i-SIP submissions are not detailed attainment and maintenance plans for each individual area of the state. States may rely on measures already in place to address the pollutant at issue or any new control measures that *the state* may choose to submit.

As stated in response to a previous comment, EPA asserts that section 110 of the CAA is only one provision that is part of the multi-faceted structure governing implementation of the NAAQS program under the CAA, as amended in 1990, and it must be read in the context of not only that structure, but also of the historical evolution of that structure. In light of the revisions to CAA section 110 since 1970 and the later-promulgated and more specific planning requirements of the CAA, section 110(a)(2)(A) does not require that an i-SIP contain enforceable emissions limits that will aid in attaining and/or maintaining the NAAQS. The i-SIPs required by CAA section 110(a) are not the appropriate place to require emission limits demonstrating future attainment with a NAAQS. Part D of title I of the CAA contains numerous requirements for the NAAQS attainment planning process. These requirements include enforceable emissions limitations, and such other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for the attainment of the NAAQS. States have up to three years from the date of a nonattainment designation to submit a SIP meeting Part D's requirements. Louisiana's submittal was submitted to comply with the requirements outlined in CAA section 110(a), not Part D. As discussed above, the state may rely on measures already in place to address the pollutant at issue or any new control measures that the state may choose to submit. Finally, as EPA stated in the Infrastructure SIP Guidance, which specifically provides guidance to states in addressing the NAAQS, ''[t]he conceptual purpose of an i-SIP submission is to assure that the air agency's SIP contains the necessary structural requirements for the new or revised NAAQS, whether by establishing that the SIP already contains the necessary provisions, by making a substantive SIP revision to update the SIP, or both.'' 2013 Infrastructure SIP Guidance at p. 2.

On April 12, 2012, EPA explained its expectations regarding the 2010 SO_2 NAAQS via letters to each of the states. EPA communicated in the April 2012 letters that all states were expected to submit SIPs meeting the ''infrastructure'' SIP requirements under section 110(a)(2) of the CAA by June 2013. At the time, EPA was undertaking a stakeholder outreach process to continue to develop possible approaches for determining attainment status under the SO_2 NAAQS and implementing this NAAQS. EPA was abundantly clear in the April 2012 letters that EPA did not expect states to submit substantive attainment demonstrations or modeling demonstrations showing attainment for areas not designated nonattainment in i-SIP submission due in June 2013. Although EPA had previously suggested in its 2010 SO_2 NAAQS preamble and in prior draft implementation guidance in 2011 that states should, in the unique SO_2 context, use the section 110(a) SIP process as the vehicle for demonstrating attainment of the NAAQS, this approach was never adopted as a binding requirement and was subsequently discarded in the April 2012 letters to states. The April 2012 letters recommended states focus i-SIPs due in June 2013, such as Louisiana's SO_2 i-SIP submission, on traditional ''infrastructure elements'' in section 110(a)(1) and (2), rather than on modeling demonstrations for future attainment for areas not designated as nonattainment. In February of 2016, EPA issued non-binding guidance for states to use in conducting, if they choose, additional analysis to support designations for the 2010 1-hour SO_2 NAAQS. *SO_2 NAAQS Designations Modeling Technical Assistance Document,* EPA Office of Air and Radiation and Office of Air Quality Planning and Standards, February 2016, available at *https://www.epa.gov/so2-pollution/technical-assistance-documents-implementing-2010-sulfur-dioxide-standard.*

Therefore, EPA asserts that SIP revisions for SO_2 nonattainment areas including measures and modeling demonstrating attainment are due by the dates statutorily prescribed under subpart 5 under part D of Title I of CAA. Those submissions are due no later than 18 months after an area is designed nonattainment for SO_2, under CAA section 191(a). Thus, the CAA directs states to submit these SIP requirements for nonattainment areas on a separate schedule from the ''structural requirements'' of 110(a)(2) which are due within three years of adoption or revision of a NAAQS. The i-SIP submission requirement does not move up the date for any required submission of a CAA Title I part D plan for areas designated nonattainment for the new NAAQS. Thus, elements relating to demonstrating attainment for areas not attaining the NAAQS are not required for i-SIP submissions, and the CAA does not provide explicit requirements for demonstrating attainment for areas that have not yet been designated regarding attainment with a particular NAAQS.

The proper inquiry at this juncture is whether Louisiana has met the basic structural SIP requirements applicable at the point in time that the SIP was submitted. Emissions limitations and other control measures needed to attain the NAAQS in areas designated nonattainment for that NAAQS are due on a different schedule from the section 110 infrastructure elements. A state, like Louisiana, may choose to reference pre-existing SIP emission limits approved by EPA as meeting CAA Title I of part D plans for previous NAAQS in an i-SIP submission for purposes of CAA section 110(a)(2)(A).

The requirements for emission reduction measures for an area designated nonattainment for the 2010 primary SO_2 NAAQS are in sections 172 and 191–192 of the CAA, and therefore, the appropriate avenue for implementing requirements for necessary emission limitations for demonstrating attainment with the 2010 SO_2 NAAQS is through the attainment planning process contemplated by those sections of the CAA. LDEQ is required to bring St. Bernard Parish into compliance with the 1-hour standard as expeditiously as practicable, but no later than, October 4, 2018. The appropriate time for examining necessity of emission limits on specific sources is within the attainment planning process. When the St. Bernard Parish SO_2 attainment demonstration is submitted by the State, EPA will take action on it in a separate rulemaking. In separate future actions, EPA intends to address the designations for all other areas for which EPA has yet to issue designations. *See, e.g.,* 79 FR 27446

(May 13, 2014) (proposing process and timetables by which state air agencies would characterize air quality around SO_2 sources through ambient monitoring and/or air quality modeling techniques and submit such data to the EPA). As previously stated, EPA's position is that the submitted i-SIPs should be evaluated on whether Louisiana has met the basic structural SIP requirements applicable at the point in time that the SIP was submitted. Utilizing the i-SIP process to require the substantive elements contained elsewhere in the CAA, as detailed above, would be disruptive and premature absent exceptional circumstances and would interfere with a state's planning process. *See, In the Matter of EME Homer City Generation LP and First Energy Generation Corp.,* Order on Petitions Numbers III–2012–06, III–2012–07, and III–2013–01 (July 30, 2014) (hereafter, *Homer City/ Mansfield Order*) at 10–19 (finding Pennsylvania SIP did not require imposition of SO_2 emission limits on sources independent of the part D nonattainment planning process contemplated by the CAA). The history of the CAA, and intent of Congress for the CAA as described above, demonstrate clearly that it is within the section 172 and general part D nonattainment planning process that Louisiana must include additional SO_2 emission limits on sources in order to demonstrate future attainment, where needed, for any areas in Louisiana or other states that may be designated nonattainment now or in the future, in order to attain the 2010 1-hour SO_2 or other NAAQS.

Sierra Club's reliance on 40 CFR 51.112 to support its argument that i-SIPs must contain emission limits adequate to provide for timely attainment and maintenance of the standard is also unsupported. As explained above, EPA notes this regulatory provision clearly applies to plans specifically designed to attain the NAAQS and not to i-SIPs which show the states have in place structural requirements necessary to implement the NAAQS. Therefore, EPA finds 40 CFR 51.112 inapplicable to its analysis of Louisiana's i-SIP submission.

Regarding the air dispersion modeling conducted by Sierra Club pursuant to AERMOD for the coal-fired EGUs, including Cleco Power's Dolet Hills Power Station and Entergy's Big Cajun II Generating Station, EPA is not in this action making a determination regarding the air quality status in the area where these EGUs are located, and is not evaluating whether emissions applicable to these EGUs are adequate to attain and maintain the NAAQS. Consequently, EPA does not find the modeling information relevant for review of an infrastructure SIP for purposes of section 110(a)(2)(A). When additional areas in Louisiana are designated under the 2010 1-hour SO_2 NAAQS, and if any additional areas in Louisiana are designated nonattainment in the future, any potential future modeling submitted by the State with designations or attainment demonstrations would need to account for any new emissions limitations Louisiana develops to support such designation or demonstration. While EPA has extensively discussed the use of modeling for attainment demonstration purposes and for designations, EPA has recommended that such modeling was not needed for the SO_2 infrastructure SIPs for the 2010 1-hour SO_2 NAAQS for purposes of section 110(a)(2)(A), which are not actions in which EPA makes determinations regarding current air quality status.[6] *See* April 12, 2012, letters to states and 2012 Draft White Paper.

In conclusion, EPA disagrees with Sierra Club's assertions that EPA must disapprove Louisiana's i-SIP submission because it does not establish specific enforceable NAAQS emission limits, and specifically enforceable emission limits for SO_2, either on coal-fired EGUs or other large SO_2 sources, in order to demonstrate attainment and maintenance with the NAAQS.

Comment 7: Sierra Club asserts that modeling is the appropriate tool for evaluating adequacy of i-SIPs and ensuring attainment and maintenance of the 2010 SO_2 NAAQS. The Commenter refers to EPA's historic use of air dispersion modeling for attainment designations as well as ''SIP revisions.'' The Commenter states that in prior EPA statements the Agency has said it used modeling for designations and attainment demonstrations, including statements in the 2010 SO_2 NAAQS preamble, EPA's 2012 Draft White Paper for Discussion on Implementing the 2010 SO_2 NAAQS, and a 1994 SO_2 Guideline Document, as modeling could better address the source-specific impacts of SO_2 emissions and historic challenges from monitoring SO_2 emissions.

The Commenter discusses statements made by EPA staff regarding (1) the use of modeling and monitoring in setting emission limitations, (2) determining ambient concentrations as a result of a source's emissions, (3) discussing performance of AERMOD as a model, including if AERMOD is capable of predicting whether the NAAQS is attained, and (4) whether individual sources contribute to SO_2 NAAQS violations. Sierra Club cites to EPA's history of employing air dispersion modeling for increment compliance verifications in the permitting process for the Prevention of Significant Deterioration (PSD) program which is required in part C of title I of the CAA.

Sierra Club asserts EPA's use of air dispersion modeling was upheld in *GenOn REMA, LLC* v. *EPA,* 722 F.3d 513 (3rd Cir. 2013) where an EGU challenged EPA's use of CAA section 126 to impose SO_2 emission limits on a source due to cross-state impacts. The Commenter claims the Third Circuit in *GenOn REMA* upheld EPA's actions after examining the record which included EPA's air dispersion modeling of the one source as well as other data.

The Commenter cites to *Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto Ins. Co.,* 463 U.S. 29, 43 (1983) and *NRDC* v. *EPA,* 571 F.3d 1245, 1254 (D.C. Cir. 2009) for the general proposition that it would be arbitrary and capricious for an agency to ignore an aspect of an issue placed before it and that an agency must consider information presented during notice-and-comment rulemaking.

Finally, Sierra Club claims that Louisiana's proposed i-SIP lacks emission limitations informed by air dispersion modeling and therefore fails to ensure Louisiana will achieve and maintain the SO_2 NAAQS. Sierra Club claims EPA must require adequate, 1-hour SO_2 emission limits in the i-SIP that show no exceedances of NAAQS when modeled.

Response 7: EPA agrees with Sierra Club that air dispersion modeling, including the use of AERMOD, can be an important tool for SO_2 designations under CAA section 107, and also as part of attainment planning under CAA sections 172 and 191–192. EPA agrees that prior EPA statements, EPA guidance, and case law support the use of air dispersion modeling in the SO_2 designations process and attainment demonstration SIP process, as well as in analyses of whether existing approved SIPs remain adequate to show attainment and maintenance of the SO_2 NAAQS. However, EPA disagrees with the Commenter that EPA must

[6] *See,* for example, EPA recently discussed modeling for characterizing air quality in the Agency's August 21, 2015, final rule at 80 FR 51052 and for nonattainment planning in the April 23, 2014, *Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions,* Stephen D. Page, Director, EPA's Office of Air Quality Planning and Standards, to Regional Air Division Directors Regions 1–10, April 23, 2014, available at *https://www.epa.gov/sites/production/files/2016-06/documents/20140423guidance_nonattainment_sip.pdf.*

disapprove the Louisiana i-SIP for its alleged failure to include source-specific SO_2 emission limits that show no exceedances of the NAAQS when modeled.

As discussed above and in the 2013 Infrastructure SIP Guidance, the conceptual purpose of an i-SIP submission is to assure that the air agency's SIP contains the necessary structural requirements for the new or revised NAAQS and that the i-SIP submission process provides an opportunity to review the basic structural requirements of the Agency's air quality management program in light of the new or revised NAAQS. *See,* Infrastructure SIP Guidance at p. 2. The attainment planning process detailed in part D of the CAA, including sections 172 and 191–192, is the appropriate place for the state to evaluate measures needed to bring SO_2 nonattainment areas into attainment with the 2010 SO_2 NAAQS and to impose additional emission limitations such as SO_2 emission limits on specific sources.

EPA had initially recommended that states submit substantive attainment demonstration SIPs based on air quality modeling in the final 2010 SO_2 NAAQS preamble (75 FR 35520) and in subsequent draft guidance issued in September 2011 for the section 110(a) SIPs due in June 2013 in order to show how areas expected to be designated as unclassifiable would attain and maintain the NAAQS. These initial statements in the preamble and 2011 draft guidance were based on EPA's expectation at the time; that by June 2012, most areas would initially be designated as unclassifiable due to limitations in the scope of the ambient monitoring network and the short time available before which states could conduct modeling to support designations recommendations in 2011. However, after conducting extensive stakeholder outreach and receiving comments from the states regarding these initial statements and the timeline for implementing the NAAQS, EPA subsequently stated in the April 12, 2012 letters and in the 2012 Draft White Paper that EPA was clarifying its implementation position and was no longer requiring such attainment demonstrations supported by air dispersion modeling for unclassifiable areas (which had not yet been designated) to be included in the June 2013 i-SIPs. EPA then reaffirmed this position in the February 6, 2013 memorandum, ''Next Steps for Area Designations and Implementation of the Sulfur Dioxide National Ambient Air Quality Standard.'' As previously mentioned, EPA had stated in the preamble to the NAAQS and in the prior 2011 draft guidance that EPA intended to develop and seek public comment on guidance for modeling and development of SO_2 SIPs for sections 110, 172 and 191–192 of the CAA. After receiving such further comment, EPA has now issued guidance for the SO_2 nonattainment area SIPs due pursuant to sections 172 and 191–192 and proposed a process for further characterization of areas with larger SO_2 sources, which could include use of air dispersion modeling. *See,* April 23, 2014 *Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions* and 79 FR 27446 (proposing process and timetables for gathering additional information on impacts from larger SO_2 sources informed through ambient monitoring and/or air quality modeling). EPA issued non-binding guidance for states to use in conducting, if they choose, additional analysis to support designations for the 2010 1-hour SO_2 NAAQS. *SO_2 NAAQS Designations Modeling Technical Assistance Document,* EPA Office of Air and Radiation and Office of Air Quality Planning and Standards, February 2016, available at *https://www.epa.gov/so2-pollution/technical-assistance-documents-implementing-2010-sulfur-dioxide-standard.*

While EPA guidance for SO_2 attainment SIPs and the proposed process for further characterizing SO_2 emissions from larger sources both discuss the use of air dispersion modeling, EPA's 2013 Infrastructure SIP Guidance did not suggest that states use air dispersion modeling to inform emission limitations for section 110(a)(2)(A) to ensure no exceedances of the NAAQS when sources are modeled, nor does the CAA or Code of Federal Regulations require that they do. Therefore, as discussed previously, the Louisiana i-SIP submittal contains the structural requirements to address elements in section 110(a)(2) as discussed in detail in the TSD accompanying the proposed approval. I–SIPs are general planning SIPs that ensure that a state has adequate resources and authority to implement a new or revised NAAQS. I–SIP submissions are not intended to act or fulfill the obligations of a detailed attainment and/or maintenance plan for each individual area of the state that is not attaining the NAAQS. While i-SIPs must address modeling authorities in general for section 110(a)(2)(K), this section requires i-SIPs to provide the state's authority for air quality modeling and for submission of modeling data to EPA, not specific air dispersion modeling. In the TSD for this rulemaking action, EPA provided a detailed explanation of Louisiana's ability and authority to conduct air quality modeling when required and its authority to submit modeling data to EPA.

EPA finds Sierra Club's discussion of case law, guidance, and EPA staff statements regarding advantages of AERMOD as an air dispersion model to be irrelevant to the analysis of Louisiana's i-SIP as this is not an attainment SIP required to demonstrate attainment of the 2010 SO_2 NAAQS pursuant to sections 172 or 192. In addition, Sierra Club's comments relating to EPA's use of AERMOD or modeling in general in SO_2 designations pursuant to section 107 are likewise irrelevant as EPA's present approval of Louisiana's i-SIP is unrelated to the section 107 designations process nor is EPA's action on this i-SIP related to any nonattainment new source review (NNSR) or PSD permit program issue. As outlined in the August 23, 2010 clarification memo, ''Applicability of Appendix W Modeling Guidance for the 1-hour SO_2 National Ambient Air Quality Standard'' (U.S. EPA, 2010a), AERMOD is the preferred model for single source modeling to address the 2010 1-hour SO_2 NAAQS as part of the NNSR/PSD permit programs. Therefore, as attainment SIPs, designations, and NNSR/PSD actions are outside the scope of a required i-SIP submission for SO_2 NAAQS for section 110(a), EPA provides no further response to the Commenter's discussion of air dispersion modeling for these applications. If Sierra Club resubmits its SO_2 air dispersion modeling for the Louisiana's EGUs, or updated modeling information in the appropriate context, *e.g.,* for designations, attainment SIPs, major source permitting, EPA will address the resubmitted modeling or updated modeling in the appropriate future context.

The Commenter correctly noted that the Third Circuit upheld EPA's Section 126 Order imposing SO_2 emissions limitations on an EGU pursuant to CAA section 126. *GenOn REMA, LLC* v. *EPA,* 722 F.3d 513. Pursuant to CAA section 126, any state or political subdivision may petition EPA for a finding that any major source or group of stationary sources emits, or would emit, any air pollutant in violation of the prohibition of section 110(a)(2)(D)(i)(I) which relates to significant contributions to nonattainment or maintenance in another state. The Third Circuit upheld EPA's authority under CAA section 126 and found EPA's actions neither arbitrary nor capricious after reviewing

EPA's supporting docket which included air dispersion modeling as well as ambient air monitoring data showing violations of the NAAQS. The Sierra Club appears to have cited to this matter to demonstrate EPA's use of modeling for certain aspects of the CAA. EPA agrees with the Commenter regarding the appropriate role air dispersion modeling has for SO_2 NAAQS designations, attainment SIPs, and demonstrating significant contributions to interstate transport. However, EPA's approval of Louisiana's i-SIP submission is based on our determination that Louisiana has the required structural requirements pursuant to CAA section 110(a)(2) in accordance with our explanation of the intent for i-SIP submissions as discussed in the 2013 Infrastructure SIP Guidance. Therefore, while air dispersion modeling may be appropriate for consideration in certain circumstances, EPA does not find air dispersion modeling of the NAAQS to be a required element before approval of i-SIP submission for CAA section 110(a) or specifically for 110(a)(2)(A) of the Act. Thus, EPA disagrees with the Commenter that EPA must require additional emission limitations in this Louisiana or other i-SIPs informed by air dispersion modeling and demonstrating attainment and maintenance of the NAAQS.

In its comments, Sierra Club relies on *Motor Vehicle Mfrs. Ass'n* and *NRDC* v. *EPA* to support its comments that EPA *must* consider the Sierra Club's modeling data on the Dolet Hills Power Station and Big Cajun II Generating Station based on administrative law principles regarding consideration of comments provided during a rulemaking process. EPA asserts that it has considered the modeling as well as all the submitted comments of Sierra Club. However, as discussed in detail in the responses above, the i-SIPs required by CAA section 110(a) are not the appropriate place to require emission limits demonstrating future attainment with a NAAQS, and as such EPA is not explicitly considering the modeling results provided by the Sierra Club insofar as they support the contention that enforceable emissions limitations are a required part of an i-SIP submission.

While i-SIP submissions are not *required* to contain emission limits, as suggested by the Commenter, EPA does recognize that in the past, states have used i-SIP submittals as a 'vehicle' for incorporating regulatory revisions or source-specific emission limits into the state's plan. *See,* 78 FR 73442 (December 6, 2013) (approving regulations Maryland submitted for incorporation into the SIP along with the 2008 Ozone i-SIP to address ethics requirements for State Boards in sections 128 and 110(a)(2)(E)(ii)). While these SIP revisions are intended to help the state meet the requirements of section 110(a)(2), these ''ride-along'' SIP revisions are not intended to signify that all i-SIP submittals should have similar regulatory revisions or source-specific emission limits. Rather, the regulatory provisions and source-specific emission limits the state relies on when showing compliance with CAA section 110(a)(2) have likely already been incorporated into the state's SIP prior to each new i-SIP submission; in some cases this was done for entirely separate CAA requirements, such as attainment plans required under section 172, or for previous NAAQS.

Comment 8: Sierra Club asserts that EPA may not approve the Louisiana proposed i-SIP submission because it fails to include enforceable emission limitations with a 1-hour averaging time that applies at all times. The Sierra Club cite to CAA section 302(k) which requires emission limits to apply on a continuous basis. The Commenter claims EPA has stated that 1-hour averaging times are necessary for the 2010 SO_2 NAAQS citing to a February 3, 2011, EPA Region 7 letter to the Kansas Department of Health and Environment regarding the need for 1-hour SO_2 emission limits in a PSD permit, an EPA Environmental Hearing Board (EHB) decision rejecting use of a 3-hour averaging time for a SO_2 limit in a PSD permit, and EPA's disapproval of a Missouri SIP which relied on annual averaging for SO_2 emission rates.[7]

Sierra Club also contends that i-SIPs approved by EPA must include monitoring of SO_2 emission limits on a continuous basis using a continuous emission monitor system or systems (CEMS) and cites to section 110(a)(2)(F) which requires a SIP to establish a system to monitor emissions from stationary sources and to require submission of periodic emission reports. Sierra Club contends i-SIPs must require such SO_2 CEMS to monitor SO_2 sources regardless of whether sources have control technology installed to ensure limits are protective of the NAAQS. Thus, Sierra Club contends EPA must require enforceable emission limits, applicable at all times, with 1-hour averaging periods, monitored continuously with CEMS of large sources of SO_2 emissions, and therefore must disapprove Louisiana's i-SIP which Sierra Club claims fails to require emission limits with adequate averaging times.

Response 8: St. Bernard Parish was designated nonattainment effective October 4, 2013. LDEQ is required to bring St. Bernard Parish into compliance with the 1-hour standard as expeditiously as practicable, but no later than October 4, 2018. When the attainment demonstration SIP is submitted by the State, we will take action on it in a separate rulemaking action. The appropriate time for examining necessity of 1-hour SO_2 emission limits on specific sources is within the attainment planning SIP rulemaking process. As such, EPA disagrees that we must disapprove the proposed Louisiana i-SIP because the submittal does not contain enforceable SO_2 emission limitations with 1-hour averaging periods that apply at all times, along with requiring CEMS, as the State has addressed its SO_2 nonattainment designation in another more appropriate document pursuant to section 107 of the CAA.[8] As explained in detail in previous responses, the purpose of the i-SIP is to ensure that a state has the structural capability to attain and maintain the NAAQS and thus, additional SO_2 emission limitations demonstrating future attainment and maintenance of the 2010 NAAQS are not required for such i-SIPs.[9] Likewise, EPA need not address, for the purpose of approving Louisiana's i-SIP, whether CEMS or some other appropriate monitoring of SO_2 emissions is necessary to demonstrate compliance with emission limits in order to show future attainment of the 2010 SO_2 NAAQS as such SO_2 emission limits and an attainment demonstration are not a prerequisite to EPA's approval of

[7] Sierra Club cited to *In re: Mississippi Lime Co.,* PSDAPLPEAL 11–01, 2011 WL 3557194, at *26–27 (EPA Aug. 9, 2011) and 71 FR 12623, 12624 (March 13, 2006) (EPA disapproval of a control strategy SO_2 SIP).

[8] *See, http://www.deq.louisiana.gov/portal/Portals/0/AirQualityAssessment/Planning/SIP/SO2%20SIP%20with%20Appendices%20-%20Final.pdf.*

[9] For a discussion on emission averaging times for emissions limitations for SO_2 attainment SIPs, *see* the April 23, 2014 *Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions.* EPA explained that it is possible, in specific cases, for states to develop control strategies that account for variability in 1-hour emissions rates through emission limits with averaging times that are longer than 1-hour, using averaging times as long as 30-days, but still provide for attainment of the 2010 SO_2 NAAQS as long as the limits are of at least comparable stringency to a 1-hour limit at the critical emission value. EPA has not yet evaluated any specific submission of such a limit, and so is not at this time prepared to take final action to implement this concept. If and when a state submits an attainment demonstration that relies upon a limit with such a longer averaging time, EPA will evaluate it then.

this or most other i-SIP submissions.[10] Therefore, because EPA finds Louisiana's i-SIP submission approvable without the additional SO_2 emission limitations showing future attainment of the NAAQS, EPA finds the issues of appropriate averaging periods and monitoring requirements for such future limitations not relevant at this time.

Sierra Club has cited to prior EPA discussion on emission limitations required in PSD permits (from an EAB decision and EPA's letter to Kansas' permitting authority) pursuant to part C of the CAA, which is neither relevant nor applicable to section 110 i-SIPs. In addition, as previously discussed, EPA disapproval of the 2006 Missouri SIP was a disapproval relating to a control strategy SIP required pursuant to part D attainment planning and is likewise not relevant to the analysis of i-SIP requirements.

EPA has explained in the TSD supporting this rulemaking action how the Louisiana SIP meets requirements in section 110(a)(2)(F) related to monitoring. Thus, EPA finds Louisiana has the authority and responsibility to monitor air quality for the relevant NAAQS pollutants at appropriate locations and to submit data to EPA in a timely manner in accordance with 110(a)(2)(F) and the Infrastructure SIP Guidance.[11] *See,* Infrastructure SIP Guidance at p. 45–46.

Comment 9: The Commenter alleges the Louisiana SIP contains exemption provisions for periods of startup and ''operating adjustments'' as well as variance provisions for ''exceptional circumstances'' which would cause undue hardship. See LAC 33:III.1507, 917, and 1505 (2012), respectively. The Commenter notes that NAAQS must be enforced at all times and sources cannot be granted variances under any circumstances, even startup, shutdown and malfunction, and cites EPA's recent SIP Call to 39 states. See State Implementation Plans: Response to Petition for Rulemaking; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunctions; Final Rule, 80 FR 33840 (June 12, 2015). The Commenter claims that LDEQ must remove such provisions from the existing Louisiana SIP rules in order to properly comply with the infrastructure requirements for the 2010 SO_2 NAAQS.

Response 9: EPA disagrees with the Commenter that EPA is required to address all potential deficiencies that may exist in the Louisiana SIP in the context of evaluating an infrastructure SIP submission. In particular, an action on a state's infrastructure SIP submission is not necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP rules related to excess emissions from sources during periods of startup, shutdown, or malfunction. It is not reasonable to read the general requirements of CAA section 110(a)(1) and the listing of elements in CAA section 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and the EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. In addition, EPA notes that the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. For example, CAA section 110(k)(5) authorizes EPA to issue a SIP call whenever EPA determines a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA. As noted by the Commenter, EPA has recently issued a SIP call to Louisiana requiring the removal of the exemption provision in LAC 33:III.1507. EPA is working closely with LDEQ to addressing the substantial inadequacies EPA identified in specific Louisiana SIP rules. See 80 FR 33967 (June 12, 2015). LDEQ is required to submit a revised SIP addressing the substantial inadequacies by November 22, 2016. EPA emphasizes that by approving Louisiana's i-SIP submission, EPA is not approving or reapproving any potentially deficient provisions that exist in the current SIP that relate to excess emissions. Furthermore, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in CAA section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time.

Comment 10: The Sierra Club claims EPA must disapprove the proposed i-SIP for the 2008 ozone NAAQS for its failure to include enforceable measures on sources of volatile organic compounds (VOCs) and nitrogen oxides (NO_X) to ensure attainment and maintenance of the NAAQS in areas not designated nonattainment and to ensure compliance with section 110(a)(2)(A) for the 2008 and future ozone NAAQS. The commenter specifically mentions EGUs as well as the oil and gas production industry as sources needing additional controls as they are major sources of ozone precursors. The Sierra Club claims stringent emission limits must apply at all times to ensure all areas in Louisiana attain and maintain the ozone NAAQS. The Commenter claims the ozone precursors can be reduced cost-effectively through installation of selective catalytic reductions (''SCR'') technology at EGUs. The commenter claims that Louisiana's EGUs do not use SCRs adequately to prevent ozone exceedances.

In addition, the Commenter asserts that the Louisiana i-SIP must contain emission limits that include mass limitations and short term averaging periods on certain large sources of NO_X such as power plants. These emission limits must apply at all times, to ensure that all areas of Louisiana attain and maintain the 2008 t8-hour ozone NAAQS. The Commenter also contends that adding control devices and emission limits on EGUs are a ''cost effective option to reduce NO_X pollution and attain and maintain the 2008 ozone NAAQS.''

Finally, the Commenter states''[d]espite knowing that Louisiana is on the precipice of exceeding the ozone NAAQS, LDEQ is taking insufficient action to limit ozone concentrations and fails to demonstrate how it plans to address these significant ozone and ozone precursors. Consequently, EPA must disapprove the state's i-SIP.''

Response 10: EPA has addressed in detail in prior responses above the Commenter's general arguments that the statutory language, legislative history, case law, EPA regulations, and prior rulemaking actions by EPA mandate the interpretation it advocates—*i.e.,* that i-SIPs must ensure attainment and maintenance of the NAAQS. EPA's position is that the i-SIP submissions required by CAA section 110(a) are not the appropriate place to require emission limits demonstrating future attainment with a NAAQS as is explained more thoroughly in an above response. Moreover, the CAA recognizes and has provisions to address changes in air quality over time. These include provisions providing for redesignation in CAA section 107(d) and provisions in

[10] The appropriate time for application of monitoring requirements to demonstrate continuous compliance by specific sources is when such 1-hour emission limits are set for specific sources whether in permits issued by Louisiana pursuant to the SIP or in attainment SIPs submitted in the part D planning process.

[11] While monitoring pursuant to NSPS requirements in 40 CFR part 60 may not be sufficient for 1-hour SO_2 emission limits, Sierra Club's comment regarding NSPS monitoring provisions is not relevant at this time because EPA finds 1-hour SO_2 emission limits and associated monitoring and averaging periods are not required for our approval of Louisiana's i-SIP.

CAA section 110(k)(5) allowing EPA to call on the state to revise its SIP, as appropriate. Finally, EPA appreciates the Commenter's information regarding EGU NO_X control measures and reduction efficiencies as well as emissions limitations applicable to new or modified EGUs which were set during the PSD or NSR permit process. Additional NO_X regulations on emissions from the EGUs would likely reduce ozone levels further in one or more areas in Louisiana. Congress established the CAA such that each state has primary responsibility for assuring air quality within the state and each state is first given the opportunity to determine an emission reduction program for its areas subject to EPA approval, with such approval dependent upon whether the SIP as a whole meets the applicable requirements of the CAA. *See Virginia* v. *EPA,* 108 F.3d at 1410. The State could choose to consider additional control measures for NO_X at EGUs to ensure attainment and maintenance of the ozone NAAQS as Louisiana moves forward to meet the more prescriptive planning requirements of the CAA in the future. However, as we have explained, the State is not required to regulate such sources for the purposes of meeting the i-SIP requirements of CAA section 110(a)(2).

In addition, emission limits with the shorter-term averaging rates suggested by the Commenter could be considered within the CAA Title I part D planning process to ensure attainment and maintenance of the 2008 NAAQS. As EPA finds Louisiana's NO_X and VOC provisions presently in the SIP sufficient for infrastructure SIP purposes and specifically for CAA section 110(a)(2)(A), further consideration of the averaging times is not appropriate or relevant at this time. Thus, EPA disagrees with the Commenter that Louisiana's i-SIP must be disapproved for failure to contain sufficient measures to ensure attainment and maintenance of the 2008 ozone NAAQS.

Comment 11: The Sierra Club alleges that the proposed i-SIP does not address sources significantly contributing to nonattainment or interfering with maintenance of the NAAQS in other states as required by section 110(a)(2)(D)(i)(I) of the CAA, and states EPA must therefore disapprove the i-SIP. Sierra Club claims its modeling shows that emissions from Dolet Hills and Big Cajun II are contributing to exceedances in other states. Sierra Club states that the CAA requires i-SIPs to address cross-state air pollution. The Commenter argues that Louisiana has not done so and that EPA must disapprove the proposed infrastructure. The Commenter references the recent Supreme Court decision, *EPA* v. *EME Homer City Generation, L.P. et al,* 134 S. Ct. 1584 (2014), which supports the states' mandatory duty to address cross-state pollution under section 110(a)(2)(D)(i)(I).

Response 11: The Sierra Club commented that Louisiana's i-SIP fails to address any cross-state impacts that are due to sources within the State. However in the proposed rulemaking for this final rule, EPA did address and propose to approve the good neighbor provisions in section 110(a)(2)(D)(i)(I) for the 2008 Pb and 2010 NO_2 NAAQS,[12] and we are finalizing those provisions in this rulemaking. The portion of the State's SIP addressing the good neighbor provision for the 2006 $PM_{2.5}$ was approved on April 15, 2014 (79 FR 21142) and the 2008 ozone was disapproved August 12, 2016 (81 FR 53308). EPA will be addressing 110(a)(2)(D)(i)(I) for 2010 SO_2 and the 2012 $PM_{2.5}$ NAAQS in future actions. Thus, the comments relating to the substance and approvability of Louisiana's good neighbor provision in its 2010 SO_2 and the 2012 $PM_{2.5}$ NAAQS i-SIP submission are not relevant to this rulemaking action. As stated herein and in the NPR, EPA will take later, separate action on Louisiana's 2010 SO_2 and the 2012 $PM_{2.5}$ NAAQS i-SIP submissions to address section 110(a)(2)(D)(i)(I).

The statutory language in the CAA supports our ability to approve Louisiana's NAAQS i-SIP submissions while taking later, separate action on the portion of the SIP submittals which address Louisiana's obligation to address section 110(a)(2)(D)(i)(I). Section 110(k)(3) of the CAA authorizes EPA to approve a plan in full, disapprove it in full, or approve it in part and disapprove it in part, depending on the extent to which such plan meets the requirements of the CAA. This authority to approve the states' SIP revisions in separable parts was included in the 1990 Amendments to the CAA to overrule a decision in the Court of Appeals for the Ninth Circuit holding that EPA could not approve individual measures in a plan submission without either approving or disapproving the plan as a whole. *See,* S. Rep. No. 101–228, at 22, 1990 U.S.C.C.A.N. 3385, 3408 (discussing the express overruling of *Abramowitz* v. *EPA,* 832 F.2d 1071 (9th Cir. 1987)).

As such, EPA has the authority under section 110(k)(3), to use our discretion to approve or conditionally approve individual elements of Louisiana's infrastructure submission for NAAQS, separate and apart from any action with respect to the requirements of section 110(a)(2)(D)(i)(I). EPA views discrete i-SIP requirements, such as the requirements of 110(a)(2)(D)(i)(I), as severable from the other infrastructure elements and section 110(k)(3) allows us to act on individual severable measures in a plan submission. The commenter raises no compelling legal or environmental rationale for an alternate interpretation. Nothing in the Supreme Court's April 2014 decision in *EME Homer City* alters our interpretation that we may act on individual severable measures including the requirements of section 110(a)(2)(D)(i)(I) in a SIP submission. *See, EPA* v. *EME Homer City Generation, L.P.,*134 S. Ct. 1584 (2014) (affirming a state's obligation to submit a SIP revision addressing section 110(a)(2)(D)(i)(I) independent of EPA's action finding significant contribution or interference with maintenance).

EPA's proposed approval of the Louisiana's i-SIP submission for NAAQS for the portions described in the NPR was therefore appropriate.

III. Final Action

EPA is approving i-SIP submissions from Louisiana submitted on May 16, 2011, October 10, 2011, June 4, 2013, and December 17, 2015, certifying that the State's current i-SIP is sufficient to meet the required infrastructure elements under sections 110(a)(1) and 110(a)(2) for the 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ with exception of certain aspects relating to CAA section 110(a)(2)(D)(i)(I) for the 2008 ozone, 2010 SO_2 and 2012 $PM_{2.5}$ and disapproval for the visibility protection portion of CAA section 110(a)(2)(D)(i)(II) for all pollutants except the 2008 Pb NAAQS. The elements in which no action is taken, or for which disapproval was given will be or have been addressed in other actions. Please see the Table 1 below.

[12] 81 FR 35674.

TABLE 1—FINAL ACTION ON LOUISIANA INFRASTRUCTURE SIP SUBMITTAL FOR VARIOUS NAAQS

Element	2006 $PM_{2.5}$	2008 Pb	2008 Ozone	2010 NO_2	2010 SO_2	2012 $PM_{2.5}$
(A): Emission limits and other control measures	A	A	A	A	A	A
(B): Ambient air quality monitoring and data system	A	A	A	A	A	A
(C)(i): Enforcement of SIP measures	A	A	A	A	A	A
(C)(ii): PSD program for major sources and major modifications	A	A	A	A	A	A
(C)(iii): Permitting program for minor sources and minor modifications	A	A	A	A	A	A
(D)(i)(I): Contribute to nonattainment/interfere with maintenance of NAAQS (requirements 1 and 2)	A*	A	No action	A	No action	No action
(D)(i)(II): PSD (requirement 3)	A	A	A	A	A	A
(D)(i)(II): Visibility Protection (requirement 4)	D	A	D	D	D	D
(D)(ii): Interstate and International Pollution Abatement	A	A	A	A	A	A
(E)(i): Adequate resources	A	A	A	A	A	A
(E)(ii): State boards	A	A	A	A	A	A
(E)(iii): Necessary assurances with respect to local agencies	A	A	A	A	A	A
(F): Stationary source monitoring system	A	A	A	A	A	A
(G): Emergency power	A	A	A	A	A	A
(H): Future SIP revisions	A	A	A	A	A	A
(I): Nonattainment area plan or plan revisions under part D	+	+	+	+	+	+
(J)(i): Consultation with government officials	A	A	A	A	A	A
(J)(ii): Public notification	A	A	A	A	A	A
(J)(iii): PSD	A	A	A	A	A	A
(J)(iv): Visibility protection	+	+	+	+	+	+
(K): Air quality modeling and data	A	A	A	A	A	A
(L): Permitting fees	A	A	A	A	A	A
(M): Consultation and participation by affected local entities	A	A	A	A	A	A

Key to Table 1: Proposed action on LA infrastructure SIP submittals for various NAAQS.
A—Approve.
A*—Approved at an earlier date.
+—Not germane to infrastructure SIPs.
No action—EPA is taking no action on this infrastructure requirements.
D—Disapprove.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final action is not a ''significant regulatory action'' and was therefore not submitted to the Office of Management and Budget for review.

B. Paperwork Reduction Act (PRA)

This final action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action merely approves or disapproves a SIP submission as not meeting the CAA.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This action does not apply on any Indian reservation land, any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it merely approves or disapproves a SIP submission as not meeting the CAA.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action merely approves or disapproves a SIP submission as not meeting the CAA requirements.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Interstate transport of pollution, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: September 29, 2016.

Samuel Coleman,

Acting Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart T—Louisiana

■ 2. Section 52.970(e) is amended by adding six entries at the end of the second table titled ''EPA Approved Louisiana Provisions and Quasi-Regulatory Measures'' to read as follows:

§ 52.970 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED LOUISIANA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	*
Infrastructure for the 2006 $PM_{2.5}$ NAAQS.	Statewide	5/16/11	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portion pertaining to PSD), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
Infrastructure for the 2008 Pb NAAQS.	Statewide	10/10/11	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L) and (M).
Infrastructure for the 2008 O_3 NAAQS.	Statewide	6/4/13	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portion pertaining to PSD), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
Infrastructure for the 2010 NO_2 NAAQS.	Statewide	6/4/13	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portions pertaining to nonattainment, interference with maintenance and PSD), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
Infrastructure for the 2010 SO_2 NAAQS.	Statewide	6/4/13	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portion pertaining PSD), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
Infrastructure for the 2012 $PM_{2.5}$ NAAQS.	Statewide	12/17/15	10/4/16 [Insert **Federal Register** citation].	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portion pertaining to PSD), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M).

■ 3. Section 52.996 is amended by adding paragraph (b) to read as follows:

§ 52.996 Disapprovals.

* * * * *

(b) The portions of the SIP submitted on May 16, 2011, June 4, 2013, and

December 17, 2015 addressing noninterference with measures required to protect visibility in any other state (Clean Air Act section 110(a)(2)(D)(i)(II)) are disapproved for the following National Ambient Air Quality Standards: 2006 $PM_{2.5}$, 2008 Ozone, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$.

[FR Doc. 2016–24036 Filed 10–3–16; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 503 and 552

[GSAR Change 76; GSAR Case 2016–G501; Docket No. 2016–0018; Sequence No. 1]

RIN 3090–AJ78

General Services Administration Acquisition Regulation (GSAR); Inflation of Acquisition-Related Thresholds

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to make editorial changes. This case updates acquisition-related thresholds to align with the Federal Acquisition Regulation (FAR).

DATES: *Effective:* October 4, 2016.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Janet Fry, Procurement Analyst, General Services Acquisition Policy Division, GSA, at 703–605–3167. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite GSAR case 2016–G501.

SUPPLEMENTARY INFORMATION:

I. Discussion of Changes

The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to make editorial changes to align acquisition thresholds with the Federal Acquisition Regulation (FAR). There are no significant content changes resulting from this case.

GSAR section 503.1004(a) is updated to remove the duplicative and unnecessary language regarding the outdated $5,000,000 FAR threshold for including FAR 52.203–14, Display of Hotline Poster(s). The remaining text regarding the $1,000,000 threshold for disaster assistance funds is retained with minor edits.

Contract GSAR clauses 552.219–71, Notice to Offerors of Subcontracting Plan Requirements, and 552.219–72, Preparation, Submission and Negotiation of Subcontracting Plans, are updated to remove reference to the acquisition threshold of $650,000 and the language is restructured to no longer state the threshold but rather direct the reader to FAR 52.219–9 which clearly addresses the thresholds for subcontracting plans. By referencing back to the FAR, future inflation updates will not require amendments to the GSAR.

GSAR clause 552.270–13, Proposals for Adjustment, is updated to replace ''$500,000'' with ''$750,000.'' Referencing the FAR for the threshold to prevent future updates was not an alternative.

II. Public Comments Not Required

41 U.S.C. 1707, Publication of proposed regulations, applies to the publication of the General Services Administration Acquisition Regulation. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form including amendment or modification thereof must be published for public comment if it has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form or has a significant cost or administrative impact on contractor or offerors. This final rule is not required to be published for public comment because it contains minor editorial updates without changing the meaning of content. The changes do not have a significant impact on the public.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Analysis does not apply to this rule because this final rule does not constitute a significant GSAR revision and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 503 and 552

Government procurement.

Dated: September 29, 2016.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, GSA is amending 48 CFR parts 503 and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 503 and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 503—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 2. Amend section 503.1004 by revising paragraph (a) to read as follows:

503.1004 Contract clauses.

(a) GSA has exercised the authority provided at FAR 3.1004(b)(1)(i) to establish a lower threshold for inclusion of clause 52.203–14, Display of Hotline Poster(s). When the contract or order is funded with disaster assistance funds, the threshold is $1,000,000.

* * * * *

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Amend section 552.219–71 by revising the date of the provision and the provision to read as follows:

552.219–71 Notice to Offerrors of Subcontracting Plan Requirements.

* * * * *

Notice to Offerrors of Subcontracting Plan Requirements (Oct 2016)

The General Services Administration (GSA) is committed to assuring that maximum practicable opportunity is provided to small, HUBZone small, small disadvantaged, women-owned, veteran-owned, and service-disabled veteran-owned small business concerns to participate in the

performance of this contract consistent with its efficient performance. GSA expects any subcontracting plan submitted pursuant to FAR 52.219–9, Small Business Subcontracting Plan, to reflect this commitment. The plan must demonstrate a creative and innovative program for involving small, HUBZone small, small disadvantaged, women-owned, veteran-owned, and service-disabled veteran-owned small business concerns as subcontractors in the performance of this contract.

* * * * *

■ 4. Amend section 552.219–72 by revising the date of the provision and paragraph (a) to read as follows:

552.219–72 Preparation, Submission, and Negotiation of Subcontracting Plans.

* * * * *

Preparation, Submission, and Negotiation of Subcontracting Plans (Oct 2016)

(a) When submitting a subcontracting plan in accordance with FAR 52.219–9, the offeror shall submit a subcontracting plan with its initial offer. The subcontracting plan will be negotiated concurrently with price and any required technical and management proposals, unless the offeror submits a previously-approved commercial plan.

* * * * *

■ 5. Amend section 552.270–13 by revising the date of the provision; and removing from paragraph (c) introductory text and paragraph (c)(2) ''500,000'' and adding ''750,000'' in their places, respectively.

The revision reads as follows.

552.270–13 Proposals for Adjustment.

* * * * *

Proposals for Adjustment (Oct 2016)

* * * * *

[FR Doc. 2016–24015 Filed 10–3–16; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 355, 356, 365, 369, 370, 373, 374, 376, 377, 378, 382, 383, 384, 385, 386, 390, 391, 392, 395, 397, and 398

RIN 2126–AB95

General Technical, Organizational, Conforming, and Correcting Amendments to the Federal Motor Carrier Safety Regulations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule.

SUMMARY: FMCSA amends its regulations by making technical corrections throughout. The Agency is making minor changes to correct errors and omissions, ensure conformity with Office of the Federal Register style guidelines, update cross references, and improve clarity and consistency of certain regulatory provisions. Further, this set of amendments removes all remaining instances of the term ''common carrier'' and ''contract carrier'' as required by the ICC Termination Act (ICCTA) and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU). This rule does not make any substantive changes to the affected regulations, except to remove obsolete provisions.

DATES: *Effective Date:* The final rule is effective September 30, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. David Miller, Federal Motor Carrier Safety Administration, Regulatory Development Division, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by telephone at (202) 366–5370 or via email at *FMCSAregs@dot.gov.* Office hours are from 9:00 a.m. to 5:00 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Legal Basis for the Rulemaking

Congress delegated certain powers to regulate interstate commerce to the United States Department of Transportation (DOT or Department) in numerous pieces of legislation, most notably in section 6 of the Department of Transportation Act (DOT Act) (Pub. L. 85–670, 80 Stat. 931 (1966)). Section 55 of the DOT Act transferred to the Department the authority of the former Interstate Commerce Commission (ICC) to regulate the qualifications and maximum hours-of-service of employees, the safety of operations, and the equipment of motor carriers in interstate commerce. See 49 United States Code (U.S.C.) 104. This authority, first granted to the ICC in the Motor Carrier Act of 1935 (Pub. L. 74–255, 49 Stat. 543, Aug. 9, 1935), now appears in 49 U.S.C. chapter 315. The regulations issued under this authority became known as the Federal Motor Carrier Safety Regulations (FMCSRs), appearing generally at 49 CFR parts 350–399. The administrative powers to enforce chapter 315 were also transferred from the ICC to the DOT in 1966 and appear in 49 U.S.C. chapter 5. The Secretary of the DOT (Secretary) delegated oversight of these provisions to the Federal Highway Administration (FHWA), a predecessor agency of FMCSA. The FMCSA Administrator has been delegated authority under 49 CFR 1.87 to carry out the motor carrier functions vested in the Secretary.

Between 1984 and 1999, a number of statutes added to FHWA's authority. Various statutes authorize the enforcement of the FMCSRs, the Hazardous Materials Regulations (HMRs), and the Commercial Regulations, and provide both civil and criminal penalties for violations of these requirements. These statutes include the Motor Carrier Safety Act of 1984 (Pub. L. 98–554, 98 Stat. 2832, Oct. 30, 1984), codified at 49 U.S.C. chapter 311, subchapter III (MCSA); the Commercial Motor Vehicle Safety Act of 1986 (Pub. L. 99–570, 100 Stat. 3207–170, Oct. 27, 1986), codified at 49 U.S.C. chapter 313; the Hazardous Materials Transportation Uniform Safety Act of 1990, as amended (Pub. L. 101–615, 104 Stat. 3244, Nov. 16, 1990), codified at 49 U.S.C. chapter 51; and the ICCTA of 1995 (Pub. L. 104–88, 109 Stat. 803, Dec. 29, 1995), codified at 49 U.S.C. chapters 131–149.

The Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L. 106–159, 113 Stat. 1748, Dec. 9, 1999) established FMCSA as a new operating administration within DOT, effective January 1, 2000. The motor carrier safety responsibilities previously assigned to both ICC and FHWA are now assigned to FMCSA.

Congress expanded, modified, and amended FMCSA's authority in the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 (Pub. L. 107–56, 115 Stat. 272, Oct. 26, 2001), SAFETEA–LU (Pub. L. 109–59, 119 Stat. 1144, Aug. 10, 2005), the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572, June 6, 2008), and the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, 126 Stat. 405, July 6, 2012).

The specific regulations amended by this rule are based on the statutes detailed above. Generally, the legal authority for each of those provisions was explained when the requirement was originally adopted and is noted at the beginning of each part in title 49 of the CFR. Title 49 CFR subtitle B, chapter III, contains all of the FMCSRs.

The Administrative Procedure Act (APA) (5 U.S.C. 551–706) specifically provides exceptions to its notice and public comment rulemaking procedures where the Agency finds there is good cause (and incorporates the finding and a brief statement of reasons therefore in the rules issued) to dispense with them. Generally, good cause exists where the Agency determines that notice and public procedures are impractical,

unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B)). The amendments made in this final rule merely correct inadvertent errors and omissions, remove or update obsolete references, and make minor changes to improve clarity and consistency. The technical amendments do not impose any new requirements, nor do they make any substantive changes to the CFR. For these reasons, FMCSA finds good cause that notice and public comment on this final rule is unnecessary.

The APA also allows agencies to make rules effective upon publication with good cause (5 U.S.C. 553(d)(3)), instead of requiring publication 30 days prior to the effective date. For the reasons already stated, FMCSA finds there is good cause for this rule to be effective on the date of publication in the **Federal Register**.

FMCSA is aware of the regulatory reform requirements imposed by section 5202 of the Fixing America's Surface Transportation Act (FAST Act) (Pub. L. 114–94, 129 Stat. 1312, at 1534, Dec. 4, 2015) concerning public participation in FMCSA rulemaking (49 U.S.C. 31136(g)). These requirements pertain to certain major rules,[1] but because this final rule is not major, they are not applicable. In any event, the Agency finds that, for the reasons stated below, publication of an advance notice of proposed rulemaking under 49 U.S.C. 31136(g)(1)(A), or a negotiated rulemaking under 49 U.S.C. 31136(g)(1)(B), is unnecessary and contrary to the public interest in accordance with the waiver provision in 49 U.S.C. 31136(g)(3).

Background

This document makes editorial changes to correct inaccurate references and citations, improve clarity, and fix errors. The reasons for each of these minor revisions are set out below, in a section-by-section description of the changes. These amendments do not impose any new requirements.

This set of amendments removes all remaining instances of the term ''common'' and ''contract'' as required by the ICCTA and SAFETEA–LU. Many instances of these terms were removed in the FMCSA Unified Registration System (URS) final rules published in 2013, 2015, and 2016,[2] and this rule removes the remaining instances found in 49 CFR chapter III, subchapter B. This rule does not make any substantive changes to the affected regulations, except to remove eight obsolete provisions. Four of the provisions relate to the use of the terms ''common'' and ''contract'' and certain property-carrier routing requirements eliminated by the ICCTA. The other four obsolete provisions relate to a Congressionally-sunset emergency commercial driver's license grant, a pre-2014 medical exam schedule, outdated medical forms, and an obsolete reporting requirement.

FMCSA is adding ''for-hire, non-exempt'' to many rules to ensure motor carriers know the rules are only applicable to for-hire, non-exempt motor carriers, similar to the amendments being made in the URS final rules.

Use of the term ''non-exempt'' in these sections and other technical amendments related to the use of the terms ''common'' and ''contract'' below is to ensure motor carriers exempted by Congress from jurisdiction under 49 U.S.C. subtitle IV, part B, and specifically sec. 13506, do not feel compelled to comply with the amended rule text. FMCSA has discovered over the years that many for-hire, exempt [3] motor carriers and their drivers (such as livestock, grain, and produce haulers), mistakenly believe that 49 U.S.C. subtitle IV, part B (secs. 13101 through 14916), are mandatory requirements applicable to their operations.

For-hire motor carriers transporting commodities, or agreeing to transport brokered loads of commodities, that are listed by statutes, FMCSA regulations, and FMCSA administrative rulings, as exempt from 49 U.S.C. subtitle IV, part B, are not subject to non-safety related rules administered by FMCSA. Such for-hire, exempt motor carriers thus are not required to comply with the following rules that are authorized under 49 U.S.C. subtitle IV, part B:

- Annual economic reporting requirements in part 369;
- Receipts and bills of lading in part 373;
- Loss and damage claim requirements in part 370;
- Property broker requirements in part 371;
- Passenger carrier regulations in part 374;
- Household goods transportation regulations in part 375;
- Lease and interchange of vehicle rules in part 376;
- Payment of transportation charge rules in part 377;
- Overcharge, duplicate payment, and overcollection claims in part 378; and
- Preservation of records in part 379.

Motor carriers and shippers should be aware of the italicized text below related to contract carriage operations, ''. . . A carrier providing transportation or service subject to jurisdiction under chapter 135 may enter into a contract with a shipper, . . . to provide specified services under specified rates and conditions. *If the shipper and carrier, in writing, expressly waive any or all rights and remedies under this part for the transportation covered by the contract, the transportation provided under the contract shall not be subject to the waived rights and remedies and may not be subsequently challenged on the ground that it violates the waived rights and remedies* . . .'' [4] [emphasis added]

The statutory reference to the waiver of ''any or all rights and remedies'' allows a shipper and a motor carrier to negotiate and enter into a private contract that establishes selected rights and remedies different from the general ''motor carrier'' rights and remedies otherwise provided under 49 U.S.C. 14101, 14706, and other statutes. The waiver provision gives the carrier and shipper the flexibility to select the rights and remedies they wish to establish by contract. They can choose to leave in place other rights and remedies to be governed by statutes and regulations applicable to ''motor carriers.'' ''. . . New 49 U.S.C. 14101 (Providing transportation and service), taken from existing 49 U.S.C. 11101, would continue the basic common carrier obligation to provide transportation or service on reasonable request and to provide safe and adequate service, equipment, and facilities. It would expressly allow carriers to enter contracts for specific shipments (other than for residential household goods movements arranged and paid for directly by the householder) under which both parties may waive their ICA rights and remedies.'' [5]

[1] A ''major rule'' is defined by the Congressional Review Act, Pub. L. 104–121, title II, section 251, Mar. 29, 1996, 110 Stat. 873, and is codified at 5 U.S.C. 804(2). See *https://www.gpo.gov/fdsys/pkg/USCODE-2014-title5/pdf/USCODE-2014-title5-partI-chap8-sec804.pdf.*

[2] *Final Rule, Unified Registration System,* 78 FR 52608 (Aug. 23, 2013), amendments, corrections, and delayed effective and compliance dates published at 80 FR 63703, October 21, 2015, and 81 FR 49553, July 28, 2016.

[3] An exempt for-hire motor carrier transports exempt (unregulated) property owned by others for compensation. The exempt commodities usually include unprocessed or unmanufactured goods, fruits, and vegetables, and other items of little or no value. For a partial listing of exempt and non-exempt commodities, please refer to Administrative Ruling No 119 at *https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/docs/Administrative_Ruling_119.pdf.* An exempt for-hire motor carrier is subject to the safety regulations in 49 CFR chapter III, subchapter B.

[4] 49 U.S.C. 14101(b)(1).

[5] Sen. Report 104–176 (1995) at 46, *https://www.gpo.gov/fdsys/pkg/CRPT-104srpt176/pdf/CRPT-104srpt176.pdf.*

See also *M. Fortunoff of Westbury Corp.* v. *Peerless Ins. Co.,* 432 F.3d 127 (2nd Cir. 2005) at 132–133 (emphasis in original):

> Congress enacted the [ICC Termination Act] in 1995 and merged the separate classifications of common and contract carrier into one classification termed ''motor carrier,'' governing any ''person providing motor vehicle transportation for compensation.'' 49 U.S.C. 13102(12). The ICCTA provided that *all* motor carriers were to register under sec. 13902(a) as opposed to the old regime of separately registered common and contract carriers. Under [49 U.S.C.] 14101, registered motor carriers *must* provide common carriage services and *may* provide contract carriage services.

With respect to all revisions to the terms ''common'' and ''contract,'' FMCSA has attempted to simply set out the governing regulatory provisions for ''motor carriers'' (or for ''for-hire motor carriers,'' which captures the ''for compensation'' language in the statutory definition of ''motor carrier'' in 49 U.S.C. 13102(14)). This leaves a motor carrier and shipper the flexibility contemplated by the statute to choose ''any or all'' rights and remedies to be waived, while those not waived remain in full effect.

It should be noted that for-hire, exempt motor carriers transporting exempted (unregulated) commodities may not submit a claim to the FMCSA-mandated $75,000 financial responsibility instrument held by an authorized property broker, their sureties, or their trust fund managers for payments owed to the exempted motor carrier, based on the authorized property broker's failure to carry out its contracts, agreements, or arrangements for the supplying of exempt (unregulated) commodity transportation by exempt motor carriers. An exempt motor carrier is not authorized by FMCSA to operate under 49 U.S.C. subtitle IV, part B, and thus does not have legitimate access to the FMCSA-authorized property broker's $75,000 financial responsibility instrument. The $75,000 financial instrument is only applicable when the FMCSA-authorized property broker fails to carry out its contracts, agreements, or arrangements for the supplying of authorized (regulated) commodity transportation by FMCSA-authorized motor carriers.

Section-by-Section Analysis

This section-by-section analysis describes the technical amendment provisions and corrections in numerical order.

Appendix A of Part 355—Guidelines for the Regulatory Review of Compatible State Laws and Regulations Affecting Interstate Motor Carrier Operations

FMCSA replaces a phrase that includes the terms common and contract with a phrase that no longer uses those two terms. Currently, the applicability section references the appendix's requirements that each State shall review its laws and regulations to achieve compatibility with the FMCSRs. Each State's ''. . . requirements must apply to all segments of the motor carrier industry common, contract, and private carriers of property and for-hire carriers of passengers.'' FMCSA replaces the phrase ''motor carrier industry common, contract,'' with the phrase ''motor carrier industry, for-hire.''

For-Hire Motor Carrier of Property Routing Requirements in §§ 356.7—356.13

Four sections are being removed from part 356 as a result of FMCSA's review of ''common'' and ''contract'' amendments. The ICCTA eliminated the need for for-hire motor carriers of property to apply to a Federal agency and be granted authority to drive on particular, specified, and declared highway routes. In considering how to change the term ''common'' to something else in §§ 356.7 to 356.13, FMCSA determined that each of these four sections is no longer applicable to anyone as each section only applied to property carriers that no longer need route authority. Therefore, FMCSA removes all four rule sections with the headings ''*Tacking,*'' ''*Elimination of routing restrictions—regular route carriers,*'' ''*Elimination of gateways—regular and irregular route carriers,*'' and ''*Redesignated highways.*''

§ 365.105 Starting the Application Process: Form OP–1

FMCSA is updating the universal resource locators (URL) for Form OP–1 to accurately reflect where to obtain the forms. Since December 2015, new applicants must apply for a USDOT number and, if applicable, operating authority, by electronically filing Form MCSA–1, the URS online application. Registrants, who had operating authority before December 2015, may still use Form OP–1 to update their registration information, but the Agency did not update the URLs where the forms may be obtained.

§ 365.205 Contents of the Protest

FMCSA updates this section to replace an outdated phone number and add an additional way to contact FMCSA for help. FMCSA no longer uses the 202 area code phone number listed in this section. FMCSA has replaced the 202 number with a toll-free telephone number and has added an online web form in which the public may contact FMCSA for further assistance in developing their evidence for filing a protest.

§ 365.413 Procedures for Changing the Name or Business Form of a Motor Carrier, Freight Forwarder, or Property Broker

FMCSA amends this section to add two additional ways for current registrants to contact FMCSA to change the name or business form of a registered motor carrier, freight forwarder, or property broker. For such registrants to make such changes, FMCSA has developed a two-page form MCSA–5889, ''Motor Carrier Records Change Form,'' Office of Management and Budget (OMB) No. 2126–0060, approved by OMB for use through July 31, 2018. FMCSA continues to allow the letter to be mailed, with the five required pieces of information in redesignated § 365.413(c)(1) through (5). But FMCSA now adds to the list of options the opportunity for form MCSA–5889 to be faxed to FMCSA at the number given, or scanned and submitted via the web form at *https://www.fmcsa.dot.gov/ask.*

Part 369—Reports of Motor Carriers

FMCSA makes several amendments related to the terms ''common'' and ''contract'' to part 369 applicable to annual reports of for-hire motor carriers. FMCSA modifies each paragraph (a) in §§ 369.1, 369.2, and 369.3 to replace the phrase ''common and contract'' with the phrase ''for-hire, non-exempt motor'' to comport with the elimination of the terms ''common'' and ''contract'' in the ICCTA.

§ 370.9 Disposition of Claims

The Agency makes one amendment related to the term ''common'' to Part 370 applicable to disposition of claims. Paragraph (b) is amended to replace ''common carrier by motor vehicle of household goods as defined in § 375.103 of this chapter'' with ''household goods motor carrier as defined in § 375.103 of this subchapter'' for use when settling a claim for loss or damage to household goods or an individual shipper's property. This paragraph will continue to use the current defined term ''household goods motor carrier'' in § 375.103 that comes from the Household Goods Mover Oversight Enforcement and Reform Act of 2005 (August 10, 2005), and any person considered to be a household goods

motor carrier under regulations, determinations, and decisions of the FMCSA on August 10, 2005.

New § 373.100 and § 374.1 Applicability

FMCSA adds two new applicability sections to ensure the public understands that parts 373 and 374 are limited to for-hire motor carriers subject to jurisdiction under 49 U.S.C. subtitle IV, part B.

§ 373.101 Motor Carrier Bills of Lading

The Agency makes two amendments related to the term ''common'' applicable to motor carrier bills of lading. FMCSA revises the heading to add ''for-hire, non-exempt'' and is amending the undesignated introductory sentence to remove the term ''common'' for the same reasons as discussed above.

§ 373.103(a) & (b) Expense bills

FMCSA makes three amendments related to the term ''common'' applicable to expense bills issued by for-hire motor carriers of property and charter service expense bills issued by for-hire motor carriers performing ''charter transportation of passengers'' as defined in § 390.5. FMCSA is also revising the heading of this section to add ''for-hire, non-exempt'' and is amending paragraphs (a) and (b) to remove the term ''common'' for the same reasons as discussed above.

Part 374 Passenger Carrier Regulations

The Agency makes several amendments to part 374 entitled Passenger Carrier Regulations. As discussed above, FMCSA adds a new § 374.1 Applicability section to ensure the public understands that part 374 is limited to for-hire motor carriers subject to jurisdiction in the ICCTA. Second, throughout part 374, FMCSA removes all references to ''common'' in headers and rule text in §§ 374.101, 374.103, 374.105, 374.107, 374.109, 374.111, 374.113, 374.201, 374.301, 374.303, 374.401, 374.403, and 374.405.

Also, ICC never assigned a paragraph (b) to § 374.401, previously designated as 49 CFR 1064.1, when it was made final on November 16, 1979 (44 FR 65987) or in any amendments after 1979. With no paragraph (b), the section reads better and will be less confusing if paragraph (a) becomes an undesignated introductory phrase and paragraphs (a)(1), (2), and (3) are renamed as paragraphs (a), (b), and (c).

Additionally, at the end of § 374.401, FMCSA removes the outdated authority citation ''(49 U.S.C. 10321, 5 U.S.C. 553),'' as it is a remnant of the pre-ICCTA statutes. Section 374.401's authority derives from the general authority cited for most of part 374—49 U.S.C. 13301 and 14101; and 49 CFR 1.87.

Finally, the Agency amends four authority citations for incidental charter rights under subpart E to part 374 that are also outdated to show only ICCTA statutes—49 U.S.C. 13301, 13501, 13506, and their delegation under 49 CFR 1.87. In the first sentence in § 374.501, the outdated reference to ''[49 U.S.C. 10932(c)]'' is removed. The citation to 49 U.S.C. 13506 is correct and will remain in § 374.501.

Part 376 Applicability of Lease and Interchange of Property-Carrying Motor Vehicles

FMCSA makes several amendments related to the terms ''common'' and ''contract'' to part 376 applicable to the lease and interchange of property-carrying motor vehicles by for-hire motor carriers. In various places throughout part 376 that reference the term ''motor common carrier'' or ''authorized common carrier'' in the rule text, FMCSA removes all applicable references to ''common.'' The references to ''common ownership'' in part 376 have been retained as that concept is unaffected by this final rule.

In § 376.1, FMCSA adds the clarifying phrase ''. . . under 49 U.S.C. subtitle IV, part B:'' to the introductory phrase in paragraph (a) to ensure the public understands these rules apply only to for-hire motor carriers subject to the ICCTA. In § 376.2, the term ''motor common carrier'' is amended to read as ''motor carrier.''

In the first four instances of the term ''common'' in § 376.31, FMCSA replaces ''common'' with the term ''motor.''

Part 377 Applicability of Payment of Transportation Charges

In the applicability paragraph of § 377.101, FMCSA removes the term ''common''; spells out cash-on-delivery for the acronym (c.o.d.); and reorganizes the paragraph to better show the two exceptions to the applicability of part 377.

In §§ 377.103 and 377.105, the Agency replaces the term ''common'' with the term ''motor'' in each section.

Part 377 Subpart B, Applicability of Extension of Credit to Shippers by Carriers and Freight Forwarders

FMCSA makes several amendments related to the terms ''common'' and ''contract'' in subpart B of part 377 applicable to the extension of credit to shippers by for-hire motor carriers and freight forwarders. The Agency revises the heading for subpart B of part 377. The current title includes the term ''common'' and the phrase ''Water Common Carriers.'' The Agency adds the phrase ''for-hire, non-exempt'' before the phrase ''motor carrier'' in the subpart B heading as well as in § 377.201(a) to ensure exempt for-hire carriers understand the subpart does not apply to their extensions of credit to shippers. As FMCSA has never been delegated responsibility for regulating water carriers, the phrase ''Water Common Carriers'' is eliminated from the heading for subpart B as well.

Also in § 377.201, FMCSA removes the exception for ''Contract carrier operations'' in paragraph (b)(1) and redesignates paragraphs (b)(2) and (3) as paragraphs (b)(1) and (2) for the reasons given above in the Background section. In § 377.217, the Agency replaces the term ''common'' with the term ''motor.''

Part 378 Applicability of Overcharge, Duplicate Payment, and Overcollection Claims Processing

FMCSA makes two amendments related to the term ''common'' to part 378. In §§ 378.1 and 378.2, the Agency removes the term ''common'' in each of the two places it appears.

§§ 382.103 and 383.3 Controlled Substances and Alcohol Testing and Commercial Driver's License (CDL) Rules, Applicability of an Exception for Farm Vehicle Employers and Drivers

FMCSA makes two amendments related to the terms ''common'' and ''contract'' that are applicable to drivers that may need a CDL to drive a commercial motor vehicle (CMV) in the United States and whether that CDL driver is subject to controlled substances and alcohol testing. In § 382.103, FMCSA revises paragraph (d)(3)(i)(C) which discusses that an operator of a farm vehicle cannot be a common or contract motor carrier. The Agency replaces the phrase ''common or contract motor carrier'' with the phrase ''for-hire motor carrier, except for an exempt motor carrier as defined in § 390.5 of this subchapter.'' Similarly, an exception for operators needing a CDL to drive a farm vehicle excludes operations by a common or contract motor carrier. It is found in § 383.3(d)(3)(i)(C). In this paragraph, the Agency is also replacing the phrase ''common or contract motor carrier'' with the phrase ''for-hire motor carrier, except for an exempt motor carrier as defined in § 390.5 of this subchapter.''

These two changes will ensure that farmers, who also may operate as an exempt motor carrier, know that their farm vehicles might be excepted from

the CDL and drug and alcohol testing requirements if the farm vehicles they use meets all of the other three conditions of the exception under § 382.103(d)(3)(i) and the CDL definition in § 383.3(d)(3)(i)(C).

§ 382.305 Controlled Substances Testing Annual Random Percentage Rate

This amendment relates to the lowered minimum annual percentage rate for random controlled substances testing made effective for all testing in 2016 and later. FMCSA amends § 382.305(b)(2) to state that the minimum annual percentage rate for random controlled substances testing shall be 25 percent of the average number of driver positions, as it has been effective since January 1, 2016. On December 24, 2015 (80 FR 80446), FMCSA announced the reduction of the minimum annual percentage rate for random controlled substances testing for drivers of CMVs requiring a CDL from 50 percent of the average number of driver positions to 25 percent of the average number of driver positions, effective in calendar year 2016. The FMCSA Administrator has the discretion to decrease the minimum annual random testing percentage rate based on the reported positive random test rate for the entire motor carrier industry. Based on the controlled substances random test data in FMCSA's Management Information System (MIS) for calendar years 2011, 2012, and 2013, the positive rate for controlled substances random testing fell below the 1.0 percent threshold for 3 consecutive calendar years. As a result, the Agency lowered the controlled substances minimum annual percentage rate for random controlled substances testing to 25 percent of the average number of driver positions.

§ 383.5 School Bus Definition for Commercial Driver's License Standards

The current definition of a school bus in § 383.5 does not include a bus used as a common carrier. In part 383, the term ''school bus'' is used only in the requirements under § 383.123 for a CDL driver to get a license endorsement after successfully passing knowledge and skills tests. FMCSA is replacing ''common'' with the phrase ''for-hire motor''.

§ 383.77 Substitute for Driving Skills Tests for Drivers With Military CMV Experience

FMCSA removes the erroneous second iteration of the word ''had'' in § 383.77(a)(5), making the sentence read, in part, as follows: ''Has not had any conviction for a violation . . .''

§§ 383.131 and 383.133 CDL Test System Model Commercial Driver Manual

In §§ 383.131 and 383.133, FMCSA adds ''or newer'' after ''July 2010'' to allow each State to use newer manual editions to comply with the requirements. Each State must provide every CLP or CDL applicant an FMCSA pre-approved driver information manual as required by § 383.131. The manual must be comparable to the American Association of Motor Vehicle Administrators' (AAMVA's) ''2005 CDL Test System Model Commercial Driver Manual,'' July 2010 or a newer version. FMCSA provides the manual as a reference for States, but does not require any specific manual published after July 2010, nor does it incorporate any manual by reference into the regulations.

§ 384.401 State Compliance With CDL Program

FMCSA amends § 384.401 to lower the withholding percentages of Federal-aid highway funds. Sec. 1404(j) of MAP–21 amended 49 U.S.C. 31314(c) changing the withholding percentages of Federal-aid highway funds based on State noncompliance with the CDL program. Federal-aid highway funds are apportioned to States under various sections of title 23 U.S.C. Amended sec. 1404(j) makes it necessary to revise the withholding provisions in § 384.401 to comply with amended 49 U.S.C. 31314(c). Specifically, MAP–21 changed the amount of Federal-aid highway funds to be withheld for noncompliance in paragraph (a) from 5 percent to 4 percent, and reduced the amount of such funds to be withheld for repeated noncompliance in paragraph (b) from 10 percent to 8 percent.

§ 384.407 Emergency CDL Grants

FMCSA removes § 384.407 because SAFETEA–LU did not renew the emergency CDL grant program in 49 U.S.C. 31107. Therefore, this section is no longer necessary.

§ 385.303 New Entrant Motor Carrier Safety Assurance Applications

FMCSA revises the universal resource locators (URL) to accurately reflect where to obtain the forms for new entrant motor carriers. Since December 2015, new applicants must apply for a USDOT number and if applicable, operating authority, by electronically filing Form MCSA–1, the URS online application. Registrants who had registered and been issued a USDOT number before December 2015 may still use form MCS–150 and if applicable, Form OP–1, to update their registration information.

Similar to changes made earlier in this document for § 365.105, FMCSA is modifying how new entrant motor carriers may contact the Agency for application materials. In § 385.303, the Agency is changing a 703 area code fax number to a 202 area code fax number and is adding the option that new entrant motor carriers may locate application materials online at one of two Web pages, the precise location determined by whether they received a USDOT number before or after December 12, 2015.

Part 385, Appendix B Restoration of Inadvertently Edited Safety Fitness Paragraph

The Agency corrects an error made in 2005 to address an inadvertent change to a provision of appendix B to 49 CFR part 385. In the 1997 Safety Fitness Procedure; Safety Ratings final rule (62 FR 60035 at 60043 (Nov. 6, 1997)), paragraph (c) of the introductory text in app. B to part 385 read as follows: ''To meet the safety fitness standard, a motor carrier must demonstrate to the FHWA that it has adequate safety management controls in place which function effectively to ensure acceptable compliance with the applicable safety requirements. A ''safety fitness methodology'' (SFRM) was developed by the FHWA, which uses data from compliance reviews (CRs) and roadside inspections to rate motor carriers.''

In the same final rule, section II.(c), read as follows: ''Critical regulations are those identified as such where noncompliance relates to management and/or operational controls. These are indicative of breakdowns in a carrier's management controls. An example of a critical regulation is § 395.3(a)(1), requiring or permitting a driver to drive more than 10 hours.''

The reference to ''FHWA'' in paragraph (c) of the introductory text was changed to ''FMCSA'' in Miscellaneous Technical Amendments on Oct. 1, 2001 (66 FR 49867, at 49872) due to the establishment of the FMCSA by the Motor Carrier Safety Improvement Act of 1999.

In the 2003 Hours of Service for Drivers final rule (68 FR 22456 at 22513 (Apr. 28, 2003)), section II.(c) was amended by FMCSA—the only change was to modify the time period at the end to ''11 hours'' from ''10 hours'' reflecting the amended provisions of § 395.3(a)(1). No change was directed to be made in paragraph (c) of the introductory text. This change in

appendix B to 49 CFR part 385, section II.(c) was correctly published in the 2004 Code of Federal Regulations and no change was made in paragraph (c) of the introductory text. See 49 CFR part 385, app. B (10/01/2004 ed.), at pages 1023–24.

In the 2005 Hours of Service for Drivers final rule (70 FR 49978 at 50070 (Aug. 25, 2005)), FMCSA again directed that section II.(c) be revised to refer to ''11 hours'' even though that change had already been published in the CFR. But no change was directed to be made in paragraph (c) of the introductory text. Nonetheless, in the 2005 compilation of the CFR, the revised text of section II.(c) was published in two places: (1) in place of the text in paragraph (c) of the introductory text, which the Agency did not intend to change; and (2) in section II.(c), which was the only place that the final rule directed that a change be made. See 49 CFR part 385, app. B (10/01/2005 ed.),[6] at pages 239–240.

This amendment corrects the error in the CFR and does not impose any new requirements; it just restores the proper paragraph (c) of the introductory text to read as set out in the regulatory text at the end of this document.

FMCSA is also republishing section II.(c) as it was correctly published in the 2004 and 2005 CFRs to give context.

FMCSR Errors Resulting From Electronic Logging Devices and Hours of Service Supporting Documents Final Rule

Four amendments are being made to the 2015 Electronic Logging Devices and Hours of Service Supporting Documents (ELD) final rule, December 16, 2015 (80 FR 78292, at 78381) below. The amendments are to two critical regulations in part 385, appendix B, the filing of various complaints under § 386.1, and adding an additional qualifying phrase to § 395.8(a)(1)(iii)(A)(*3*) about how to determine whether a commercial motor vehicle was manufactured before model year 2000.

Part 385, Appendix B List of Critical and Acute Regulations

While reviewing the list of acute and critical regulations, found in appendix B of part 385, FMCSA discovered that the terminology used to identify two of the critical violations is confusing. In these provisions, the critical violations occur when a motor carrier fails to ensure that drivers (or third parties) submit records of duty status (or supporting documents); while there is still a violation if those documents are submitted late, late submissions are not typically critical violations that could affect the motor carrier's safety rating. It is only when the motor carrier fails completely to require drivers to submit the documents that such an effect could occur. Thus, the two provisions described above that are identified as critical regulations in section VII. List of Acute and Critical Regulations in appendix B, are being revised to remove the words ''in a timely manner,'' as set out below:

- § 395.8(a)(2)(ii) Failure to require a driver to submit record of duty status (critical); and
- § 395.11(b) Failing to require a driver to submit supporting documents (critical)

This change reflects the way that FMCSA treats violations currently, and will therefore have no direct impact on motor carriers.

§ 386.1 Filing of Substantial Complaints, Filing of Harassment Complaints, and Filing of Coercion Complaints

In the same 2015 ELD rule, FMCSA changed § 386.1, *Scope of rules in this part,* to include references to complaints of substantial violation, coercion, and harassment. However, the Agency overlooked the recent addition of a new paragraph § 386.1(c) in its separate Coercion final rule[7] published two weeks before the ELD rule, and made the amendatory instruction incorrectly. To correct this inadvertent error, this technical amendment adds new § 386.1(c)(1), (2), and (3), as was explained in the amendatory instructions of the ELD rule. New § 386.1(c)(1), (2), and (3) concern the filing of substantial complaints, the filing of harassment complaints, and the filing of coercion complaints, respectively. Similarly, the ELD rule failed to modify a reference to the coercion complaint process made necessary by the rule's restructuring of § 386.12. This rule corrects the applicable cross-reference in § 390.6(b)(1), replacing the reference to § 386.12(e) with § 386.12(c).

§ 391.42 Schedule for Use of Medical Examiners Listed on the National Registry

FMCSA removes § 391.42. The requirement that all medical examinations performed ''on or after May 21, 2014 . . . must be conducted by a medical examiner'' listed on the National Registry is not necessary as it duplicates the requirements in § 391.43.

§ 391.43 Medical Examination and Certificate of Physical Examination

FMCSA makes several amendments to a driver's medical exam, the form used to record the results of the exam, and the certificate issued upon completion of the exam. FMCSA amends § 391.43(a) to remove the reference to § 391.42, which is being deleted as discussed above.

The Agency also amends paragraph (f), first by removing paragraph (f)(1) because the use of the previous form authorized by that paragraph is no longer permitted. Second, the remaining text (from paragraph (f)(2) which went into effect on December 22, 2015) is revised to remove the effective date. Third, the latest approved version of Medical Examination Report (MER) Form, MCSA–5875 replaces the previous version.

Similar changes are made in paragraph (h) of § 391.43. First, FMCSA removes paragraph (h)(1) because the use of the previous form authorized by that paragraph is no longer permitted. Second, the Agency revises the remaining text (from paragraph (h)(2) which went into effect on December 22, 2015) to remove the effective date. Third, the Agency updates the version of Medical Examiner's Certificate (MEC) Form, MCSA–5876. Both the MER and MEC forms have been approved by OMB for use through August 31, 2018, under OMB number 2126–0006.

§ 392.9b Safety Registration

FMCSA revises the heading for paragraph (a) in § 392.9b, as well as the text within paragraph (a) to replace the term ''USDOT Registration'' with ''safety registration.'' This change should have been made as part of the Unified Registration System rule that was published on August 23, 2013 (78 FR 52608), and it should have gone into effect along with other changes to this section on November 1, 2013. FMCSA revises the term to conform to the terminology that is currently in place within the Unified Registration System, where there is no ''USDOT Registration.'' Rather, there are USDOT numbers, operating authority registration, and safety registration. As a result, this change should have no impact on the type of registrations that a motor carrier could receive from FMCSA.

§ 395.1 Restoration of Supporting Documents Exception for 100 Air-Mile Radius Drivers

FMCSA revises § 395.1(e)(1) to restore the supporting documents exception for 100 air-mile radius drivers inadvertently

[6] See *https://www.gpo.gov/fdsys/pkg/CFR-2005-title49-vol5/pdf/CFR-2005-title49-vol5-part385-appB.pdf.*

[7] November 30, 2015 (80 FR 74695, at 74709).

removed by a FAST Act final rule [8] published on July 22, 2016. The ELD [9] rule added the supporting documents exception for 100 air-mile radius drivers, but the FAST Act rule inadvertently removed it when FMCSA revised § 395.1(e)(1) to add new 49 U.S.C. 31502(f)(1) that exempts drivers of ready-mixed concrete delivery vehicles from keeping records of duty status under certain circumstances. FMCSA revises the introductory text of paragraph (e)(1) to restore it to read as set out in the regulatory text at the end of this document.

§ 395.8 Driver's Record of Duty Status

Since publication of the ELD rule in December 2015, FMCSA has received a significant number of questions asking how a motor carrier can determine whether a commercial motor vehicle was manufactured before model year 2000, thus allowing its driver to use paper records of duty status instead of the ELD required in most other cases. FMCSA amends § 395.8 to include an additional qualifying phrase to paragraph (a)(1)(iii)(A)(*4*) inserted after ''model year 2000.'' The model year 2000 will be determined during roadside inspections ''as reflected in the vehicle identification number as shown on the vehicle's registration.'' The vehicle identification number includes the model year. This will be particularly useful in light of the installation of truck-tractor glider kits. This technical correction eliminates any ambiguity.

§ 397.73 Hazardous Material (HM) Public Information and Reporting Requirements

FMCSA provides routing agencies with an alternative email address for reporting changes to their HM route registries. Each State and Indian tribe, through its routing agency, must provide information to FMCSA under § 397.73 identifying all non-radioactive hazardous material (NRHM) routing designations that exist within its jurisdiction. A similar requirement in § 397.103 requires reporting of preferred routes for highway route controlled shipments of radioactive materials. FMCSA is adding an optional, electronic way to send FMCSA the required information in both sections. Currently the regulation restricts transmittal to an address using certified mail, return receipt requested.

§ 397.101 Highway-Route Controlled Quantity Shipments of Radioactive Materials

Currently, § 397.101 requires each carrier that accepts for transportation a highway route controlled quantity of hazardous material, as defined in 49 CFR 173.403, to file certain information with FMCSA after accepting the package for transportation. FMCSA no longer uses this information, and therefore removes paragraph (g) from § 397.101.

§ 398.1 Transportation of Migrant Workers

FMCSA amends the definition of a migrant worker motor carrier to be consistent with the ICCTA's elimination of the terms ''contract'' and ''common'' in the phrases ''contract carrier by motor vehicle'' and ''common carrier by motor vehicle.'' FMCSA revises the definition to read as set out in the regulatory text at the end of this document.

Rulemaking Analyses

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

FMCSA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866, as supplemented by Executive Order 13563 (76 FR 3821, Jan. 18, 2011), or within the meaning of the DOT regulatory policies and procedures (44 FR 1103, Feb. 26, 1979). Thus, the Office of Management and Budget (OMB) did not review this document. We expect the final rule will have no costs; therefore, a full regulatory evaluation is unnecessary.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA) of 1980 (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FMCSA is not required to prepare a final regulatory flexibility analysis under 5 U.S.C. 604(a) for this final rule because the Agency has not issued a notice of proposed rulemaking prior to this action. FMCSA has determined that it has good cause to adopt the rule without notice and comment.

Unfunded Mandates Reform Act

The final rule will not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532, *et seq.*), that will result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $155 million (which is the value of $100 million in 2015 after adjusting for inflation) or more in any 1 year.

E.O. 13132 (Federalism)

A final rule has implications for Federalism under section 1(a) of Executive Order 13132 if it has ''substantial direct effects on the States, on the relationship between national government and the States, or on the distribution of power and responsibilities among various levels of government.'' FMCSA has determined that this rule will not have substantial direct effects on States, nor will it limit the policymaking discretion of States. Nothing in this document preempts or modifies any provision of State law or regulation, imposes substantial direct unreimbursed compliance costs on any State, or diminishes the power of any State to enforce its own laws. Accordingly, this rulemaking does not have Federalism implications warranting the application of E.O. 13132.

E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rule.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175 titled, ''Consultation and Coordination with Indian Tribal Governments,'' because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. FMCSA determined that no new information collection requirements are associated with this final rule, nor are there any revisions to existing, approved collections of information. Therefore, the PRA does not apply to this final rule.

National Environmental Policy Act

FMCSA analyzed this final rule for the purpose of ascertaining the applicability of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined under our Environmental Procedures

[8] *Amendments To Implement Certain Provisions of the Fixing America's Surface Transportation Act or ''FAST Act,''* July 22, 2016 (81 FR 47714, at 47721).

[9] *Electronic Logging Devices and Hours of Service Supporting Documents* final rule, December 16, 2015 (80 FR 78292, at 78381).

Order 5610.1, issued March 1, 2004 (69 FR 9680), that this action would not have any effect on the quality of the environment. In addition, this final rule is categorically excluded from further analysis and documentation under the Categorical Exclusion (CE) in paragraph 6(b) of Appendix 2 of FMCSA Order 5610.1. This CE addresses minor editorial corrections such as those found in this rulemaking; therefore, preparation of an environmental assessment or environmental impact statement is not necessary.

FMCSA also analyzed this rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 42 U.S.C. 7506(c)), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it does not affect direct or indirect emissions of criteria pollutants.

E.O. 12898 (Environmental Justice)

This final rule is not subject to Executive Order 12898 (59 FR 7629, Feb. 16, 1994). Executive Order 12898 establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. FMCSA determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not change the substance of any of the FMCSRs.

E.O. 13211 (Energy Effects)

FMCSA has analyzed this final rule under Executive Order 13211 titled, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' The Agency has determined that it is not a ''significant energy action'' under that Executive Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, no Statement of Energy Effects is required.

E.O. 13045 (Protection of Children)

Executive Order 13045 titled, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, Apr. 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. As discussed previously, this rule is not economically significant. Therefore, no analysis of the impacts on children is required. Nevertheless, as this final rule does not change the substance of any of the FMCSRs, FMCSA does not believe it will have any environmental health or safety impacts on children.

E.O. 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988 titled, ''Civil Justice Reform,'' to minimize litigation, eliminate ambiguity, and reduce burden.

E.O. 12630 (Taking of Private Property)

This final rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630 titled, ''Governmental Actions and Interference with Constitutionally Protected Property Rights.''

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) requires Federal agencies proposing to adopt technical standards to consider whether voluntary consensus standards are available. If the Agency chooses to adopt its own standards in place of existing voluntary consensus standards, it must explain its decision in a separate statement to OMB. Because this final rule does not adopt technical standards, there is no need to submit a separate statement to OMB on this matter.

Privacy Impact Assessment

Section 522(a)(5) of the Transportation, Treasury, Independent Agencies, and General Government Appropriations Act, 2005 (Pub. L. 108–447, Division H, Title I, 118 Stat. 2809 at 3268, Dec. 8, 2004) requires DOT and certain other Federal agencies to conduct a privacy impact assessment of each rule that will affect the privacy of individuals. Because this final rule will not affect the privacy of individuals, FMCSA did not conduct a separate privacy impact assessment.

List of Subjects

49 CFR Part 355

Highway safety, Intergovernmental relations, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 356

Administrative practice and procedure, Freight forwarders, Highways and roads, Motor carriers.

49 CFR Part 365

Administrative practice and procedure, Brokers, Buses, Freight forwarders, Maritime carriers, Mexico, Motor carriers, Moving of household goods.

49 CFR Part 369

Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 370

Freight forwarders, Investigations, Motor carriers.

49 CFR Part 373

Buses, Freight, Freight forwarders, Motor carriers, Moving of household goods.

49 CFR Part 374

Aged, Blind, Buses, Civil rights, Freight, Individuals with disabilities, Motor carriers, Smoking.

49 CFR Part 376

Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 377

Credit, Freight forwarders, Maritime carriers, Motor carriers, Moving of household goods.

49 CFR Part 378

Freight forwarders, Investigations, Motor carriers, Motor of household goods.

49 CFR Part 382

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

49 CFR Part 385

Administrative practice and procedure, Highway safety, Mexico, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 386

Administrative practice and procedure, Brokers, Freight forwarders, Hazardous materials transportation, Highway safety, Motor carriers, Motor vehicle safety, Penalties.

49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation.

49 CFR Part 392

Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

49 CFR Part 395

Highway safety, Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 397

Administrative practice and procedure, Hazardous materials transportation, Highway safety, Intergovernmental relations, Motor carriers, Parking, Radioactive materials, Reporting and recordkeeping requirements, Rubber and rubber products.

49 CFR Part 398

Highway safety, Migrant labor, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA is amending 49 CFR chapter III, subchapter B, parts 355, 356, 365, 369, 370, 373, 374, 376, 377, 378, 382, 383, 384, 385, 386, 390, 391, 392, 395, 397, and 398, as set forth below:

PART 355—COMPATIBILITY OF STATE LAWS AND REGULATIONS AFFECTING INTERSTATE MOTOR CARRIER OPERATIONS

■ 1. The authority citation for part 355 continues to read as follows:

Authority: 49 U.S.C. 504 and 31101 *et seq.;* and 49 CFR 1.87.

■ 2. Revise the applicability section of appendix A to part 355 to read as follows:

Appendix A to Part 355—Guidelines for the Regulatory Review

* * * * *

Applicability

The requirements must apply to all segments of the motor carrier industry, for-hire and private carriers of property and for-hire carriers of passengers.

* * * * *

PART 356—MOTOR CARRIER ROUTING REGULATIONS

■ 3. The authority citation for part 356 continues to read as follows:

Authority: 5 U.S.C. 553; 49 U.S.C. 13301 and 13902; and 49 CFR 1.87.

§ 356.7 [Removed]

■ 4. Remove § 356.7.

§ 356.9 [Removed]

■ 5. Remove § 356.9.

§ 356.11 [Removed]

■ 6. Remove § 356.11.

§ 356.13 [Removed]

■ 7. Remove § 356.13.

PART 365—RULES GOVERNING APPLICATIONS FOR OPERATING AUTHORITY

■ 8. The authority citation for part 365 continues to read as follows:

Authority: 5 U.S.C. 553 and 559; 49 U.S.C. 13101, 13301, 13901–13906, 14708, 31138, and 31144; sec. 5524 of Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 9. Amend § 365.105 by revising paragraph (b) to read as follows:

§ 365.105 Starting the application process: Form OP–1.

* * * * *

(b) Obtain forms at a FMCSA Division Office in each State or at one of the FMCSA Service Centers. Addresses and phone numbers for the Division Offices and Service Centers can be found at: *https://www.fmcsa.dot.gov/mission/field-offices.* The forms and information about filing procedures can be downloaded at: *https://www.fmcsa.dot.gov/registration/registration-forms.*

■ 10. Amend § 365.205 by revising paragraph (d) to read as follows:

§ 365.205 Contents of the protest.

* * * * *

(d) Protests must respond directly to the statutory standards for FMCSA review of the application. As these standards vary for particular types of applications, potential protestants should refer to the general criteria addressed at § 365.107 and may consult the FMCSA at 800–832–5660 or via the web form at *https://www.fmcsa.dot.gov/ask* for further assistance in developing their evidence.

■ 11. Amend § 365.413 by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 365.413 Procedures for changing the name or business form of a motor carrier, freight forwarder, or property broker.

* * * * *

(b) *Procedures.* To accomplish these changes, a letter or signed copy of form MCSA–5889, ''Motor Carrier Records Change Form,'' OMB No. 2126–0060, must be submitted to the Federal Motor Carrier Safety Administration. It must be submitted in one of the following three ways.

(1) Scanned and submitted via the web form at *https://www.fmcsa.dot.gov/ask;*

(2) Faxed to (202–366–3477); or

(3) Mailed to the Federal Motor Carrier Safety Administration, Office of Registration and Safety Information (MC–RS), 1200 New Jersey Ave. SE., Washington, DC 20590–0001. The envelope should be marked ''NAME CHANGE''.

(c) The registrant must provide:

(1) The docket number(s) and name of the carrier, freight forwarder, or property broker requesting the change;

(2) A copy of the articles of incorporation and the State certificate reflecting the incorporation;

(3) The name(s) of the owner(s) of the stock and the distribution of the shares;

(4) The names of the officers and directors of the corporation; and

(5) A statement that there is no change in the ownership, management, or control of the business. When this procedure is being used to transfer operating rights from a deceased or incapacitated spouse to the other spouse, documentation that the other spouse has the legal right to effect such change must be included with the request. The fee for filing a name change request is in § 360.3(f) of this chapter.

PART 369—REPORTS OF MOTOR CARRIERS

■ 12. The authority citation for part 369 continues to read as follows:

Authority: 49 U.S.C. 14123; 49 CFR 1.87.

■ 13. Amend § 369.1 by revising the heading and paragraph (a) to read as follows:

§ 369.1 Annual reports of for-hire, non-exempt motor carriers of property, motor carriers of household goods, and dual property carriers.

(a) *Annual Report Form M.* All class I and class II for-hire, non-exempt motor carriers of property, including household goods and dual property motor carriers, must file Motor Carrier Annual Report Form M (Form M). Carriers must file the annual report on or before March 31 of the year following

the year to which it relates. For classification criteria, see § 369.2.
* * * * *

■ 14. Amend § 369.2 by revising the heading and the introductory text of paragraph (a) to read as follows:

§ 369.2 Classification of carriers—for-hire, non-exempt motor carriers of property, household goods carriers, and dual property carriers.

(a) For-hire, non-exempt motor carriers of property are grouped into the following three classes:
* * * * *

■ 15. Amend § 369.3 by revising the heading and the introductory text of paragraph (a) to read as follows:

§ 369.3 Classification of carriers—for-hire, non-exempt motor carriers of passengers.

(a) For-hire, non-exempt motor carriers of passengers are grouped into the following two classes:
* * * * *

PART 370—PRINCIPLES AND PRACTICES FOR THE INVESTIGATION AND VOLUNTARY DISPOSITION OF LOSS AND DAMAGE CLAIMS AND PROCESSING SALVAGE

■ 16. The authority citation for part 370 continues to read as follows:

Authority: 49 U.S.C. 13301 and 14706; and 49 CFR 1.87.

■ 17. Amend § 370.9 by revising paragraph (b) to read as follows:

§ 370.9 Disposition of claims.
* * * * *

(b) When settling a claim for loss or damage, a household goods motor carrier as defined in § 375.103 of this subchapter shall use the replacement costs of the lost or damaged item as a base to apply a depreciation factor to arrive at the current actual value of the lost or damaged item.

PART 373—RECEIPTS AND BILLS

■ 18. The authority citation for part 373 continues to read as follows:

Authority: 49 U.S.C. 13301, 13531, and 14706; and 49 CFR 1.87.

■ 19. Add § 373.100 to read as follows:

§ 373.100 Applicability.

This subpart applies to motor carriers subject to 49 U.S.C. subtitle IV, part B (secs. 13101–14916).

■ 20. Amend § 373.101 by revising the heading and introductory text to read as follows:

§ 373.101 For-hire, non-exempt motor carrier bills of lading.

Every motor carrier subject to § 373.100 shall issue a receipt or bill of lading for property tendered for transportation in interstate or foreign commerce containing the following information:
* * * * *

■ 21. Amend § 373.103 by revising the heading and paragraphs (a) introductory text and (b) introductory text to read as follows:

§ 373.103 For-hire, non-exempt expense bills.

(a) *Property.* Every for-hire, non-exempt motor carrier shall issue a freight or expense bill for each shipment transported containing the following information:
* * * * *

(b) *Charter transportation of passenger service.* Every for-hire, non-exempt motor carrier providing charter transportation of passenger service shall issue an expense bill containing the following information:
* * * * *

PART 374— PASSENGER CARRIER REGULATIONS

■ 22. The authority citation for part 374 continues to read as follows:

Authority: 49 U.S.C. 13301 and 14101; and 49 CFR 1.87.

■ 23. Add § 374.1 before subpart A to read as follows:

§ 374.1 Applicability.

This part applies to motor carriers subject to 49 U.S.C. subtitle IV, part B (secs. 13101–14916).

■ 24. Revise the heading for subpart A to read as follows:

Subpart A—Discrimination in Operations of Interstate Motor Carriers of Passengers

§ 374.101 [Amended]

■ 25. In § 374.101, remove the word ''common''.

§ 374.103 [Amended]

■ 26. In § 374.103, remove the word ''common''.

§ 374.105 [Amended]

■ 27. In § 374.105, remove the word ''common''.

§ 374.107 [Amended]

■ 28. In § 374.107, remove the word ''common'' and the word ''Common''.

§ 374.109 [Amended]

■ 29. In § 374.109, remove the word ''common''.

§ 374.111 [Amended]

■ 30. In § 374.111, remove the word ''common''.

§ 374.113 [Amended]

■ 31. In § 374.113, paragraph (a), remove the word ''common''.

§ 374.201 [Amended]

■ 32. In § 374.201, remove the word ''common''.

■ 33. Revise the heading for subpart C to read as follows:

Subpart C—Adequacy of Intercity Motor Carrier Passenger Service

§ 374.301 [Amended]

■ 34. In § 374.301, remove the word ''common''.

§ 374.303 [Amended]

■ 35. In § 374.303, paragraph (a), remove the word ''common''.

■ 36. Revise § 374.401 to read as follows:

§ 374.401 Minimum permissible limitations for baggage liability.

Motor carriers of passengers and baggage subject to 49 U.S.C. 13501 may not publish tariff provisions limiting their liability for loss or damage to baggage checked by a passenger transported in regular route or special operations unless:

(a) The amount for which liability is limited is $250 or greater per adult fare; and

(b) The provisions permit the passenger, for an additional charge, to declare a value in excess of the limited amount, and allow the passenger to recover the increased amount (but not higher than the actual value) in event of loss or damage. The carriers may publish a maximum value for which they will be liable, but that maximum value may not be less than $1,000. Appropriate identification must be attached securely by the passenger to each item of baggage checked, indicating in a clear and legible manner the name and address to which the baggage should be forwarded if lost and subsequently recovered. Identification tags shall be made immediately available by the carriers to passengers upon request.

(c) Carriers need not offer excess value coverage on articles listed in § 374.307(c)(3).

§ 374.403 [Amended]

■ 37. In § 374.403, paragraph (a), remove the word ''common''.

§ 374.405 [Amended]

■ 38. In § 374.405, remove the word ''common''.

Subpart E—Incidental Charter Rights

■ 39. The authority citation for subpart E to part 374 is revised to read as follows:

Authority: 49 U.S.C. 13301, 13501, 13506; and 49 CFR 1.87.

§ 374.501 [Amended]

■ 40. Amend § 374.501 by removing ''[49 U.S.C. 10932(c)]''.

PART 376—LEASE AND INTERCHANGE OF VEHICLES

■ 41. The authority citation for part 376 continues to read as follows:

Authority: 49 U.S.C. 13301 and 14102; and 49 CFR 1.87.

■ 42. Amend § 376.1 by revising the introductory text and paragraph (c) to read as follows:

§ 376.1 Applicability.

The regulations in this part apply to the following actions by motor carriers registered with the Secretary to transport property under 49 U.S.C. subtitle IV, part B:

* * * * *

(c) The interchange of equipment between for-hire motor carriers in the performance of transportation regulated by the Secretary.

§ 376.2 [Amended]

■ 43. Amend § 376.2 by removing the term ''common'' in paragraph (c).

■ 44. Amend § 376.31 as follows:

■ a. Revise the introductory text; and

■ b. Revise the introductory text of paragraph (d), the first sentence of paragraph (d)(1), and the first sentence of paragraph (d)(2).

The revisions read as follows:

§ 376.31 Interchange of equipment.

Authorized for-hire motor carriers may interchange equipment under the following conditions:

* * * * *

(d) *Identification of equipment.* The authorized for-hire motor carrier receiving the equipment shall identify equipment operated by it in interchange service as follows:

(1) The authorized for-hire motor carrier shall identify power units in accordance with FMCSA's requirements in 49 CFR part 390 (Identification of Vehicles). * * *

(2) Unless a copy of the interchange agreement is carried on the equipment, the authorized for-hire motor carrier shall carry a statement with each vehicle during interchange service certifying that it is operating the equipment. * * *

* * * * *

PART 377—PAYMENT OF TRANSPORTATION CHARGES

■ 45. The authority citation for part 377 continues to read as follows:

Authority: 49 U.S.C. 13101, 13301, 13701, 13702, 13706, 13707, and 14101; and 49 CFR 1.87.

■ 46. Revise § 377.101 to read as follows:

§ 377.101 Applicability.

(a) *Applicability.* The rules and regulations in this part apply to the transportation by motor vehicle of cash-on-delivery (c.o.d.) shipments by all for-hire motor carriers of property subject to 49 U.S.C. 13702.

(b) *Exceptions.* (1) The rules in this part do not apply to transportation which is auxiliary to or supplemental of transportation by railroad and performed on railroad bills of lading.

(2) The rules in this part do not apply to transportation which is performed for freight forwarders and on freight forwarder bills of lading.

§ 377.103 [Amended]

■ 47. Amend § 377.103 by removing the term ''common'' and adding in its place the term ''motor''.

§ 377.105 [Amended]

■ 48. Amend § 377.105 by removing the term ''common'' and adding in its place the term ''motor''.

■ 49. Revise the heading to subpart B of part 377 to read as follows:

Subpart B—Extension of Credit to Shippers by For-Hire, Non-Exempt Motor Carriers and Household Goods Freight Forwarders

■ 50. Revise § 377.201 to read as follows:

§ 377.201 Scope.

(a) *General.* These regulations apply to the extension of credit in the transportation of property under Federal Motor Carrier Safety Administration regulation by for-hire, non-exempt motor carriers and household goods freight forwarders subject to 49 U.S.C. subtitle IV, part B, except as otherwise provided.

(b) *Exceptions.* These regulations do not apply to—

(1) Transportation for—

(i) The United States or any department, bureau, or agency thereof;

(ii) Any State or political subdivision thereof; or

(iii) The District of Columbia.

(2) Property transportation incidental to passenger operations.

§ 377.217 [Amended]

■ 51. Amend § 377.217 by removing the term ''common'' and adding in its place the term ''motor''.

PART 378—PROCEDURES GOVERNING THE PROCESSING, INVESTIGATION, AND DISPOSITION OF OVERCHARGE, DUPLICATE PAYMENT, OR OVERCOLLECTION CLAIMS

■ 52. The authority citation for part 378 continues to read as follows:

Authority: 49 U.S.C. 13321, 14101, 14704 and 14705; and 49 CFR 1.87.

§ 378.1 [Amended]

■ 53. Amend § 378.1 by removing the term ''common''.

§ 378.2 [Amended]

■ 54. Amend § 378.2 by removing the term ''common'' in paragraph (a).

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

■ 55. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31301 *et seq.,* 31502; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

■ 56. Amend § 382.103 by revising paragraph (d)(3)(i)(C) to read as follows:

§ 382.103 Applicability.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(C) Not used in the operations of a for-hire motor carrier, except for an exempt motor carrier as defined in § 390.5 of this subchapter;

* * * * *

§ 382.305 [Amended]

■ 57. In § 382.305, amend paragraph (b)(2) by removing ''50 percent'' and adding in its place ''25 percent''.

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 58. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 *et seq.,* and 31502; secs. 214 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56, 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 7208 of Pub. L. 114–94, 129 Stat. 1312, 1593; and 49 CFR 1.87.

■ 59. Amend § 383.3 by revising paragraph (d)(1)(iii) to read as follows:

§ 383.3 Applicability.

* * * * *

(d) * * *

(1) * * *

(iii) Not used in the operations of a for-hire motor carrier, except for an exempt motor carrier as defined in § 390.5 of this subchapter;

* * * * *

■ 60. Amend § 383.5 by revising the definition of *School bus* to read as follows:

§ 383.5 Definitions.

* * * * *

School bus means a CMV used to transport pre-primary, primary, or secondary school students from home to school, from school to home, or to and from school-sponsored events. School bus does not include operations of a for-hire motor carrier.

* * * * *

■ 61. Amend § 383.77 by revising paragraph (a)(5) to read as follows:

§ 383.77 Substitute for driving skills tests for drivers with military CMV experience.

* * * * *

(a) * * *

(5) Has not had any conviction for a violation of military, State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with any traffic accident, and has no record of an accident in which he/she was at fault; and

* * * * *

§ 383.131 [Amended]

■ 62. Amend § 383.131 by removing all references to ''July 2010'' and adding in its place the phrase ''July 2010 or newer''.

§ 383.133 [Amended]

■ 63. Amend § 383.133 by removing all references to ''July 2010'' and adding in its place the phrase ''July 2010 or newer''.

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 64. The authority citation for part 384 is continues to read as follows:

Authority: 49 U.S.C. 31136, 31301, *et seq.,* and 31502; secs. 103 and 215 of Pub. L. 106–59, 113 Stat. 1753, 1767; and 49 CFR 1.87.

■ 65. Revise § 384.401 to read as follows:

§ 384.401 Withholding of funds based on noncompliance.

(a) *Following the first year of noncompliance.* An amount up to 4 percent of the Federal-aid highway funds required to be apportioned to any State under each of sections 104(b)(1), (b)(3), and (b)(4) of title 23 U.S.C. shall be withheld from a State on the first day of the fiscal year following such State's first year of noncompliance under this part.

(b) *Following second and subsequent year(s) of noncompliance.* An amount up to 8 percent of the Federal-aid highway funds required to be apportioned to any State under each of sections 104(b)(1), (b)(3), and (b)(4) of title 23 U.S.C. shall be withheld from a State on the first day of the fiscal year following such State's second or subsequent year(s) of noncompliance under this part.

§ 384.407 [Removed and Reserved]

■ 66. Remove and reserve § 384.407.

PART 385—SAFETY FITNESS PROCEDURES

■ 67. The authority citation for part 385 continues to read as follows:

Authority: 49 U.S.C. 113, 504, 521(b), 5105(d), 5109, 13901–13905, 31133, 31135, 31136, 31137, 31144, 31148, and 31502; Sec. 113(a), Pub. L. 103–311; Sec. 408, Pub. L. 104–88, 109 Stat. 803, 958; Sec. 350, Pub. L. 107–87; and 49 CFR 1.87.

■ 68. Revise § 385.303 to read as follows:

§ 385.303 How does a motor carrier register with the FMCSA?

A motor carrier may contact the FMCSA by internet (*www.fmcsa.dot.gov*); or Washington, DC headquarters by mail at, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590–0001; fax 202–366–3477; or telephone 1–800–832–5660, and request the application materials for a new entrant motor carrier. Forms can also be downloaded from *https://www.fmcsa.dot.gov/registration/registration-forms.* A motor carrier which does not already have a USDOT number must apply online via the Unified Registration System (URS) at *www.fmcsa.dot.gov/urs.*

■ 69. Amend appendix B to part 385 as follows:

■ a. Revise paragraph (c) of the introductory text.

■ b. Republish section II.(c).

■ c. In section VII, revise the entries for §§ 395.8(a)(2)(ii) and 395.11(b).

The revisions read as follows:

Appendix B to Part 385—Explanation of Safety Rating Process

* * * * *

(c) To meet the safety fitness standard, a motor carrier must demonstrate to the FMCSA that it has adequate safety management controls in place which function effectively to ensure acceptable compliance with the applicable safety requirements. A ''safety fitness methodology'' (SFRM) was developed by the FMCSA, which uses data from compliance reviews (CRs) and roadside inspections to rate motor carriers.

* * * * *

II. Converting CR Information Into a Safety Rating

* * * * *

(c) Critical regulations are those identified as such where noncompliance relates to management and/or operational controls. These are indicative of breakdowns in a carrier's management controls. An example of a critical regulation is § 395.3(a)(1), requiring or permitting a property-carrying commercial motor vehicle driver to drive more than 11 hours.

* * * * *

VII. List of Acute and Critical Regulations

* * * * *

§ 395.8(a)(2)(ii) Failure to require a driver to submit record of duty status (critical).

* * * * *

§ 395.11(b) Failing to require a driver to submit supporting documents (critical).

* * * * *

PART 386—RULES OF PRACTICE FOR FMCSA PROCEEDINGS

■ 70. The authority citation for part 386 is revised to read as follows:

Authority: 49 U.S.C. 113; 49 U.S.C. chapters 5, 51, 59, 131–141, 145–149, 311, 313, and 315; Sec. 204, Pub. L. 104–88, 109 Stat. 803, 941 (49 U.S.C. 701 note); Sec. 217, Pub. L. 105–159, 113 Stat. 1748, 1767; Sec. 206, Pub. L. 106–159, 113 Stat. 1763; subtitle B, title IV of Pub. L. 109–59; Sec. 701 of Pub. L. 114–74, 129 Stat. 584, 599; and 49 CFR 1.81 and 1.87.

■ 71. Amend § 386.1 by revising paragraph (c) to read as follows:

§ 386.1 Scope of rules in this part.

* * * * *

(c)(1) The rules in § 386.12(a) govern the filing of a complaint of a substantial violation and the handling of the complaint by the appropriate Division Administrator.

(2) The rules in § 386.12(b) govern the filing by a driver and the handling by the appropriate Division Administrator of a complaint of harassment in violation of § 390.36 of this subchapter.

(3) The rules in § 386.12(c) govern the filing by a driver and the handling by the appropriate Division Administrator of a complaint of coercion in violation of § 390.6 of this subchapter.

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 72. The authority citation for part 390 is revised to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31149, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677–1678; sec. 212, 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as transferred by sec. 4114 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743–1744); sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; sec. 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; sec. 5518, 5524, Pub. L. 114–94, 129 Stat. 1312, 1558, 1560; and 49 CFR 1.81, 1.81a, and 1.87.

■ 73. Amend § 390.6 by revising paragraph (b)(1) to read as follows:

§ 390.6 Coercion prohibited.

* * * * *

(b) * * *

(1) A driver who believes he or she was coerced to violate a regulation described in paragraph (a)(1) or (2) of this section may file a written complaint under § 386.12(c) of this subchapter.

* * * * *

PART 391—QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION VEHICLE (LCV) DRIVER INSTRUCTORS

■ 74. The authority citation for part 391 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31133, 31136, 31149, and 31502; sec. 4007(b) of Pub. L. 102–240, 105 Stat. 1914, 2152; sec. 114 of Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215 of Pub. L. 106–159, 113 Stat. 1748, 1767; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524 of Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

§ 391.42 [Removed]

■ 75. Remove § 391.42.

■ 76. Amend § 391.43 by revising paragraphs (a), (f), and (h) to read as follows:

§ 391.43 Medical examination; certificate of physical examination.

(a) Except as provided by paragraph (b) of this section, the medical examination must be performed by a medical examiner listed on the National Registry of Certified Medical Examiners under subpart D of part 390 of this chapter.

* * * * *

(f) The medical examination shall be performed, and its results shall be recorded on the Medical Examination Report Form, MCSA–5875, set out below:

BILLING CODE 4910–EX–P

Form MCSA-5875 OMB No. 2126-0006

Public Burden Statement
A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2126-0006. Public reporting for this collection of information is estimated to be approximately 25 minutes per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Motor Carrier Safety Administration, MC-RRA, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

U.S. Department of Transportation
Federal Motor Carrier
Safety Administration

Medical Examination Report Form
(for Commercial Driver Medical Certification)

MEDICAL RECORD #
_____
(or sticker)

SECTION 1. Driver Information *(to be filled out by the driver)*

PERSONAL INFORMATION

Last Name: _____ First Name: _____ Middle Initial: ____ Date of Birth: _____ Age: ___

Street Address: _____ City: _____ State/Province: _____ Zip Code: _____

Driver's License Number: _____ Issuing State/Province: _____ Phone: _____ Gender: ○ M ○ F

E-mail *(optional)*: _____ CLP/CDL Applicant/Holder*: ○ Yes ○ No

Driver ID Verified By**: _____

Has your USDOT/FMCSA medical certificate ever been denied or issued for less than 2 years? ○ Yes ○ No ○ Not Sure

*CLP/CDL Applicant/Holder: See instructions for definitions.

**Driver ID Verified By: Record what type of photo ID was used to verify the identity of the driver, e.g., CDL, driver's license, passport.

DRIVER HEALTH HISTORY

Have you ever had surgery? If "yes," please list and explain below. ○ **Yes** ○ **No** ○ **Not Sure**

Are you currently taking medications *(prescription, over-the-counter, herbal remedies, diet supplements)*? If "yes," please describe below. ○ **Yes** ○ **No** ○ **Not Sure**

(Attach additional sheets if necessary)

This document contains sensitive information and is for official use only. Improper handling of this information could negatively affect individuals. Handle and secure this information appropriately to prevent inadvertent disclosure by keeping the documents under the control of authorized persons. Properly dispose of this document when no longer required to be maintained by regulatory requirements.

Form MCSA-5875 OMB No. 2126-0006

Last Name: _____ First Name: _____ DOB: _____ Exam Date: _____

DRIVER HEALTH HISTORY *(continued)*

Do you have or have you ever had:	Yes	No	Not Sure
1. Head/brain injuries or illnesses *(e.g., concussion)*	○	○	○
2. Seizures, epilepsy	○	○	○
3. Eye problems *(except glasses or contacts)*	○	○	○
4. Ear and/or hearing problems	○	○	○
5. Heart disease, heart attack, bypass, or other heart problems	○	○	○
6. Pacemaker, stents, implantable devices, or other heart procedures	○	○	○
7. High blood pressure	○	○	○
8. High cholesterol	○	○	○
9. Chronic (long-term) cough, shortness of breath, or other breathing problems	○	○	○
10. Lung disease *(e.g., asthma)*	○	○	○
11. Kidney problems, kidney stones, or pain/problems with urination	○	○	○
12. Stomach, liver, or digestive problems	○	○	○
13. Diabetes or blood sugar problems	○	○	○
Insulin used	○	○	○
14. Anxiety, depression, nervousness, other mental health problems	○	○	○
15. Fainting or passing out	○	○	○
16. Dizziness, headaches, numbness, tingling, or memory loss	○	○	○
17. Unexplained weight loss	○	○	○
18. Stroke, mini-stroke (TIA), paralysis, or weakness	○	○	○
19. Missing or limited use of arm, hand, finger, leg, foot, toe	○	○	○
20. Neck or back problems	○	○	○
21. Bone, muscle, joint, or nerve problems	○	○	○
22. Blood clots or bleeding problems	○	○	○
23. Cancer	○	○	○
24. Chronic (long-term) infection or other chronic diseases	○	○	○
25. Sleep disorders, pauses in breathing while asleep, daytime sleepiness, loud snoring	○	○	○
26. Have you ever had a sleep test *(e.g., sleep apnea)*?	○	○	○
27. Have you ever spent a night in the hospital?	○	○	○
28. Have you ever had a broken bone?	○	○	○
29. Have you ever used or do you now use tobacco?	○	○	○
30. Do you currently drink alcohol?	○	○	○
31. Have you used an illegal substance within the past two years?	○	○	○
32. Have you ever failed a drug test or been dependent on an illegal substance?	○	○	○

Other health condition(s) not described above: ○ Yes ○ No ○ Not Sure

Did you answer "yes" to any of questions 1-32? If so, please comment further on those health conditions below. ○ Yes ○ No ○ Not Sure

(Attach additional sheets if necessary)

CMV DRIVER'S SIGNATURE

I certify that the above information is accurate and complete. I understand that inaccurate, false or missing information may invalidate the examination and my Medical Examiner's Certificate, that submission of fraudulent or intentionally false information is a violation of 49 CFR 390.35, and that submission of fraudulent or intentionally false information may subject me to civil or criminal penalties under 49 CFR 390.37 and 49 CFR 386 Appendices A and B.

Driver's Signature: _____ Date: _____

SECTION 2. Examination Report *(to be filled out by the medical examiner)*

DRIVER HEALTH HISTORY REVIEW

Review and discuss pertinent driver answers and any available medical records. Comment on the driver's responses to the "health history" questions that may affect the driver's safe operation of a commercial motor vehicle (CMV).

(Attach additional sheets if necessary)

Form MCSA-5875 OMB No. 2126-0006

Last Name: _____ First Name: _____ DOB: _____ Exam Date: _____

TESTING

Pulse rate: _____ Pulse rhythm regular: ○ Yes ○ No Height: ___ feet ___ inches Weight: ____ pounds

Blood Pressure	Systolic	Diastolic
Sitting		
Second reading (optional)		

Urinalysis	Sp. Gr.	Protein	Blood	Sugar
Urinalysis is required. Numerical readings must be recorded.				

Other testing if indicated

Protein, blood, or sugar in the urine may be an indication for further testing to rule out any underlying medical problem.

Vision

Standard is at least 20/40 acuity (Snellen) in each eye with or without correction. At least 70° field of vision in horizontal meridian measured in each eye. The use of corrective lenses should be noted on the Medical Examiner's Certificate.

Acuity	Uncorrected	Corrected	Horizontal Field of Vision
Right Eye:	20/____	20/____	Right Eye: ____ degrees
Left Eye:	20/____	20/____	Left Eye: ____ degrees
Both Eyes:	20/____	20/____	

	Yes	No
Applicant can recognize and distinguish among traffic control signals and devices showing red, green, and amber colors	○	○
Monocular vision	○	○
Referred to ophthalmologist or optometrist?	○	○
Received documentation from ophthalmologist or optometrist?	○	○

Hearing

*Standard: Must first perceive whispered voice at not less than 5 feet **OR** average hearing loss of less than or equal to 40 dB, in better ear (with or without hearing aid).*

Check if hearing aid used for test: ☐ Right Ear ☐ Left Ear ☐ Neither

Whisper Test Results	Right Ear	Left Ear
Record distance *(in feet)* from driver at which a forced whispered voice can first be heard		

OR

Audiometric Test Results

Right Ear			Left Ear		
500 Hz	1000 Hz	2000 Hz	500 Hz	1000 Hz	2000 Hz

Average (right): _____ Average (left): _____

PHYSICAL EXAMINATION

The presence of a certain condition may not necessarily disqualify a driver, particularly if the condition is controlled adequately, is not likely to worsen, or is readily amenable to treatment. Even if a condition does not disqualify a driver, the Medical Examiner may consider deferring the driver temporarily. Also, the driver should be advised to take the necessary steps to correct the condition as soon as possible, particularly if neglecting the condition could result in a more serious illness that might affect driving.

Check the body systems for abnormalities.

Body System	Normal	Abnormal	Body System	Normal	Abnormal
1. General	○	○	8. Abdomen	○	○
2. Skin	○	○	9. Genito-urinary system including hernias	○	○
3. Eyes	○	○	10. Back/Spine	○	○
4. Ears	○	○	11. Extremities/joints	○	○
5. Mouth/throat	○	○	12. Neurological system including reflexes	○	○
6. Cardiovascular	○	○	13. Gait	○	○
7. Lungs/chest	○	○	14. Vascular system	○	○

Discuss any abnormal answers in detail in the space below and indicate whether it would affect the driver's ability to operate a CMV. Enter applicable item number before each comment.

(Attach additional sheets if necessary)

Form MCSA-5875 OMB No. 2126-0006

Last Name: _____ First Name: _____ DOB: _____ Exam Date: _____

Please complete only one of the following (Federal or State) Medical Examiner Determination sections:

MEDICAL EXAMINER DETERMINATION (Federal)

Use this section for examinations performed in accordance with the Federal Motor Carrier Safety Regulations (49 CFR 391.41-391.49):

◯ Does not meet standards *(specify reason)*: _____

◯ Meets standards in 49 CFR 391.41; qualifies for 2-year certificate

◯ Meets standards, but periodic monitoring required *(specify reason)*: _____

Driver qualified for: ◯ 3 months ◯ 6 months ◯ 1 year ◯ other *(specify)*: _____

☐ Wearing corrective lenses ☐ Wearing hearing aid ☐ Accompanied by a waiver/exemption *(specify type)*: _____

☐ Accompanied by a Skill Performance Evaluation (SPE) Certificate ☐ Qualified by operation of 49 CFR 391.64 *(Federal)*

☐ Driving within an exempt intracity zone *(see 49 CFR 391.62) (Federal)*

☐ Determination pending *(specify reason)*: _____

☐ Return to medical exam office for follow-up on *(must be 45 days or less)*: _____

☐ Medical Examination Report amended *(specify reason)*: _____

(if amended) Medical Examiner's Signature: _____ Date: _____

☐ Incomplete examination *(specify reason)*: _____

If the driver meets the standards outlined in 49 CFR 391.41, then complete a Medical Examiner's Certificate as stated in 49 CFR 391.43(h), as appropriate.

I have performed this evaluation for certification. I have personally reviewed all available records and recorded information pertaining to this evaluation, and attest that to the best of my knowledge, I believe it to be true and correct.

Medical Examiner's Signature: _____

Medical Examiner's Name *(please print or type)*: _____

Medical Examiner's Address: _____ City: _____ State: _____ Zip Code: _____

Medical Examiner's Telephone Number: _____ Date Certificate Signed: _____

Medical Examiner's State License, Certificate, or Registration Number: _____ Issuing State: _____

☐ MD ☐ DO ☐ Physician Assistant ☐ Chiropractor ☐ Advanced Practice Nurse

☐ Other Practitioner *(specify)*: _____

National Registry Number: _____ Medical Examiner's Certificate Expiration Date: _____

Form MCSA-5875 OMB No. 2126-0006

Last Name: _____ First Name: _____ DOB: _____ Exam Date: _____

MEDICAL EXAMINER DETERMINATION (State)

Use this section for examinations performed in accordance with the Federal Motor Carrier Safety Regulations (49 CFR 391.41-391.49) with any applicable State variances (which will only be valid for intrastate operations):

◯ Does not meet standards in 49 CFR 391.41 with any applicable State variances *(specify reason)*: _____

◯ Meets standards in 49 CFR 391.41 with any applicable State variances

◯ Meets standards, but periodic monitoring required *(specify reason)*: _____

Driver qualified for: ◯ 3 months ◯ 6 months ◯ 1 year ◯ other *(specify)*: _____

☐ Wearing corrective lenses ☐ Wearing hearing aid ☐ Accompanied by a waiver/exemption *(specify type)*: _____

☐ Accompanied by a Skill Performance Evaluation (SPE) Certificate ☐ Grandfathered from State requirements *(State)*

If the driver meets the standards outlined in 49 CFR 391.41, with applicable State variances, then complete a Medical Examiner's Certificate, as appropriate.

I have performed this evaluation for certification. I have personally reviewed all available records and recorded information pertaining to this evaluation, and attest that to the best of my knowledge, I believe it to be true and correct.

Medical Examiner's Signature: _____

Medical Examiner's Name *(please print or type)*: _____

Medical Examiner's Address: _____ City: _____ State: _____ Zip Code: _____

Medical Examiner's Telephone Number: _____ Date Certificate Signed: _____

Medical Examiner's State License, Certificate, or Registration Number: _____ Issuing State: _____

☐ MD ☐ DO ☐ Physician Assistant ☐ Chiropractor ☐ Advanced Practice Nurse

☐ Other Practitioner *(specify)*: _____

National Registry Number: _____ Medical Examiner's Certificate Expiration Date: _____

Instructions for Completing the Medical Examination Report Form (MCSA-5875)

I. Step-By-Step Instructions

Driver:

Section 1: Driver information

- **Personal Information**: Please complete this section using your name as written on your driver's license, your current address and phone number, your date of birth, age, gender, driver's license number and issuing state.
  - **CLP/CDL Applicant/Holder**: Check "yes" if you are a commercial learner's permit (**CLP**) or commercial driver's license (**CDL**) holder, or are applying for a CLP or CDL. CDL means a license issued by a State or the District of Columbia which authorizes the individual to operate a class of a commercial motor vehicle (**CMV**). A CMV that requires a CDL is one that: (1) has a gross combination weight rating or gross combination weight of 26,001 pounds or more inclusive of a towed unit with a gross vehicle weight rating (**GVWR**) or gross vehicle weight (**GVW**) of more than 10,000 pounds; or (2) has a GVWR or GVW of 26,001 pounds or more; or (3) is designed to transport 16 or more passengers, including the driver; or (4) is used to transport either hazardous materials requiring hazardous materials placards on the vehicle or any quantity of a select agent or toxin.
  - **Driver ID Verified By**: The Medical Examiner/staff completes this item and notes the type of photo ID used to verify the driver's identity such as, commercial driver's license, driver's license, or passport, etc.
  - **Question: Has your USDOT/FMCSA medical certificate ever been denied or issued for less than two years?** Please check the correct box "yes" or "no" and if you aren't sure check the "not sure" box.
- **Driver Health History**:
  - **Have you ever had surgery:** Please check "yes" if you have ever had surgery and provide a written explanation of the details (type of surgery, date of surgery, etc.)
  - **Are you currently taking medications (prescription, over-the-counter, herbal remedies, diet supplements):** Please check "yes" if you are taking any diet supplements, herbal remedies, or prescription or over the counter medications. In the box below the question, indicate the name of the medication and the dosage.
  - **#1-32:** Please complete this section by checking the "yes" box to indicate that you have, or have ever had, the health condition listed or the "No" box if you have not. Check the "not sure" box if you are unsure.
  - **Other Health Conditions not described above**: If you have, or have had, any other health conditions not listed in the section above, check "Yes" and in the box provided and list those condition(s).
  - **Any yes answers to questions #1-32 above:** If you have answered "yes" to any of the questions in the Driver Health History section above, please explain your answers further in the box below the question. For example, if you answered "yes" to question #5 regarding heart disease, heart attack, bypass, or other heart problem, indicate which type of heart condition. If you checked "yes" to question #23 regarding cancer, indicate the type of cancer. Please add any information that will be helpful to the Medical Examiner.
- **CMV Driver Signature and Date:** Please read the certification statement, sign and date it, indicating that the information you provided in Section 1 is accurate and complete.

Medical Examiner:

Section 2: Examination Report

- **Driver Health History Review:** Review answers provided by the driver in the driver health history section and discuss any "yes" and "not sure" responses. In addition, be sure to compare the medication list to the health history responses ensuring that the medication list matches the medical conditions noted. Explore with the driver any answers that seem unclear. Record any information that the driver omitted. As the Medical Examiner conducting the driver's physical examination you are required to complete the entire medical examination even if you detect a medical condition that you consider disqualifying, such as deafness. Medical Examiners are expected to determine the driver's physical qualification for operating a commercial vehicle safely. Thus, if you find a disqualifying condition for which a driver may receive a Federal Motor Carrier Safety Administration medical exemption, please record that on the driver's Medical Examiner's Certificate, Form MCSA-5876, as well as on the Medical Examination Report Form, MCSA-5875.
- **Testing:**
  - **Pulse rate and rhythm, height, and weight:** record these as indicated on the form.
  - **Blood Pressure:** record the blood pressure (systolic and diastolic) of the driver being examined. A second reading is optional and should be recorded if found to be necessary.
  - **Urinalysis:** record the numerical readings for the specific gravity, protein, blood and sugar.
  - **Vision:** The current vision standard is provided on the form. When other than the Snellen chart is used, give test results in Snellen-comparable values. When recording distance vision, use 20 feet as normal. Record the vision acuity results and indicate if the driver can recognize and distinguish among traffic control signals and devices showing red, green, and amber colors; has monocular vision; has been referred to an ophthalmologist or optometrist; and if documentation has been received from an ophthalmologist or optometrist.
  - **Hearing:** The current hearing standard is provided on the form. Hearing can be tested using either a whisper test or audiometric test. Record the test results in the corresponding section for the test used.
- **Physical Examination:** Check the body systems for abnormalities and indicate normal or abnormal for each body system listed. Discuss any abnormal answers in detail in the space provided and indicate whether it would affect the driver's ability to safely operate a commercial motor vehicle.

In this next section, you will be completing either the Federal or State determination, not both.

- **Medical Examiner Determination (Federal):** Use this section for examinations performed in accordance with the FMCSRs (49 CFR 391.41-391.49). Complete the medical examiner determination section completely. When determining a driver's physical qualification, please note that English language proficiency (49 CFR part 391.11: General qualifications of drivers) is not factored into that determination.
  - **Does not meet standards:** Select this option when a driver is determined to be not qualified and provide an explanation of why the driver does not meet the standards in 49 CFR 391.41.
  - **Meets standards in 49 CFR 391.41; qualifies for 2-year certification:** Select this option when a driver is determined to be qualified and will be issued a 2-year Medical Examiner's Certificate.

- **Meets standards, but periodic monitoring is required:** Select this option when a driver is determined to be qualified but needs periodic monitoring and provide an explanation of why periodic monitoring is required. Select the corresponding time frame that the driver is qualified and if selecting other, specify the time frame.
  - **Determination that driver meets standards:** Select all categories that apply to the driver's certification (e.g., wearing corrective lenses, accompanied by a waiver/exemption, driving within an exempt intracity zone, etc.).
- **Determination pending:** Select this option when more information is needed to make a qualification decision and specify a date, on or before the 45 day expiration date, for the driver to return to the medical exam office for follow-up. This will allow for a delay of the qualification decision for as many as 45 days. If the disposition of the pending examination is not updated via the National Registry on or before the 45 day expiration date, FMCSA will notify the examining medical examiner and the driver in writing that the examination is no longer valid and that the driver is required to be re-examined.
  - **MER amended:** A Medical Examination Report Form (MER), MCSA-5875, may only be amended while in determination pending status for situations where new information (e.g., test results, etc.) has been received or there has been a change in the driver's medical status since the initial examination, but prior to a final qualification determination. Select this option when a Medical Examination Report Form, MCSA-5875, is being amended; provide the reason for the amendment, sign and date. In addition, initial and date any changes made on the Medical Examination Report Form, MCSA-5875. A Medical Examination Report Form, MCSA-5875, cannot be amended after an examination has been in determination pending status for more than 45 days or after a final qualification determination has been made. The driver is required to obtain a new physical examination and a new Medical Examination Report Form, MCSA-5875, should be completed.
- **Incomplete examination:** Select this when the physical examination is not completed for any reason (e.g., driver decides they do not want to continue with the examination and leaves) other than situations outlined under determination pending.
- **Medical Examiner information, signature and date:** Provide your name, address, phone number, occupation, license, certificate, or registration number and issuing state, national registry number, signature and date.
- **Medical Examiner's Certificate Expiration Date**: Enter the date the **driver's** Medical Examiner's Certificate (MEC) expires.

- **Medical Examiner Determination (State):** Use this section for examinations performed in accordance with the FMCSRs (49 CFR 391.41-391.49) with any applicable State variances (which will only be valid for intrastate operations). Complete the medical examiner determination section completely.
  - **Does not meet standards in 49 CFR 391.41 with any applicable State variances:** Select this option when a driver is determined to be not qualified and provide an explanation of why the driver does not meet the standards in 49 CFR 391.41 with any applicable State variances.
  - **Meets standards in 49 CFR 391.41 with any applicable State variances:** Select this option when a driver is determined to be qualified and will be issued a 2-year Medical Examiner's Certificate.
  - **Meets standards, but periodic monitoring is required:** Select this option when a driver is determined to be qualified but needs periodic monitoring and provide an explanation of why periodic monitoring is required. Select the corresponding time frame that the driver is qualified and if selecting other, specify the time frame.
    - **Determination that driver meets standards:** Select all categories that apply to the driver's certification (e.g., wearing corrective lenses, accompanied by a waiver/exemption, etc.).

Instructions MCSA-5875

- **Medical Examiner information, signature and date:** Provide your name, address, phone number, occupation, license, certificate, or registration number and issuing state, national registry number, signature and date.
- **Medical Examiner's Certificate Expiration Date**: Enter the date the **driver's** Medical Examiner's Certificate (MEC) expires.

II. **If updating an existing exam, you must resubmit the new exam results, via the Medical Examination Results Form, MCSA-5850, to the National Registry, and the most recent dated exam will take precedence.**

III. **To obtain additional information regarding this form go to the Medical Program's page on the Federal Motor Carrier Safety Administration's website at http://www.fmcsa.dot.gov/regulations/medical.**

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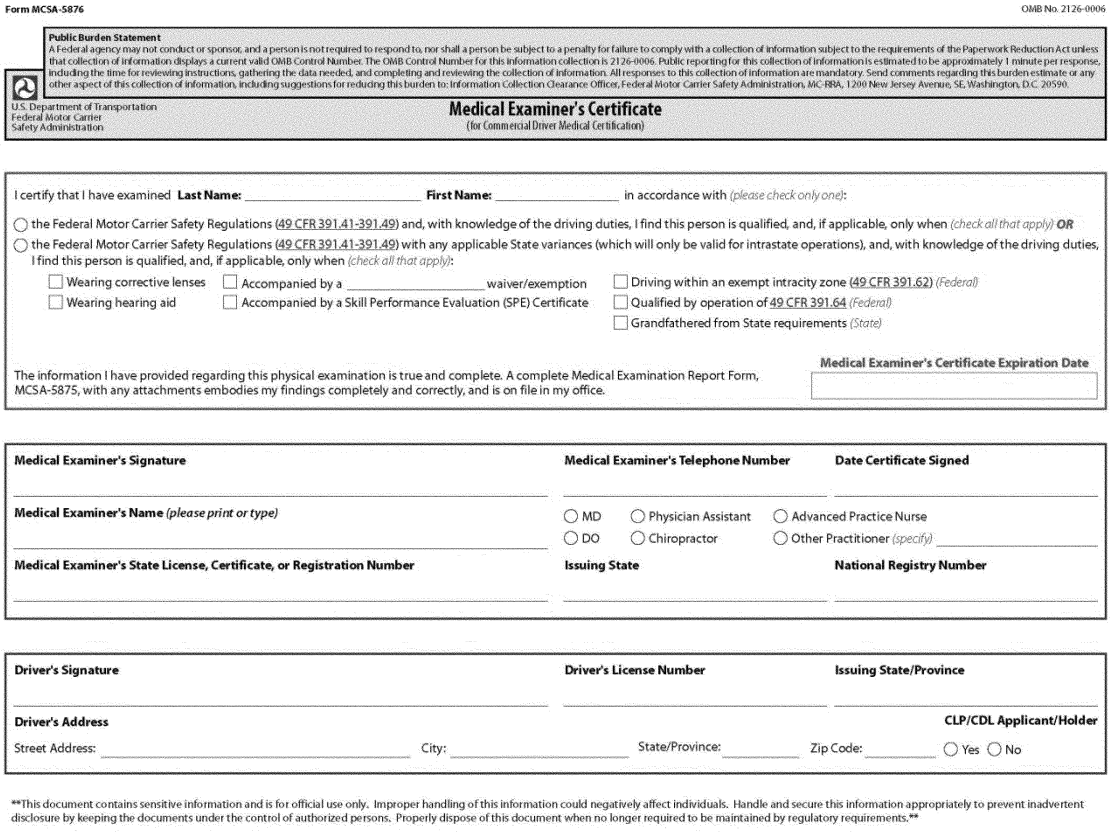
* * * * *

(h) The medical examiner's certificate shall be completed in accordance with the following Form MCSA–5876, Medical Examiner's Certificate:



Form MCSA-5876 OMB No. 2126-0006

Public Burden Statement
A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2126-0006. Public reporting for this collection of information is estimated to be approximately 1 minute per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Motor Carrier Safety Administration, MC-RRA, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

U.S. Department of Transportation
Federal Motor Carrier
Safety Administration

Medical Examiner's Certificate
(for Commercial Driver Medical Certification)

I certify that I have examined **Last Name:** _____ **First Name:** _____ in accordance with *(please check only one)*:

◯ the Federal Motor Carrier Safety Regulations (49 CFR 391.41-391.49) and, with knowledge of the driving duties, I find this person is qualified, and, if applicable, only when *(check all that apply)* ***OR***

◯ the Federal Motor Carrier Safety Regulations (49 CFR 391.41-391.49) with any applicable State variances (which will only be valid for intrastate operations), and, with knowledge of the driving duties, I find this person is qualified, and, if applicable, only when *(check all that apply)*:

☐ Wearing corrective lenses ☐ Accompanied by a _____ waiver/exemption ☐ Driving within an exempt intracity zone (49 CFR 391.62) *(Federal)*
☐ Wearing hearing aid ☐ Accompanied by a Skill Performance Evaluation (SPE) Certificate ☐ Qualified by operation of 49 CFR 391.64 *(Federal)*
☐ Grandfathered from State requirements *(State)*

The information I have provided regarding this physical examination is true and complete. A complete Medical Examination Report Form, MCSA-5875, with any attachments embodies my findings completely and correctly, and is on file in my office.

Medical Examiner's Certificate Expiration Date

Medical Examiner's Signature | **Medical Examiner's Telephone Number** | **Date Certificate Signed**

Medical Examiner's Name *(please print or type)*
◯ MD ◯ Physician Assistant ◯ Advanced Practice Nurse
◯ DO ◯ Chiropractor ◯ Other Practitioner *(specify)* _____

Medical Examiner's State License, Certificate, or Registration Number | **Issuing State** | **National Registry Number**

Driver's Signature | **Driver's License Number** | **Issuing State/Province**

Driver's Address
Street Address: _____ City: _____ State/Province: _____ Zip Code: _____

CLP/CDL Applicant/Holder
◯ Yes ◯ No

This document contains sensitive information and is for official use only. Improper handling of this information could negatively affect individuals. Handle and secure this information appropriately to prevent inadvertent disclosure by keeping the documents under the control of authorized persons. Properly dispose of this document when no longer required to be maintained by regulatory requirements.

BILLING CODE 4910–EX–C

* * * * *

PART 392—DRIVING OF COMMERCIAL MOTOR VEHICLES

■ 77. The authority citation for part 392 continues to read as follows:

Authority: 49 U.S.C. 504, 13902, 31136, 31151, 31502; Section 112 of Pub. L. 103–311, 108 Stat. 1673, 1676 (1994), as amended by sec. 32509 of Pub. L. 112–141, 126 Stat. 405, 805 (2012); sec. 5524 of Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 78. Amend § 392.9b by revising paragraph (a) to read as follows:

§ 392.9b Prohibited transportation.

(a) *Safety registration required.* A commercial motor vehicle providing transportation in interstate commerce must not be operated without a safety registration and an active USDOT Number.

* * * * *

PART 395—HOURS OF SERVICE OF DRIVERS

■ 79. The authority citation for part 395 continues to read as follows:

Authority: 49 U.S.C. 504, 31133, 31136, 31137, and 31502; sec. 113, Pub. L. 103–311, 108 Stat. 1673, 1676; sec. 229, Pub. L. 106–159 (as transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743, 1744); sec. 4133, Pub. L. 109–59, 119 Stat. 1144, 1744; sec. 108, Pub. L. 110–432, 122 Stat. 4860–4866; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; sec. 5206(b) of Pub. L. 114–94, 129 Stat. 1312, 1537; and 49 CFR 1.87.

■ 80. Amend § 395.1 by revising the introductory text of paragraph (e)(1) to read as follows:

§ 395.1 Scope of rules in this part.

* * * * *

(e) *Short-haul operations*—(1) *100 air-mile radius driver.* A driver is exempt from the requirements of §§ 395.8 and 395.11 if:

* * * * *

■ 81. Amend § 395.8 by revising paragraph (a)(1)(iii)(A)(*4*) to read as follows:

§ 395.8 Driver's record of duty status.

(a) * * *
(1) * * *
(iii) * * *
(A) * * *

(*4*) That was manufactured before model year 2000, as reflected in the vehicle identification number as shown on the vehicle's registration.

* * * * *

PART 397—TRANSPORTATION OF HAZARDOUS MATERIALS; DRIVING AND PARKING RULES

■ 82. The authority citation for part 397 continues to read as follows:

Authority: 49 U.S.C. 322; 49 CFR 1.87. Subpart A also issued under 49 U.S.C. 5103, 31136, 31502, and 49 CFR 1.97. Subparts C, D, and E also issued under 49 U.S.C. 5112, 5125.

■ 83. Amend § 397.73 by revising paragraph (b) to read as follows:

§ 397.73 Public information and reporting requirements.

* * * * *

(b) *Reporting and publishing requirements.* (1) Each State or Indian tribe, through its routing agency, shall provide information identifying all NRHM routing designations that exist within its jurisdiction by:

(i) Electronically, by email to *HMRouting@dot.gov;* or

(ii) Mail to the Federal Motor Carrier Safety Administration, Office of Enforcement and Compliance (MC–EC), 1200 New Jersey Ave. SE., Washington, DC 20590–0001.

(2) States and Indian tribes shall also submit to FMCSA the current name of the State or Indian tribal agency responsible for NHRM highway routing designations. The State or Indian tribe shall include descriptions of these routing designations, along with the dates they were established. Information on any subsequent changes or new NRHM routing designations shall be furnished within 60 days after establishment to the FMCSA. This

information will be available from the FMCSA, consolidated by the FMCSA, and published annually in whole or as updates in the **Federal Register**. Each State or Indian tribe may also publish this information in its official register of State or tribal regulations.

* * * * *

§ 397.101 [Amended]

■ 84. Amend § 397.101 by removing paragraph (g).

■ 85. Amend § 397.103 by revising paragraph (c)(1) to read as follows:

§ 397.103 Requirements for State routing designations.

* * * * *

(c) * * *

(1) The State gives written notice to the Federal Motor Carrier Safety Administration:

(i) By email to *HMRouting@dot.gov;* or

(ii) By certified mail, return receipt requested, to the Federal Motor Carrier Safety Administration, Office of Enforcement and Compliance (MC–EC), 1200 New Jersey Ave., SE., Washington, DC 20590–0001. Attention: National Hazardous Materials Route Registry.

* * * * *

PART 398—TRANSPORTATION OF MIGRANT WORKERS

■ 86. The authority citation for part 398 continues to read as follows:

Authority: 49 U.S.C. 13301, 13902, 31132, 31133, 31136, 31502, and 31504; sec. 204, Pub. L. 104–88, 109 Stat. 803, 941 (49 U.S.C. 701 note); sec. 212, Pub. L. 106–159, 113 Stat. 1748, 1766; and 49 CFR 1.87.

■ 87. Amend § 398.1 by revising paragraph (b) to read as follows:

§ 398.1 Definitions.

* * * * *

(b) *Carrier of migrant workers by motor vehicle.* ''Carrier of migrant worker by motor vehicle'' means any person, including any for-hire, non-exempt motor carrier conducting contract carriage operations as defined in 49 U.S.C. 13102(4)(B), but not including any for-hire, non-exempt motor carrier subject to other requirements in 49 U.S.C. subtitle IV, part B besides contract carriage operations, who or which transports in interstate or foreign commerce at any one time three or more migrant workers to or from their employment by any motor vehicle other than a passenger automobile or station wagon, except a migrant worker transporting himself/herself or his/her immediate family.

* * * * *

Issued under authority delegated in 49 CFR 1.87 on: September 15, 2016.

T.F. Scott Darling, III,

Administrator.

[FR Doc. 2016–22996 Filed 9–30–16; 11:15 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 593

[Docket No. NHTSA–2016–0081]

List of Nonconforming Vehicles Decided To Be Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This document revises the list of vehicles not originally manufactured to conform to the Federal Motor Vehicle Safety Standards (FMVSS) that NHTSA has decided to be eligible for importation. This list is published in an appendix to the agency's regulations that prescribe procedures for import eligibility decisions. The list has been revised to add all vehicles that NHTSA has decided to be eligible for importation since October 1, 2015, and to remove all previously listed vehicles that are now more than 25 years old and need no longer comply with all applicable FMVSS to be lawfully imported. NHTSA is required by statute to publish this list annually in the **Federal Register**.

DATES: Effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: George Stevens, Office of Vehicle Safety Compliance, NHTSA, (202) 366–5308.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS. Where there is no substantially similar U.S.-certified motor vehicle, 49 U.S.C. 30141(a)(1)(B) permits a nonconforming motor vehicle to be admitted into the United States if its safety features comply with, or are capable of being altered to comply with, all applicable FMVSS based on destructive test data or such other evidence as the Secretary of Transportation decides to be adequate.

Under 49 U.S.C. 30141(a)(1), import eligibility decisions may be made ''on the initiative of the Secretary of Transportation or on petition of a manufacturer or importer registered under [49 U.S.C. 30141(c)].'' The Secretary's authority to make these decisions has been delegated to NHTSA. The agency publishes notices of eligibility decisions as they are made.

Under 49 U.S.C. 30141(b)(2), a list of all vehicles for which import eligibility decisions have been made must be published annually in the **Federal Register**. On October 1, 1996, NHTSA added the list as an appendix to 49 CFR part 593, the regulations that establish procedures for import eligibility decisions (61 FR 51242). As described in the notice, NHTSA took that action to ensure that the list is more widely disseminated to government personnel who oversee vehicle imports and to interested members of the public. See 61 FR 51242–43. In the notice, NHTSA expressed its intention to annually revise the list as published in the appendix to include any additional vehicles decided by the agency to be eligible for importation since the list was last published. See 61 FR 51243. The agency stated that issuance of the document announcing these revisions will fulfill the annual publication requirements of 49 U.S.C. 30141(b)(2). *Ibid.*

Regulatory Analyses and Notices

A. Executive Order 12866, Regulatory Planning and Review

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations about whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees,

or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This rule will not have any of these effects and was not reviewed under Executive Order 12866. It is not significant within the meaning of the DOT Regulatory Policies and Procedures. The effect of this rule is not to impose new requirements. Instead it provides a summary compilation of decisions on import eligibility that have already been made and does not involve new decisions. This rule will not impose any additional burden on any person. Accordingly, the agency believes that the preparation of a regulatory evaluation is not warranted for this rule.

B. Environmental Impacts

We have not conducted an evaluation of the impacts of this rule under the National Environmental Policy Act. This rule does not impose any change that would result in any impacts to the quality of the human environment. Accordingly, no environmental assessment is required.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, we have considered the impacts of this rule on small entities (5 U.S.C. Sec. 601 *et seq.*). I certify that this rule will not have a significant economic impact upon a substantial number of small entities within the context of the Regulatory Flexibility Act. The following is our statement providing the factual basis for the certification (5 U.S.C. Sec. 605(b)). This rule will not have any significant economic impact on a substantial number of small businesses because the rule merely furnishes information by revising the list in the Code of Federal Regulations of vehicles for which import eligibility decisions have previously been made. Accordingly, we have not prepared a Final Regulatory Flexibility Analysis.

D. Executive Order 13132, Federalism

Executive Order 13132 requires NHTSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' Executive Order 13132 defines the term ''Policies that have federalism implications'' to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, NHTSA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or NHTSA consults with State and local officials early in the process of developing the regulation.

This rule will have no 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 as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

E. The Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. This rule will not result in additional expenditures by State, local or tribal governments or by any members of the private sector. Therefore, the agency has not prepared an economic assessment pursuant to the Unfunded Mandates Reform Act.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This rule does not impose any new collection of information requirements for which a 5 CFR part 1320 clearance must be obtained. DOT previously submitted to OMB and OMB approved the collection of information associated with the vehicle importation program in OMB Clearance No. 2127–0002.

G. Civil Justice Reform

Pursuant to Executive Order 12988, ''Civil Justice Reform,'' we have considered whether this rule has any retroactive effect. We conclude that it will not have such an effect.

H. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

—Have we organized the material to suit the public's needs?
—Are the requirements in the rule clearly stated?
—Does the rule contain technical language or jargon that is not clear?
—Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
—Would more (but shorter) sections be better?
—Could we improve clarity by adding tables, lists, or diagrams?
—What else could we do to make the rule easier to understand?

If you wish to do so, please comment on the extent to which this final rule effectively uses plain language principles.

I. National Technology Transfer and Advancement Act

Under the National Technology and Transfer and Advancement Act of 1995 (Public Law 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' This rule does not require the use of any technical standards.

J. 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).

K. Executive Order 13045, Economically Significant Rules Disproportionately Affecting Children

This rule is not subject to Executive Order 13045 because it is not ''economically significant'' as defined under Executive Order 12866, and does not concern an environmental, health, or safety risk that NHTSA has reason to believe may have a disproportionate effect on children.

L. Notice and Comment

NHTSA finds that prior notice and opportunity for comment are unnecessary under 5 U.S.C. 553(b)(3)(B) because this action does not impose any regulatory requirements. This rule

merely revises the list of vehicles not originally manufactured to conform to the FMVSS that NHTSA has decided to be eligible for importation into the United States since the last list was published in September, 2015.

In addition, so that the list of vehicles for which import eligibility decisions have been made may be included in the next edition of 49 CFR parts 572 to 999, which is due for revision on October 1, 2016, good cause exists to dispense with the requirement in 5 U.S.C. 553(d) for the effective date of the rule to be delayed for at least 30 days following its publication.

List of Subjects in 49 CFR Part 593

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, part 593 of Title 49 of the Code of Federal Regulations is amended as follows:

PART 593—[AMENDED]

■ 1. The authority citation for part 593 continues to read as follows:

Authority: 49 U.S.C. 322 and 30141(b); delegation of authority at 49 CFR 1.95.

■ 2. Appendix A to part 593 is revised to read as follows:

Appendix A to Part 593—List of Vehicles Determined To Be Eligible for Importation

(a) Each vehicle on the following list is followed by a vehicle eligibility number. The importer of a vehicle admissible under any eligibility decision must enter that number on the HS–7 Declaration Form accompanying entry to indicate that the vehicle is eligible for importation.

(1) ''VSA'' eligibility numbers are assigned to all vehicles that are decided to be eligible for importation on the initiative of the Administrator under Sec. 593.8.

(2) ''VSP'' eligibility numbers are assigned to vehicles that are decided to be eligible under Sec. 593.7(f), based on a petition from a manufacturer or registered importer submitted under Sec. 593.5(a)(1), which establishes that a substantially similar U.S.-certified vehicle exists.

(3) ''VCP'' eligibility numbers are assigned to vehicles that are decided to be eligible under Sec. 593.7(f), based on a petition from a manufacturer or registered importer submitted under Sec. 593.5(a)(2), which establishes that the vehicle has safety features that comply with, or are capable of being altered to comply with, all applicable FMVSS.

(b) Vehicles for which eligibility decisions have been made are listed alphabetically, first by make, then by model, then by model year.

(c) All hyphens used in the Model Year column mean ''through'' (for example, ''1995–1999'' means ''1995 through 1999'').

(d) The initials ''MC'' used in the Make column mean ''Motorcycle.''

(e) The initials ''SWB'' used in the Model Type column mean ''Short Wheel Base.''

(f) The initials ''LWB'' used in the Model Type column mean ''Long Wheel Base.''

(g) For vehicles with a European country of origin, the term ''Model Year'' ordinarily means calendar year in which the vehicle was produced.

(h) All vehicles are left-hand-drive (LHD) vehicles unless noted as RHD. The initials ''RHD'' used in the Model Type column mean ''right-hand-drive.''

(i) For vehicle models that have been determined to be eligible for importation based on a petition submitted under Sec. 593.5(a)(1), which establishes that a substantially similar U.S.-certified vehicle exists, and no specific body style(s) are listed, only the body style(s) of that vehicle model that were U.S.-certified by the original manufacturer are eligible for importation. For example, if the original manufacturer manufactured both sedan and wagon body styles for the described model, but only certified the sedan for the U.S. market, the wagon body style would not be eligible for importation under that determination.

VEHICLES CERTIFIED BY THEIR ORIGINAL MANUFACTURER AS COMPLYING WITH ALL APPLICABLE CANADIAN MOTOR VEHICLE SAFETY STANDARDS

(a) All passenger cars manufactured on or after September 1, 1989, and before September 1, 1996, that, as originally manufactured, are equipped with an automatic restraint system that complies with Federal Motor Vehicle Safety Standard (FMVSS) No. 208;	VSA–80
(b) All passenger cars manufactured on or after September 1, 1996, and before September 1, 2002, that, as originally manufactured, are equipped with an automatic restraint system that complies with FMVSS No. 208, and that comply with FMVSS No. 214;	
(c) All passenger cars manufactured on or after September 1, 2002, and before September 1, 2007, that, as originally manufactured, are equipped with an automatic restraint system that complies with FMVSS No. 208, and that comply with FMVSS Nos. 201, 214, 225, and 401;	
(d) All passenger cars manufactured on or after September 1, 2007, and before September 1, 2008, that, as originally manufactured, comply with FMVSS Nos. 110, 118, 138, 201, 208, 213, 214, 225, and 401;	
(e) All passenger cars manufactured on or after September 1, 2008 and before September 1, 2009 that, as originally manufactured, comply with FMVSS Nos. 110, 118, 138, 201, 202a, 206, 208, 213, 214, 225, and 401;	
(f) All passenger cars manufactured on or after September 1, 2009 and before September 1, 2010 that, as originally manufactured, comply with FMVSS Nos. 118, 138, 201, 202a, 206, 208, 213, 214, 225, and 401;	
(g) All passenger cars manufactured on or after September 1, 2010 and before September 1, 2011 that, as originally manufactured, comply with FMVSS Nos. 118, 138, 201, 202a, 206, 208, 213, 214, and 225;	
(h) All passenger cars manufactured on or after September 1, 2011 and before September 1, 2017 that, as originally manufactured, comply with FMVSS Nos. 138, 201, 206, 208, 213, 214, and 225.	
(a) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less that were manufactured on and after September 1, 1991, and before September 1, 1993 and that, as originally manufactured, comply with FMVSS Nos. 202 and 208;	VSA–81
(b) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less that were manufactured on or after September 1, 1993, and before September 1, 1998, and that, as originally manufactured, comply with FMVSS Nos. 202, 208, and 216;	
(c) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less that were manufactured on or after September 1, 1998, and before September 1, 2002, and that, as originally manufactured, comply with FMVSS Nos. 202, 208, 214, and 216;	
(d) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less that were manufactured on or after September 1, 2002, and before September 1, 2007, and that, as originally manufactured, comply with FMVSS Nos. 201, 202, 208, 214, and 216, and, insofar as it is applicable, with FMVSS No. 225;	
(e) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less manufactured on or after September 1, 2007 and before September 1, 2008, that, as originally manufactured, comply with FMVSS Nos. 110, 118, 201, 202, 208, 213, 214, and 216, and insofar as they are applicable, with FMVSS Nos. 138 and 225;	
(f) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less manufactured on or after September 1, 2008 and before September 1, 2009, that, as originally manufactured, comply with FMVSS Nos. 110, 118, 201, 202a, 206, 208, 213, 214, and 216, and insofar as they are applicable, with FMVSS Nos. 138 and 225;	

VEHICLES CERTIFIED BY THEIR ORIGINAL MANUFACTURER AS COMPLYING WITH ALL APPLICABLE CANADIAN MOTOR VEHICLE SAFETY STANDARDS—Continued

(g) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less manufactured on or after September 1, 2009 and before September 1, 2011, that, as originally manufactured, comply with FMVSS Nos. 118, 201, 202a, 206, 208, 213, 214, and 216, and insofar as they are applicable, with FMVSS Nos. 138 and 225;	VSA–81 continued
(h) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less manufactured on or after September 1, 2011 and before September 1, 2012, that, as originally manufactured, comply with FMVSS Nos. 201, 202a, 206, 208, 213, 214, and 216, and insofar as they are applicable, with FMVSS Nos. 138 and 225;	
(i) All multipurpose passenger vehicles, trucks, and buses with a GVWR of 4,536 kg (10,000lb) or less manufactured on or after September 1, 2012 and before September 1, 2017, that, as originally manufactured, comply with FMVSS Nos. 201, 206, 208, 213, 214, and 216, and insofar as they are applicable, with FMVSS Nos. 138 222, and 225;	
All multipurpose passenger vehicles, trucks, and buses with a GVWR greater than 4,536 kg (10,000 lb) that are less than 25 years old.	VSA–82
All trailers and motorcycles less than 25 years old.	VSA–83

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Acura	Legend		1991–1992	305	
AHLM	SPT 16–25 trailer		2012		55
Alfa Romeo	164		1991	76	
Alfa Romeo	164		1994	156	
Alfa Romeo	8C Spider		2010		61
Alfa Romeo	8C SPIDER		2008–2009	580	
Alfa Romeo	Spider		1992	503	
Alpina	B10 Series		1991–1996		54
Alpina	B11	Sedan	1991–1994		48
Alpina	B12	Coupe	1991–1996		43
Alpina	B12 5.0	Sedan	1991–1994		41
Alpina	B5 series (manufactured before 9/1/06)		2005–2007		53
Al-Spaw	EMA Mobile Stage Trailer		2009		42
Aston Martin	Vanquish		2002–2004	430	
Aston Martin	Vantage		2006–2007	530	
Aston Martin	Vantage V8		2008	582	
Audi	100		1993	244	
Audi	100		1991–1992	317	
Audi	A4		1996–2000	352	
Audi	A4, RS4, S4	8D	2000–2001	400	
Audi	A6		1998–1999	332	
Audi	A8		2000	424	
Audi	A8		1997–2000	337	
Audi	A8 Avant Quattro		1996	238	
Audi	RS6 & RS Avant		2003	443	
Audi	S6		1996	428	
Audi	S8		2000	424	
Audi	TT		2000–2001	364	
Bentley	Arnage (manufactured 1/1/01–12/31/01)		2001	473	
Bentley	Azure (LHD & RHD)		1998	485	
Bentley	Flying Spur	4-door Saloon 2-door Continental	2014	588	
Bimota (MC)	DB4		2000	397	
Bimota (MC)	SB6		1994–1999	523	
Bimota (MC)	SB8		1999–2000	397	
BMW	3 Series		1998	462	
BMW	3 Series		1999	379	
BMW	3 Series		2000	356	
BMW	3 Series		2001	379	
BMW	3 Series		1992–1994	550	
BMW	3 Series		1995–1997	248	
BMW	3 Series		2003–2004	487	
BMW	320i		1991	283	
BMW	325i	4-door	1991	96	
BMW	325i		1992–1996	197	
BMW	5 Series		2000	345	
BMW	5 Series		1991–1995	194	
BMW	5 Series		1995–1997	249	
BMW	5 Series		1998–1999	314	
BMW	5 Series		2000–2002	414	
BMW	5 Series		2003–2004	450	
BMW	5 Series (manufactured prior to 9/1/2006)		2005–2007	555	
BMW	7 Series		1991	299	
BMW	7 Series		1992	232	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
BMW	7 Series		1993–1994	299	
BMW	7 Series		1995–1999	313	
BMW	7 Series		1999–2001	366	
BMW	760i		2004	559	
BMW	8 Series		1991–1995	361	
BMW	850 Series		1997	396	
BMW	M3	Convertible	1991		60
BMW	M3		2006–2010	571	
BMW	M3 (manufactured prior to 9/1/06)		2006	520	
BMW	X5 (manufactured 1/1/03–12/31/04)		2003–2004	459	
BMW	Z3		2002	568	
BMW	Z3		1996–1998	260	
BMW	Z3 (European market)		1999	483	
BMW	Z4		2010	553	
BMW	Z8		2002	406	
BMW	Z8		2000–2001	350	
BMW (MC)	C1		2000–2003		40
BMW (MC)	K1		1991–1993	228	
BMW (MC)	K100		1991–1992	285	
BMW (MC)	K1100, K1200		1993–1998	303	
BMW (MC)	K1200 GT		2003	556	
BMW (MC)	K75		1996		36
BMW (MC)	K75S		1991–1995	229	
BMW (MC)	R1100		1994–1997	231	
BMW (MC)	R1100		1998–2001	368	
BMW (MC)	R1100 S		2002	557	
BMW (MC)	R1100RS		1994	177	
BMW (MC)	R1150GS		2000	453	
BMW (MC)	R1200C		1998–2001	359	
BMW (MC)	R80, R100		1991–1995	295	
BMW (MC)	S1000RR		2011–2012	563	
Buell (MC)	1125R, Ulysses XB, Lightning XB, and Blast.		2009	579	
Buell (MC)	All Models		1995–2002	399	
Cadillac	DeVille		1994–1999	300	
Cadillac	DeVille (manufactured 8/1/99–12/31/00)		2000	448	
Cadillac	Escalade		2008	572	
Cadillac	Seville		1991	375	
Cagiva (MC)	Gran Canyon 900		1999	444	
Carrocerias	Cimarron trailer		2006–2007		37
Chevrolet	400SS		1995	150	
Chevrolet	Astro Van		1997	298	
Chevrolet	Blazer (plant code of "K" or "2" in the 11th position of the VIN).		1997	349	
Chevrolet	Blazer (plant code of "K" or "2" in the 11th position of the VIN).		2001	461	
Chevrolet	Camaro		1999	435	
Chevrolet	Cavalier		1997	369	
Chevrolet	Corvette		1992	365	
Chevrolet	Corvette	Coupe	1999	419	
Chevrolet	Corvette		2007	544	
Chevrolet	Suburban		2005	541	
Chevrolet	Suburban		1991–1991	242	
Chevrolet	Tahoe		2000	504	
Chevrolet	Tahoe		2001	501	
Chevrolet	Trailblazer (manufactured prior to 9/1/07 for sale in the Kuwaiti market).		2007	514	
Chevy	Impala		1996	561	
Chrysler	Daytona		1992	344	
Chrysler	Grand Voyager		1998	373	
Chrysler	LHS (Mexican market)		1996	276	
Chrysler	Town and Country		1993	273	
Citroen	XM		1991–1992		1
Dodge	Durango		2007	534	
Dodge	Ram		1994–1995	135	
Dodge	Ram 1500 Laramie Crew Cab		2009	535	
Ducati (MC)	600SS		1992–1996	241	
Ducati (MC)	748		1999–2003	421	
Ducati (MC)	748 Biposto		1996–1997	220	
Ducati (MC)	888		1993	500	
Ducati (MC)	900		2001	452	
Ducati (MC)	900SS		1991–1996	201	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Ducati (MC)	916		1999–2003	421	
Ducati (MC)	996 Biposto		1999–2001	475	
Ducati (MC)	996R		2001–2002	398	
Ducati (MC)	MH900E		2001–2002	524	
Ducati (MC)	Monster 600		2001	407	
Ducati (MC)	ST4S		1999–2005	474	
Ducati (MC)	Multistrada		2011	585	
E. Lancashine Coachbuilders Limited.	Double Decker Bus	Volvo B7L chassis	2000		59
Eagle	Vision		1994	323	
Ferrari	348 TB		1992	86	
Ferrari	348 TS		1992	161	
Ferrari	360		2001	376	
Ferrari	360	Spider & Coupe	2003	410	
Ferrari	360 (manufactured after 9/31/02)		2002	433	
Ferrari	360 (manufactured before 9/1/02)		2002	402	
Ferrari	360 Modena		1999–2000	327	
Ferrari	360 Series		2004	446	
Ferrari	456		1995	256	
Ferrari	456 GT & GTA		1999	445	
Ferrari	456 GT & GTA		1997–1998	408	
Ferrari	512 TR		1993	173	
Ferrari	550		2001	377	
Ferrari	550 Marinello		1997–1999	292	
Ferrari	575		2002–2003	415	
Ferrari	575		2004–2005	507	
Ferrari	599 (manufactured prior to 9/1/06)		2006	518	
Ferrari	599 GTB (Manufactured September 1, 2006 through August 31, 2007).		2006–2007	576	
Ferrari	599		2008–2011	587	
Ferrari	612 Scagletti (Manufactured before 9/1/06).		2006	573	
Ferrari	612 Scaglietti		2005	545	
Ferrari	California (Manufactured for the European Market).		2010	570	
Ferrari	Enzo		2003–2004	436	
Ferrari	F355		1995	259	
Ferrari	F355		1999	391	
Ferrari	F355		1996–1998	355	
Ferrari	F430 (manufactured prior to 9/1/06)		2005–2006	479	
Ferrari	F50		1995	226	
Fisker	Karma		2012	577	
Ford	Bronco (manufactured in Venezuela)		1995–1996	265	
Ford	Escape (manufactured prior to 9/1/2006)		2007	551	
Ford	Escort (Nicaraguan market)		1996	322	
Ford	Escort RS Cosworth		1994–1995		9
Ford	Explorer (manufactured in Venezuela)		1991–1998	268	
Ford	F150		2000	425	
Ford	F–150		2009	575	
Ford	F–150 Crew Cab (manufactured for sale in the Mexican market).		2004	548	
Ford	Mustang		1993	367	
Ford	Mustang		1997	471	
Ford	Windstar		1995–1998	250	
Freightliner	FLD12064ST		1991–1996	179	
Freightliner	FTLD112064SD		1991–1996	178	
Gemala	Saranaupaya 1600 Double Axle trailer		2001		58
GMC	Suburban		1992–1994	134	
Harley-Davidson (MC)	FL Series		2010	528	
Harley-Davidson (MC)	FX, FL, XL & VR Series		2004	422	
Harley-Davidson (MC)	FX, FL, XL & VR Series		2008	517	
Harley-Davidson (MC)	FX, FL, XL & VR Series		2009	522	
Harley-Davidson (MC)	FX, FL, XL & VR Series		2011–2014	567	
Harley-Davidson (MC)	FX, FL, XL Series		1998	253	
Harley-Davidson (MC)	FX, FL, XL Series		1999	281	
Harley-Davidson (MC)	FX, FL, XL Series		2000	321	
Harley-Davidson (MC)	FX, FL, XL Series		2001	362	
Harley-Davidson (MC)	FX, FL, XL Series		2002	372	
Harley-Davidson (MC)	FX, FL, XL Series		2003	393	
Harley-Davidson (MC)	FX, FL, XL Series		2005	472	
Harley-Davidson (MC)	FX, FL, XL Series		2006	491	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Harley-Davidson (MC)	FX, FL, XL Series		1991–1997	202	
Harley-Davidson (MC)	FX, FL, XL, & VR Series		2007	506	
Harley-Davidson (MC)	FX, XL & VR Series		2010	578	
Harley-Davidson (MC)	FXSTC Soft Tail Custom		2007	499	
Harley-Davidson (MC)	VRSCA		2002	374	
Harley-Davidson (MC)	VRSCA		2003	394	
Harley-Davidson (MC)	VRSCA		2004	422	
Hatty	45 ft double axle trailer		1999–2000		38
Heku	750 KG boat trailer		2005		33
Hobby	Exclusive 650 KMFE Trailer		2002–2003		29
Honda	Accord		1991	280	
Honda	Accord		1992–1999	319	
Honda	Accord (RHD)	Sedan & Wagon	1994–1997	451	
Honda	CRV		2002	447	
Honda	CR–V		2005	489	
Honda	Prelude		1994–1997	309	
Honda (MC)	CB 750 (CB750F2T)		1996	440	
Honda (MC)	CBR 250		1991–1994		22
Honda (MC)	NT700V (Deauville)		2006–2013		57
Honda (MC)	RVF 400		1994–2000	358	
Honda (MC)	VF750		1994–1998	290	
Honda (MC)	VFR 400		1994–2000	358	
Honda (MC)	VFR 400, RVF 400		1991–1993		24
Honda (MC)	VFR750		1991–1997	315	
Honda (MC)	VFR800		1998–1999	315	
Honda (MC)	VT600		1991–1998	294	
Hyundai	Elantra		1992–1995	269	
Hyundai	XG350		2004	494	
Ifor Williams	LM85G trailer		2005		49
Jaguar	Sovereign		1993	78	
Jaguar	S-Type		2000–2002	411	
Jaguar	XJ8		2002	536	
Jaguar	XJS		1991	175	
Jaguar	XJS		1992	129	
Jaguar	XJS		1994–1996	195	
Jaguar	XK–8		1998	330	
Jaguar	XKR		2005	560	
Jeep	Cherokee		1993	254	
Jeep	Cherokee (European market)		1991	211	
Jeep	Cherokee (LHD & RHD)		1994	493	
Jeep	Cherokee (LHD & RHD)		1995	180	
Jeep	Cherokee (LHD & RHD)		1996	493	
Jeep	Cherokee (RHD)		1997–2001	515	
Jeep	Cherokee (LHD)		1997–1998	516	
Jeep	Cherokee (Venezuelan market)		1992	164	
Jeep	Grand Cherokee		1994	404	
Jeep	Grand Cherokee		1997	431	
Jeep	Grand Cherokee		2001	382	
Jeep	Grand Cherokee (LHD—Japanese market).		1997	389	
Jeep	Liberty		2002	466	
Jeep	Liberty		2005	505	
Jeep	Liberty (Mexican market)		2004	457	
Jeep	Wrangler		1992	562	
Jeep	Wrangler		1993	217	
Jeep	Wrangler		1995	255	
Jeep	Wrangler		1998	341	
Jeep	Wrangler (manufactured for sale in the Mexican market).		2003	547	
Jeep	Wrangler (manufactured for sale in the Mexican market).		2012	584	
Jeep	Wrangler (RHD)		2000–2003		50
Kawasaki (MC)	EL250		1992–1994	233	
Kawasaki (MC)	Ninja ZX–6R		2002		44
Kawasaki (MC)	VN1500–P1/P2 series		2003	492	
Kawasaki (MC)	ZR750		2000–2003	537	
Kawasaki (MC)	ZX400		1991–1997	222	
Kawasaki (MC)	ZX6, ZX7, ZX9, ZX10, ZX11		1991–1999	312	
Kawasaki (MC)	ZX600		1991–1998	288	
Kawasaki (MC)	ZZR1100		1993–1998	247	
Ken-Mex	T800		1991–1996	187	
Kenworth	T800		1992	115	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Komet	Standard, Classic & Eurolite trailer		2000–2005	477	
KTM (MC)	Duke II		1995–2000	363	
Lamborghini	Diablo SE30		1994–1995	586	
Lamborghini	Diablo	Coupe	1997		26
Lamborghini	Diablo (except 1997 Coupe)		1996–1997	416	
Lamborghini	Gallardo (manufactured 1/1/04–12/31/04)		2004	458	
Lamborghini	Gallardo (manufactured 1/1/06–8/31/06)		2006	508	
Lamborghini	Murcielago	Roadster	2005	476	
Land Rover	Defender 110		1993	212	
Land Rover	Defender 90	VIN & Body Limited	1994–1995	512	
Land Rover	Defender 90 (manufactured before 9/1/97) and VIN "SALDV224*VA" or "SALDV324*VA".		1997	432	
Land Rover	Discovery		1994–1998	338	
Land Rover	Discovery (II)		2000	437	
Land Rover	Range Rover		2004	509	
Land Rover	Range Rover		2006	538	
Lexus	GS300		1998	460	
Lexus	GS300		1993–1996	293	
Lexus	RX300		1998–1999	307	
Lexus	SC300		1991–1996	225	
Lexus	SC400		1991–1996	225	
Lincoln	Mark VII		1992	144	
M&V	Type NS4G31 trailer		2008–2010		46
Magni (MC)	Australia, Sfida		1996–1999	264	
Mazda	MPV		2000	413	
Mazda	MX–5 Miata		1991–1993	184	
Mazda	RX–7		1991–1995	279	
Mazda	Xedos 9		1995–2000	351	
McLaren	MP4–12C		2012	569	
Mercedes-Benz	190 E	201.024	1991	45	
Mercedes-Benz	190 E	201.028	1992	71	
Mercedes-Benz	190 E	201.018	1992	126	
Mercedes-Benz	190 E		1993	454	
Mercedes-Benz	200 E	124.012	1991	109	
Mercedes-Benz	200 E	124.019	1993	75	
Mercedes-Benz	220 E		1993	168	
Mercedes-Benz	220 TE	Station Wagon	1993–1996	167	
Mercedes-Benz	230 CE	124.043	1991	84	
Mercedes-Benz	230 CE	123.043	1992	203	
Mercedes-Benz	230 E	124.023	1991	74	
Mercedes-Benz	230 E	124.023	1993	127	
Mercedes-Benz	250 D		1992	172	
Mercedes-Benz	250 E		1991–1993	245	
Mercedes-Benz	260 E	124.026	1992	105	
Mercedes-Benz	280 E		1993	166	
Mercedes-Benz	300 CE	124.051	1991	83	
Mercedes-Benz	300 CE	124.050	1992	117	
Mercedes-Benz	300 CE	124.061	1993	94	
Mercedes-Benz	300 E	124.031	1992	114	
Mercedes-Benz	300 E 4-Matic		1991–1993	192	
Mercedes-Benz	300 SL	129.006	1992	54	
Mercedes-Benz	300 TE		1992	193	
Mercedes-Benz	320 CE		1993	310	
Mercedes-Benz	320 SL		1992–1993	142	
Mercedes-Benz	350 CLS		2004		45
Mercedes-Benz	400 SE		1992–1994	296	
Mercedes-Benz	420 E		1993	169	
Mercedes-Benz	420 SE		1991	230	
Mercedes-Benz	500 E	124.036	1991	56	
Mercedes-Benz	500 SE	140.050	1991	26	
Mercedes-Benz	500 SEL	126.037	1991	63	
Mercedes-Benz	500 SL	126.066	1991	33	
Mercedes-Benz	500 SL	129.006	1992	60	
Mercedes-Benz	560 SEC		1991	333	
Mercedes-Benz	560 SEL	140	1991	469	
Mercedes-Benz	600 SEC	Coupe	1993	185	
Mercedes-Benz	600 SEL	140.057	1993–1998	271	
Mercedes-Benz	600 SL	129.076	1992	121	
Mercedes-Benz	C 320	203	2001–2002	441	
Mercedes-Benz	C Class		1994–1999	331	
Mercedes-Benz	C Class	203	2000–2001	456	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Mercedes-Benz	C Class (manufactured prior to 9/1/2006)	W203	2003–2006	521	
Mercedes-Benz	CL 500		1998	277	
Mercedes-Benz	CL 500		1999–2001	370	
Mercedes-Benz	CL 600		1999–2001	370	
Mercedes-Benz	CLK 320		1998	357	
Mercedes-Benz	CLK Class		1999–2001	380	
Mercedes-Benz	CLK Class	209	2002–2005	478	
Mercedes-Benz	CLS Class (manufactured prior to 9/1/06)		2006	532	
Mercedes-Benz	E 200		1994	207	
Mercedes-Benz	E 200		1995–1998	278	
Mercedes-Benz	E 220		1994–1996	168	
Mercedes-Benz	E 250		1994–1995	245	
Mercedes-Benz	E 280		1994–1996	166	
Mercedes-Benz	E 320		1994–1998	240	
Mercedes-Benz	E 320	Station Wagon	1994–1999	318	
Mercedes-Benz	E 320	211	2002–2003	418	
Mercedes-Benz	E 420		1994–1996	169	
Mercedes-Benz	E 500		1994	163	
Mercedes-Benz	E 500		1995–1997	304	
Mercedes-Benz	E Class	W210	1996–2002	401	
Mercedes-Benz	E Class	211	2003–2004	429	
Mercedes-Benz	E Series		1991–1995	354	
Mercedes-Benz	G Class	463 Chassis	1991		51
Mercedes-Benz	G Class	463 Chassis, LWB	2005	549	
Mercedes-Benz	G Class	463 Chassis, LWB	2009	583	
Mercedes-Benz	G Class LWB	463 Chassis	2006–2007	527	
Mercedes-Benz	G-Wagon	463	1996		11
Mercedes-Benz	G-Wagon	463	1997		15
Mercedes-Benz	G-Wagon	463	1998		16
Mercedes-Benz	G-Wagon	463	1999–2000		18
Mercedes-Benz	G-Wagon 300 GE LWB	463.228	1993		3
Mercedes-Benz	G-Wagon 300 GE LWB	463.228	1994		5
Mercedes-Benz	G-Wagon 300 GE LWB	463.228	1991–1992		5
Mercedes-Benz	G-Wagon 320 LWB	463	1995		6
Mercedes-Benz	G-Wagon 5 DR LWB	463	2001		21
Mercedes-Benz	G-Wagon LWB	463 5 DR	2002	392	
Mercedes-Benz	G-Wagon LWB V–8	463	1992–1996		13
Mercedes-Benz	G-Wagon SWB	463 Cabriolet & 3DR	2004		28
Mercedes-Benz	G-Wagon SWB	463	2005		31
Mercedes-Benz	G-Wagon SWB	463	1991–1996		14
Mercedes-Benz	G-Wagon SWB	463 Cabriolet & 3DR	2001–2003		25
Mercedes-Benz	G-Wagon SWB (manufactured before 9/1/06)	463 Cabriolet & 3DR	2006		35
Mercedes-Benz	Maybach		2004	486	
Mercedes-Benz	S 280	140.028	1994	85	
Mercedes-Benz	S 320		1994–1998	236	
Mercedes-Benz	S 420		1994–1997	267	
Mercedes-Benz	S 500		1994–1997	235	
Mercedes-Benz	S 500		2000–2001	371	
Mercedes-Benz	S 600	Coupe	1994	185	
Mercedes-Benz	S 600		1995–1999	297	
Mercedes-Benz	S 600		2000–2001	371	
Mercedes-Benz	S 600L		1994	214	
Mercedes-Benz	S Class		1993	395	
Mercedes-Benz	S Class		2012	565	
Mercedes-Benz	S Class	140	1991–1994	423	
Mercedes-Benz	S Class		1995–1998	342	
Mercedes-Benz	S Class		1998–1999	325	
Mercedes-Benz	S Class	W220	1999–2002	387	
Mercedes-Benz	S Class	220	2002–2004	442	
Mercedes-Benz	S Class		2007–2010	566	
Mercedes-Benz	S Class (manufactured prior to 9/1/2006)		2005–2006	525	
Mercedes-Benz	SE Class		1992–1994	343	
Mercedes-Benz	SEL Class	140	1992–1994	343	
Mercedes-Benz	SL (Manufactured before 9/1/06)		2006	574	
Mercedes-Benz	SL Class		1993–1996	329	
Mercedes-Benz	SL Class	W129	1997–2000	386	
Mercedes-Benz	SL Class	R230	2001–2002		19
Mercedes-Benz	SL Class (European market)	230	2003–2005	470	
Mercedes-Benz	SLK		1997–1998	257	
Mercedes-Benz	SLK		2000–2001	381	
Mercedes-Benz	SLK Class		2014	581	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Mercedes-Benz	SLK Class (manufactured between 8/31/04 and 8/31/06).	171 Chassis	2005–2006	511	
Mercedes-Benz	SLR (manufactured prior to 9/1/2006)		2005–2006	558	
Mercedes-Benz (truck)	Sprinter		2001–2005	468	
Mini	Cooper (European market)	Convertible	2005	482	
Mitsubishi	Outlander		2011	564	
Moto Guzzi (MC)	California		2000–2001	495	
Moto Guzzi (MC)	California EV		2002	403	
Moto Guzzi (MC)	Daytona		1993	118	
Moto Guzzi (MC)	Daytona RS		1996–1999	264	
MV Agusta (MC)	F4		2000	420	
Nissan	GTS & GTR (RHD), a.k.a. ''Skyline,'' manufactured 1/96–6/98.	R33	1996–1998		32
Nissan	Pathfinder		2002	412	
Nissan	Pathfinder		1991–1995	316	
Plymouth	Voyager		1996	353	
Pontiac	Firebird Trans Am		1995	481	
Pontiac	Trans Sport	MPV	1993	189	
Porsche	911		1991	526	
Porsche	911	997	2009	542	
Porsche	911		1997–2000	346	
Porsche	911 (996) Carrera		2002–2004	439	
Porsche	911 (996) GT3		2004	438	
Porsche	911 Carrera		1993	165	
Porsche	911 Carrera		1994	103	
Porsche	911 Carrera		1995–1996	165	
Porsche	911 Carrera (manufactured prior to 9/1/06).	Cabriolet	2005–2006	513	
Porsche	911 Carrera (manufactured prior to 9/1/06).		2005–2006	531	
Porsche	911 Carrera 2 & Carrera 4		1992	52	
Porsche	911 Turbo		1992	125	
Porsche	911 Turbo		2001	347	
Porsche	928		1991–1996	266	
Porsche	928		1993–1998	272	
Porsche	946 Turbo		1994	116	
Porsche	Boxster		1997–2001	390	
Porsche	Boxster (manufactured before 9/1/02)		2002	390	
Porsche	Carrera GT		2004–2005	463	
Porsche	Carrera Series	964	1992	546	
Porsche	Cayenne		2003–2004	464	
Porsche	Cayenne (manufactured prior to 9/1/06)		2006	519	
Porsche	Cayenne S		2009	543	
Porsche	GT2		2001		20
Porsche	GT2		2002	388	
Porsche	GT3 RS		2012	552	
Rice	Beaufort Double		1991	529	
Rolls Royce	Bentley Brooklands		1993	186	
Rolls Royce	Bentley Continental R		1991–1993	258	
Rolls Royce	Bentley Turbo R		1995	243	
Rolls Royce	Bentley Turbo R		1992–1993	291	
Rolls Royce	Phantom		2004	455	
Saab	9.3		2003	426	
Saab	900 SE		1995	213	
Saab	900 SE		1991–1994	219	
Saab	900 SE		1996–1997	219	
Saab	9000		1994	334	
Smart Car	Fortwo coupe & cabriolet (incl. trim levels passion, pulse, & pure).		2005		30
Smart Car	Fortwo coupe & cabriolet (incl. trim levels passion, pulse, & pure).		2002–2004		27
Smart Car	Fortwo coupe & cabriolet (incl. trim levels passion, pulse, & pure) manufactured before 9/1/06.		2006		34
Smart Car	Fortwo coupe & cabriolet (incl. trim levels passion, pulse, & pure) manufactured before 9/1/06.		2007		39
Subaru	Forester		2006–2007	510	
Suzuki (MC)	GSF 750		1996–1998	287	
Suzuki (MC)	GSX1300R, a.k.a. ''Hayabusa''		1999–2006	484	
Suzuki (MC)	GSX1300R, a.k.a. ''Hayabusa''		2007–2011	533	
Suzuki (MC)	GSX–R 1100		1991–1997	227	

VEHICLES MANUFACTURED FOR OTHER THAN THE CANADIAN MARKET—Continued

Make	Model type(s)	Body/chassis	Model years(s)	VSP	VCP
Suzuki (MC)	GSX–R 750		1991–1998	275	
Suzuki (MC)	GSX–R 750		1999–2003	417	
Thule	3008BL boat trailer		2011		52
Toyota	4-Runner		1998	449	
Toyota	Avalon		1995–1998	308	
Toyota	Land Cruiser		1991–1996	218	
Toyota	Land Cruiser (manufactured prior to 9/1/2006).	IFS 100 series	1999–2006	539	
Toyota	MR2		1991	324	
Toyota	Previa		1991–1992	326	
Toyota	Previa		1993–1997	302	
Toyota	RAV4		1996	328	
Toyota	RAV4		2005	480	
Triumph (MC)	Thunderbird		1995–1999	311	
Vespa (MC)	ET2, ET4		2001–2002	378	
Vespa (MC)	LX and PX		2004–2005	496	
Volkswagen	Bora		1999	540	
Volkswagen	Eurovan		1993–1994	306	
Volkswagen	Golf		2005	502	
Volkswagen	Golf III		1993	92	
Volkswagen	GTI (Canadian market)		1991	149	
Volkswagen	Jetta		1994–1996	274	
Volkswagen	Passat	4-door Sedan	1992	148	
Volkswagen	Passat	Wagon & Sedan	2004	488	
Volkswagen	Transporter		1991	554	
Volvo	740 GL		1992	137	
Volvo	850 Turbo		1995–1998	286	
Volvo	940 GL		1992	137	
Volvo	940 GL		1993	95	
Volvo	945 GL	Wagon	1994	132	
Volvo	960	Sedan & Wagon	1994	176	
Volvo	C70		2000	434	
Volvo	S70		1998–2000	335	
Westfalia	14ft Double Axle Cargo trailer		1994&1997		56
Yamaha (MC)	Drag Star 1100		1999–2007	497	
Yamaha (MC)	FJ1200 (4 CR)		1991	113	
Yamaha (MC)	FJR 1300		2002		23
Yamaha (MC)	R1		2000	360	
Yamaha (MC)	Virago		1991–1998	301	

Authority: 49 U.S.C. 30141(b); 49 CFR 593.9; delegations of authority at 49 CFR 1.95 and 501.8.

Issued on: September 27, 2016.

Mark R. Rosekind,

Administrator.

[FR Doc. 2016–23941 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE925

Fisheries of the Exclusive Economic Zone Off Alaska; Several Groundfish Species 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; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the non-specified reserve to the initial total allowable catch (ITAC) of Bering Sea (BS) Pacific ocean perch, Bering Sea and Aleutian Islands (BSAI) Kamchatka flounder, BSAI ''other flatfish,'' BSAI northern rockfish, BSAI skates, BSAI sculpins, and BSAI squids in the BSAI management area. This action is necessary to allow the fisheries to continue operating. It is intended to promote the goals and objectives of the fishery management plan for the BSAI management area.

DATES: Effective September 29, 2016 through 2400 hrs, Alaska local time, December 31, 2016. Comments must be received at the following address no later than 4:30 p.m., Alaska local time, October 19, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0118, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to, *http://www.regulations.gov/docket?D=NOAA-NMFS-2015-0118,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change.

All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 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 2016 ITAC of BS Pacific ocean perch was established as 6,800 metric tons (mt), the 2016 ITAC of BSAI Kamchatka flounder was established as 4,250 mt, the 2016 ITAC of BSAI ''other flatfish'' was established as 2,125 mt, the 2016 ITAC of BSAI northern rockfish was established as 3,825 mt, the 2016 ITAC of BSAI skates was established as 22,100 mt, the 2016 ITAC of BSAI sculpins was established as 3,825 mt, and the 2016 ITAC of BSAI squids was established as 1,275 mt by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016). In accordance with § 679.20(a)(3) the Regional Administrator, Alaska Region, NMFS, has reviewed the most current available data and finds that the ITACs for BS Pacific ocean perch, BSAI Kamchatka flounder, BSAI ''other flatfish,'' BSAI northern rockfish, BSAI skates BSAI sculpins, and BSAI squids need to be supplemented from the non-specified reserve to promote efficiency in the utilization of fishery resources in the BSAI and allow fishing operations to continue.

Therefore, in accordance with § 679.20(b)(3), NMFS apportions from the non-specified reserve of groundfish 1,400 mt to the BS Pacific ocean perch ITAC, 300 mt to the BSAI Kamchatka flounder ITAC, 737 mt to the BSAI ''other flatfish'' ITAC, 550 mt to the BSAI northern rockfish ITAC, 5,000 mt to the BSAI skates ITAC, 500 mt to the BSAI sculpins ITAC, and 30 mt to the BSAI squids ITAC. These apportionments are consistent with § 679.20(b)(1)(i) and do not result in overfishing of any target species because the revised ITACs and total allowable catch (TAC) are equal to or less than the specifications of the acceptable biological catch in the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

The harvest specification for the 2016 ITACs and TACs included in the harvest specifications for groundfish in the BSAI are revised as follows: The 2016 ITAC is increased to 4,550 mt for BSAI Kamchatka flounder, 2,862 mt for BSAI ''other flatfish,'' 4,375 mt for BSAI northern rockfish, 27,100 mt for BSAI skates, 4,325 mt for BSAI sculpins, and 1,305 mt for BSAI squids. The ITAC is increased to the full TAC of 8,200 mt for BS Pacific ocean perch.

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) and § 679.20(b)(3)(iii)(A) as such a 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 apportionment of the non-specified reserves of groundfish to the BS Pacific ocean perch, BSAI Kamchatka flounder, BSAI ''other flatfish,'' BSAI northern rockfish, BSAI skates, BSAI sculpins, and BSAI squids in the BSAI. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet and processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 26, 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.

Under § 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES**) until October 19, 2016.

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: September 29, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–23969 Filed 9–29–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 192
Tuesday, October 4, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9185; Directorate Identifier 2016–NM–077–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 757–200, –200PF, and –200CB series airplanes. This proposed AD was prompted by an analysis of the cam support assemblies of the main cargo door which indicated that the existing maintenance program for the cam support assemblies is not adequate to reliably detect cracks before two adjacent cam support assemblies could fail. This proposed AD would require an inspection to determine part numbers, repetitive inspections to detect cracking of affected cam support assemblies of the main cargo door, and replacement if necessary. We are proposing this AD to detect and correct cracking of the cam support assemblies of the main cargo door, which could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by November 18, 2016.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9185.

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–2016–9185; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9185; Directorate Identifier 2016–NM–077–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received an analysis of the cam support assemblies of the main cargo door which indicated that the existing maintenance program for the cam support assemblies is not adequate to reliably detect cracks before two adjacent cam support assemblies could fail on certain Boeing Model 757–200, –200PF, and –200CB series airplanes.

The main cargo door is on the upper left side of the forward fuselage between body stations 480 and 620. The door is hinged on its upper edge and opens outward to a canopy or a fully open position. The main cargo door has eight cam support assemblies along the bottom of the door that support the latch cams. The door latch cams engage with latch pins on the fuselage and hold the door closed. The cam support assemblies of the main cargo door are subject to ground loads, flight loads, and cabin pressure loads.

Cracking of the cam support assemblies of the main cargo door could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015. The service information describes procedures for doing an ultrasonic inspection of the cam support assemblies of the main cargo door, and replacement of the cam support assemblies. 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.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9185.

Differences Between This Proposed AD and the Service Information

The effectivity of Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015, is limited to certain Model 757–200, –200PF, and –200CB series airplanes. However, the applicability of this proposed AD includes all Model 757–200, –200PF, and –200CB series airplanes because all airplanes must be inspected to determine if affected cam support assemblies of the main cargo door are installed. For all airplanes affected by this AD, including those airplanes not listed in the effectivity of Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015, compliance with paragraph (h) of this AD must be done using Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015. Therefore, an alternative method of compliance (AMOC) approval is not necessary for those airplanes if Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015, is used. This difference has been coordinated with Boeing.

Costs of Compliance

We estimate that this proposed AD affects 212 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	6 work-hours × $85 per hour = $510 per inspection cycle.	$0	$510 per inspection cycle	$108,120 per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement (per pair of cam support assemblies)	60 work-hours × $85 per hour = $5,100	$15,298	$20,398

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–9185; Directorate Identifier 2016–NM–077–AD.

(a) Comments Due Date

We must receive comments by November 18, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, –200PF, and –200CB series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Unsafe Condition

This AD was prompted by an analysis of the cam support assemblies of the main cargo door which indicated that the existing maintenance program for the cam support assemblies is not adequate to reliably detect cracks before two adjacent cam support assemblies could fail. We are issuing this AD to detect and correct cracking of the cam support assemblies of the main cargo door, which could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

(f) Compliance

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

(g) Inspection To Determine Part Numbers

At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Inspect the cam support assemblies of the main cargo door to determine whether part number (P/N) 69–23588–5, 69–23588–6, 69–23588–7, 69–23588–8, 69–23588–9, or 69–23588–10 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number(s) of the cam support assemblies of the main cargo door can be conclusively determined from that review.

(1) Before the accumulation of 18,000 total flight cycles.

(2) Within 2,743 flight cycles or 27 months after the effective date of this AD, whichever occurs later.

(h) Inspections and Corrective Actions

If, during any inspection required by paragraph (g) of this AD, any cam support assembly of the main cargo door having P/N 69–23588–5, 69–23588–6, 69–23588–7, 69–23588–8, 69–23588–9, or 69–23588–10 is determined to be installed: At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD, do an ultrasonic inspection to detect cracking of the affected cam support assemblies of the main cargo door; and do all applicable replacements; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–52A0094, dated December 23, 2015. Do all applicable replacements before further flight. Repeat the inspections thereafter at intervals not to exceed 6,000 flight cycles. Replacement of a cam support assembly of the main cargo door does not terminate the repetitive inspections required by this paragraph.

(i) Alternative Methods of Compliance (AMOCs)

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

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

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

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

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled ''RC Exempt,'' then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

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

(j) Related Information

(1) For more information about this AD, contact Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

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

Issued in Renton, Washington, on September 27, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–23936 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–9184; Directorate Identifier 2016–NM–060–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 727 airplanes. This proposed AD was prompted by analysis of the cam support assemblies of the main cargo door that indicated the repetitive high frequency eddy current (HFEC) inspections required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. This proposed AD would require repetitive ultrasonic inspections for cracking of the cam support assemblies of the main cargo door and replacement if necessary. We are proposing this AD to detect and correct cracking of the cam support assemblies of the main cargo door. Such cracking could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by November 18, 2016.

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

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

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

this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9184.

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–2016–9184; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9184; Directorate Identifier 2016–NM–060–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received a report indicating that the analysis of the cam support assemblies of the main cargo door, having part numbers 69–23588–5 and 69–23588–6, indicated that the repetitive HFEC inspections required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. This condition, if not corrected, could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016. The service information describes procedures for an ultrasonic inspection of the cam support assemblies of the main cargo door for cracking, and replacement if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9184.

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016, only affects Model 727C, 727–100C, and 727–200F series airplanes. The applicability of this proposed AD extends to all Model 727 airplanes. Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016, only affects certain part numbers. We are extending the list of affected part numbers to include 69–23588–1 and 69–23588–2, which were not referenced in Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016. These differences exist to ensure all affected parts are inspected in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016. For all airplanes affected by this AD, including airplanes not listed in the effectivity of Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016, compliance with paragraph (h) of this AD must be done using Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016. Therefore, an alternative method of compliance (AMOC) approval is not necessary for those airplanes if Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016, is used. This difference has been coordinated with Boeing.

Costs of Compliance

We estimate that this proposed AD affects 45 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	6 work-hours × $85 per hour = $510 per inspection cycle.	$0	$510 per inspection cycle	$22,950 per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	60 work-hours × $85 per hour = $5,100	$14,107	$19,207

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–9184; Directorate Identifier 2016–NM–060–AD.

(a) Comments Due Date

We must receive comments by November 18, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category,

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Unsafe Condition

This AD was prompted by analysis of the cam support assemblies of the main cargo door that indicated the repetitive high frequency eddy current (HFEC) inspection required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. We are issuing this AD to detect and correct cracking of the cam support assemblies of the main cargo door. Such cracking could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

(f) Compliance

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

(g) Inspection To Determine Part Numbers

At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Inspect the cam support assemblies of the main cargo door to determine whether part number (P/N) 69–23588–1, 69–23588–2, 69–23588–5, 69–23588–6, 69–23588–9, or 69–23588–10 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number(s) of the cam support assemblies of the main cargo door can be conclusively determined from that review.

(1) Before the accumulation of 18,000 total flight cycles.

(2) Within 1,771 flight cycles or 27 months after the effective date of this AD, whichever occurs later.

(h) Repetitive Inspections of the Cam Support Assemblies of the Main Cargo Door and Corrective Actions

If, during any inspection required by paragraph (g) of this AD, any cam support assembly of the main cargo door having P/N 69–23588–1, 69–23588–2, 69–23588–5, 69–23588–6, 69–23588–9, or 69–23588–10 is determined to be installed: At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD, do an ultrasonic inspection to detect cracking of the affected cam support assemblies of the main cargo door; and do all applicable replacements; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016. Do all applicable replacements before further flight. Repeat the inspections thereafter at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 727–52A0151, dated February 12, 2016.

(i) Alternative Methods of Compliance (AMOCs)

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

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

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

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

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

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

(j) Related Information

(1) For more information about this AD, contact Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

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

Issued in Renton, Washington, on September 27, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–23938 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9183; Directorate Identifier 2016–NM–059–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 707 airplanes. This proposed AD was prompted by analysis of the cam support assemblies of the main cargo door that indicated the repetitive high frequency eddy current (HFEC) inspections required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. This proposed AD would require repetitive ultrasonic inspections for cracking of the cam support assemblies of the main cargo door and replacement if necessary. We are proposing this AD to detect and correct cracking of the cam support assemblies of the main cargo door. Such cracking could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by November 18, 2016.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9183.

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–2016–9183; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9183; Directorate Identifier 2016–NM–059–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received a report indicating that the analysis of the cam support assemblies of the main cargo door, part numbers 69–23588–5 and 69–23588–6, indicated that the repetitive HFEC inspections required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. This condition, if not corrected, could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016. The service information describes procedures for an ultrasonic inspection of the cam support assemblies of the main cargo door for cracking, and replacement if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9183.

Differences Between This Proposed AD and the Service Information

Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, only affects Model 707–300B and –300C airplanes. The applicability of this proposed AD extends to all Model 707 airplanes. Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, only affects certain part numbers. We are extending the list of affected part numbers to include 69–23588–1 and 69–23588–2, which are not referenced in Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016. These differences exist to ensure all affected parts are inspected in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016. For all airplanes affected by this AD, including airplanes not listed in the effectivity of Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, compliance with paragraph (h) of this AD must be done using Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016. Therefore, an alternative method of compliance (AMOC) approval is not necessary for those airplanes if Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, is used. This difference has been coordinated with Boeing.

Costs of Compliance

We estimate that this proposed AD affects 12 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	6 work-hours × $85 per hour = $510 per inspection cycle.	$0	$510 per inspection cycle	$22,950 per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	60 work-hours × $85 per hour = $5,100	$14,107	$19,207.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–9183; Directorate Identifier 2016–NM–059–AD.

(a) Comments Due Date

We must receive comments by November 18, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 707–100 Long Body, –200, –100B Long Body, and –100B Short Body series airplanes; and Model 707–300, –300B, –300C, and –400 series airplanes; certificated in any category,

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Unsafe Condition

This AD was prompted by analysis of the cam support assemblies of the main cargo door that indicated the repetitive high frequency eddy current (HFEC) inspections required by the existing maintenance program are not adequate to detect cracks before two adjacent cam support assemblies of the main cargo door could fail. We are issuing this AD to detect and correct cracking of the cam support assemblies of the main cargo door. Such cracking could result in reduced structural integrity of the main cargo door and consequent rapid decompression of the airplane.

(f) Compliance

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

(g) Inspection To Determine Part Numbers

At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Inspect the cam support assemblies of the main cargo door to determine whether part number (P/N) 69–23588–1, 69–23588–2, 69–23588–5, 69–23588–6, 69–23588–9, or 69–23588–10 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number(s) of the cam support assemblies of the main cargo door can be conclusively determined from that review.

(1) Before the accumulation of 18,000 total flight cycles.

(2) Within 1,790 flight cycles or 24 months after the effective date of this AD, whichever occurs later.

(h) Repetitive Inspections for the Cam Support Assemblies of the Main Cargo Door and Corrective Actions

If, during any inspection required by paragraph (g) of this AD, any cam support assembly of the main cargo door having P/N 69–23588–1, 69–23588–2, 69–23588–5, 69–23588–6, 69–23588–9, or 69–23588–10 is determined to be installed: Except as required by paragraph (i) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, do an ultrasonic inspection to detect cracking of the affected cam support assemblies of the main cargo door, and do all applicable replacements, in accordance with the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016. Do all applicable replacements before further flight. Repeat the inspections thereafter at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016.

(i) Service Information Exception

Where Boeing 707 Alert Service Bulletin A3542, dated February 12, 2016, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(j) Alternative Methods of Compliance (AMOCs)

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

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

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

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

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

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

(k) Related Information

(1) For more information about this AD, contact Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

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

Issued in Renton, Washington, on September 27, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–23939 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–163113–02]

RIN 1545–BB71

Estate, Gift, and Generation-Skipping Transfer Taxes; Restrictions on Liquidation of an Interest; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to a notice of proposed rulemaking (REG–163113–02) that was published in the **Federal Register** on Thursday, August 4, 2016 (81 FR 51413). The proposed regulations concern the valuation of interests in corporations and partnerships for estate, gift, and generation-skipping transfer tax purposes.

DATES: Written or electronic comments and outlines of topics to be discussed at the public hearing scheduled for December 1, 2016, for the notice of proposed rulemaking at 81 FR 51413, August 4, 2016, are still being accepted and must be received by November 2, 2016.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–163113–02), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–163113–02), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically, via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–163113–02).

FOR FURTHER INFORMATION CONTACT: John D. MacEachen, at (202) 317–6859 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of this document is under section 2704 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG–163113–02) contains an error that is misleading and is in need of clarification.

Correction to Publication

Accordingly, the notice of proposed rulemaking, that is the subject of FR Doc. 2016–18370, is corrected as follows:

1. On page 51418, in the third column, under the paragraph heading ''Effective Dates'', in the second line from the top of the paragraph, the language ''proposed to be effective on and after the'' is corrected to read ''proposed to be effective on the''.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2016–23957 Filed 10–3–16; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0291; FRL–9952–12–Region 9]

Approval of California Air Plan Revisions, Sacramento Metropolitan Air Quality Management District and San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD) and the San Diego County Air Pollution Control District (SDCAPCD) portions of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from architectural coatings. We are proposing to approve local rules and a rule rescission to regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: Any comments on this proposal must arrive by November 3, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0291 at *http://www.regulations.gov,* or via email to *Steckel.Andrew@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972–3024, *lazarus.arnold@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA. This proposal addresses the following local rules: SMAQMD Rule 442, SDCAPCD Rule 67.0 (rescinded) and SDCAPCD Rule 67.0.1 (the replacement rule). In the Rules and Regulations section of this **Federal Register**, we are approving these local rules and rule rescission in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: August 24, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2016–23838 Filed 10–3–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2016–0086; 4500030113]

RIN 1018–BB52

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Western Glacier Stonefly as an Endangered or Threatened Species; Proposed Threatened Species Status for Meltwater Lednian Stonefly and Western Glacier Stonefly

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; 12-month petition finding and status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding for the western glacier stonefly (*Zapada glacier*). After a review of the best available scientific and commercial information, we find that listing the western glacier stonefly is warranted. We are also announcing the proposed listing rule for the candidate species meltwater lednian stonefly (*Lednia tumana*). Therefore, we are proposing to list both the meltwater lednian stonefly and the western glacier stonefly, two insect species from Glacier National Park and northwestern Montana, as threatened species under the Endangered Species Act (Act). If we finalize this rule as proposed, it would extend the Act's protections to these species. The effect of this regulation will be to add these species to the Federal List of Endangered and Threatened Wildlife. The Service seeks data and comments from the public on this proposed listing rule.

DATES: We will accept comments received or postmarked on or before December 5, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 18, 2016.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R6–ES–2016–0086, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R6–ES–2016–0086; U.S. Fish and Wildlife Service Headquarters, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments* below for more information).

FOR FURTHER INFORMATION CONTACT: Jodi Bush, Field Supervisor, U.S. Fish and Wildlife Service, Montana Ecological Services Field Office, 585 Shepard Way, Helena, MT 59601, by telephone 406–449–5225 or by facsimile 406–449–5339. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule. In the near future, we intend to publish a proposal to designate critical habitat for meltwater lednian stonefly and western glacier stonefly. Designation of critical habitat is prudent, but not determinable at this time.

This document proposes the listing of the meltwater lednian stonefly and the western glacier stonefly as threatened species. The meltwater lednian stonefly is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation has been precluded by other higher priority listing activities. We were petitioned to list the western glacier stonefly and published a substantial 90-day finding in 2011. We assessed all information regarding status of and threats to both the meltwater lednian stonefly and the western glacier stonefly that was available through August 11, 2016. However, we received additional information on western glacier stonefly on August 12, 2016, indicating a larger range than previously known. Because we received this new information late in the status review process, we were unable to fully incorporate and analyze the new information in this document in time to meet the settlement agreement deadline of submitting a 12-month finding for western glacier stonefly to the **Federal Register** by September 30, 2016. As such, we plan to reopen the comment period on this proposed listing rule in the near future when we have been able to fully incorporate and analyze the new information and allow the public to comment on the new information and our analysis of it at that time. The current document consists of the 12-month finding for the western glacier stonefly, for which we find listing is warranted, and proposed rules to list both stonefly species.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. We have determined that habitat fragmentation and degradation resulting from climate change are current and future threats to the viability of both the meltwater lednian stonefly and the western glacier stonefly. Drought is expected to be a threat to both stonefly species in the foreseeable future.

We will seek peer review. We will seek comments from appropriate and independent specialists to ensure that our determination is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment on our listing proposal. Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal. We particularly seek comments concerning:

(1) The meltwater lednian stonefly and the western glacier stonefly biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, their habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to these species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of these species, including the locations of any additional populations.

As referenced above in the Executive Summary, we will be reopening the comment period for this proposed listing rule in the near future once we incorporate and analyze the new information we recently obtained on western glacier stonefly, which is further described under *Distribution and Abundance* below. During the reopening of the comment period, we will seek comments concerning the new information describing the expanded range and additional populations of western glacier stonefly.

Please include sufficient information with your submission (such as scientific

journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we are seeking the expert opinions of three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determinations are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in stonefly biology, habitat, and life history. We invite comment from the peer reviewers during the public comment periods.

Previous Federal Action

Meltwater Lednian Stonefly

On July 30, 2007, we received a petition from Forest Guardians (now WildEarth Guardians) requesting that the Service: (1) Consider all full species in our Mountain Prairie Region ranked by the organization NatureServe as G1 or G1G2 (which includes the meltwater lednian stonefly), except those that are currently listed, proposed for listing, or candidates for listing; and (2) list each species as either endangered or threatened (Forest Guardians 2007, pp. 1–37). We replied to the petition on August 24, 2007, and stated that, based on preliminary review, we found no compelling evidence to support an emergency listing for any of the species covered by the petition, and that we planned work on the petition in Fiscal Year (FY) 2008.

On March 19, 2008, WildEarth Guardians filed a complaint (1:08–CV–472–CKK) indicating that the Service failed to comply with its mandatory duty to make a preliminary 90-day finding on their two multiple species petitions in two of the Service's administrative regions—one for the Mountain-Prairie Region and one for the Southwest Region (*WildEarth Guardians* v. *Kempthorne* 2008, case 1:08–CV–472–CKK). We subsequently published two initial 90-day findings on January 6, 2009 (74 FR 419), and February 5, 2009 (74 FR 6122), identifying species for which we were then making negative 90-day findings, and species for which we were still working on a determination. On March 13, 2009, the Service and WildEarth Guardians filed a stipulated settlement in the District of Columbia Court, agreeing that the Service would submit to the **Federal Register** a finding as to whether WildEarth Guardians' petition presents substantial information indicating that the petitioned action may be warranted for 38 Mountain-Prairie Region species by August 9, 2009 (*WildEarth Guardians* v. *Salazar* 2009, case 1:08–CV–472–CKK).

On August 18, 2009, we published a partial 90-day finding for the 38 Mountain-Prairie Region species, and found that the petition presented substantial information to indicate that listing of the meltwater lednian stonefly may be warranted based on threats from habitat loss and degradation due to climate change, and specifically the melting of glaciers associated with the species' habitat; and went on to request further information pertaining to the species (74 FR 41649, 41659–41660).

On April 5, 2011, we published a 12-month finding (76 FR 18684) for the meltwater lednian stonefly indicating that listing was warranted, but precluded by higher priority listing actions. At that time, the meltwater lednian stonefly was added to our list of candidate species with a listing priority number (LPN) of 4. In the 2011 candidate notice of review (76 FR 66370, October 24, 2011; p. 66376), we announced a revised LPN of 5 for the species due to research that showed the meltwater lednian stonefly was no longer considered to be a monotypic genus. In each successive year since then we reaffirmed our 2011 finding of warranted but precluded and maintained a listing priority number of 5 for the species.

Western Glacier Stonefly

On January 10, 2011, we received a petition to list the western glacier stonefly from the Xerces Society and Center for Biological Diversity. We replied to the petition on August 3, 2011, indicating that emergency listing was not warranted. On December 19, 2011, we published a 90-day finding (76 FR 78601) for the western glacier stonefly indicating there was substantial scientific information indicating that listing of the species may be warranted. On April 15, 2015, the Center for Biological Diversity filed an amended complaint (1:15–CV–00229–EGS) seeking 12-month findings for several species, including the western glacier stonefly. On September 15, 2015, the Service and the Center for Biological Diversity filed a stipulated settlement in the District of Columbia Court, agreeing that the Service would submit to the **Federal Register** a 12-month finding for the western glacier stonefly by September 30, 2016 (*Center for Biological Diversity* v. *Jewell* 2009, case 1:15–CV–00229–EGS). This document contains the status review and 12-month finding for the species.

Because both stonefly species occupy similar habitat in the same geographic region of northwestern Montana and are faced with similar threats, we have batched them into one status review and subsequent proposed rule for efficiency. Therefore, this document constitutes both the 12-month finding and proposed listing rule for the western glacier stonefly, and the proposed listing rule for the meltwater lednian stonefly.

Background

Taxonomy and Species Description

The meltwater lednian and western glacier stoneflies are small insects that begin life as eggs, hatch into aquatic nymphs, and later mature into winged adults, surviving briefly on land before reproducing and dying. The nymph, or aquatic juvenile stage, of the meltwater lednian stonefly is dark red-brown on its dorsal surface and pink on the ventral surface, with light grey-green legs (Baumann and Stewart 1980, p. 658). Mature nymphs can range in size from 4.5 to 6.5 millimeters (mm) (0.18 to 0.26 in.; Baumann and Stewart 1980, p. 655). Nymphs mature into the adult terrestrial phase that has wings and body sizes ranging from 4 to 6 mm (0.16 to 0.24 in.; Baumann 1975, p. 79). Western glacier stonefly nymphs are similar in color and size to meltwater stonefly nymphs. Western glacier stonefly adults are generally brown in color with yellowish brown legs and possess two sets of translucent wings (Baumann and Gaufin 1971, p. 275). Adults range from 6.5 to 10.0 millimeters (mm) (0.26 to 0.39 inches (in)) in body length (Baumann and Gaufin 1971, p. 275). Western glacier stonefly nymphs cannot be distinguished from other *Zapada* nymphs using gross morphological characteristics. Thus, DNA barcoding (in which DNA sequences of unidentified nymphs are compared with those of positively identified adults) must be used to positively identify western glacier stonefly nymphs.

The meltwater lednian stonefly was originally described by Ricker in 1952 (Baumann 1975, p. 18) from the Many Glacier area of Glacier National Park (GNP), Montana (Baumann 1982, pers. comm.). The meltwater lednian stonefly belongs to the phylum Arthropoda, class Insecta, order Plecoptera (stoneflies), family Nemouridae, and subfamily Nemourinae. Until recently, the meltwater lednian stonefly was believed to be the only species in the genus *Lednia* (Baumann 1975, p. 19; Stewart and Harper 1996, p. 263; Stark *et al.* 2009, entire; 76 FR 18688). However, three additional species (*L. borealis–Cascade Range, Washington; L. sierra–Sierra Madre Range, California; and L. tetonica–Wind River Range, Wyoming*) have been described in the genus *Lednia* since 2010 (Baumann and Kondratieff 2010, entire; Baumann and Call 2012, entire). Thus, the Service no longer considers the genus *Lednia* to be monotypic. The meltwater lednian stonefly is recognized as a valid species by the scientific community (*e.g.,* Baumann 1975, p. 18; Baumann *et al.* 1977, pp. 7, 34; Newell *et al.* 2008, p. 181; Stark *et al.* 2009, entire), and no information is available that disputes this finding. Consequently, we conclude that the meltwater lednian stonefly (*Lednia tumana*) is a valid species and, therefore, a listable entity under section 3(16) of the Act.

The western glacier stonefly was first described in 1971 from adult specimens collected from five locations in GNP, Montana (Baumann and Gaufin 1971, p. 277). The western glacier stonefly is in the same family as the meltwater lednian stonefly (*i.e.,* family Nemouridae; Baumann 1975, pp. 1, 31; Service 2011, p. 18688), but a different genus (*Zapada*). Members of the *Zapada* genus are the most common of the Nemouridae family (Baumann 1975, p. 31). The western glacier stonefly is recognized as a valid species by the scientific community (Baumann 1975, p. 30; Stark 1996, entire; Stark *et al.* 2009, p. 8), and no information is available that disputes this finding. Consequently, we conclude that the western glacier stonefly is a valid species and, therefore, a listable entity under section 3(16) of the Act.

Distribution and Abundance

Meltwater Lednian Stonefly

Fifty-eight populations of meltwater lednian stoneflies are known to occur; these are located primarily within GNP, with a few populations recorded south of GNP on National Forest and tribal lands (Figure 1; Giersch and Muhlfeld 2015, in progress). Meltwater lednian stonefly occupy relatively short reaches of streams [mean = 565 meters (m) (1,854 feet; ft); range = 1–2,355 m (3–7,726 ft)] below meltwater sources (for description, see Habitat section below; Giersch and Muhlfeld 2015, in progress). Meltwater lednian stoneflies can attain moderate to high densities [(350–5,800 per square m) (32–537 per square ft)] (*e.g.,* Logan Creek: Baumann and Stewart 1980, p. 658; NPS 2009, entire; Muhlfeld *et al.* 2011, p. 342; Giersch 2016, pers. comm.). Given this range of densities and a coarse assessment of available habitat, the abundance of meltwater lednian stonefly is estimated to be in the millions of individuals, however, no population trend information is available for the meltwater lednian stonefly.

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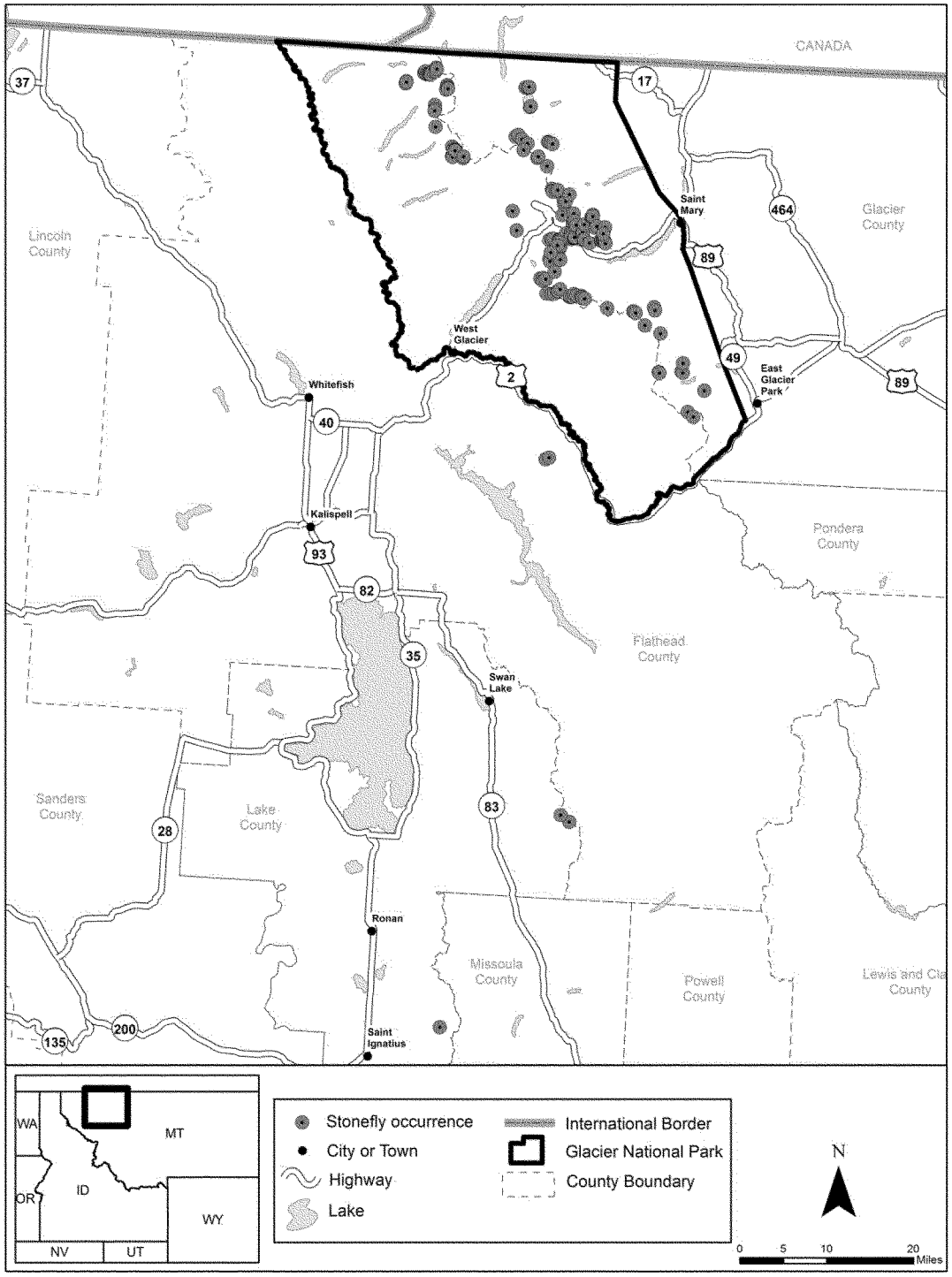

Figure 1. Documented occurrence of the meltwater lednian stonefly (*Lednia tumana*) from 1997 to 2015 in Glacier National Park, Great Bear Wilderness, Bob Marshall Wilderness, and the Mission Mountain Tribal Wilderness. Number of populations was determined in a separate analysis.

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Western Glacier Stonefly

Four populations of the western glacier stonefly are known to occur, all within the boundaries of GNP (Figure 2; Giersch and Muhlfeld 2015, in progress). Similar to the meltwater lednian stonefly, western glacier stoneflies are found on relatively short reaches of strems in close proximity to meltwater sources [means = 508 m (1,667 ft.); range = 15–1407 m (49–4,616 ft.)] (Giersch and Muhlfeld 2015, in progress). Western glafier stoneflies can attain moderate densities [(400–2,300 per square m) (37–213 per square ft)] (Giersch 2016, pers. comm.). Given this

range of densities and a coarse assessment of available habitat, the abundance of the western glacier stonefly is estimated to be in the tens of thousands of individuals, less numerous than the meltwater lednian stonefly.

Western glacier sotneflies have decreased in distribution among and within 6 streams where the species occurred in the 1960s and 1970s in GNP (Giersch *et al.* 2015, p. 58). Of the four known populations of the western glacier stonelfy, three were first documented relatively recently in GNP (Giersch *et al.* 2015, p.59; giersch and Muhlfeld 2015, in progress). In August 2016, we received new information indicating that the distribution of western glacier stonefly extends outside of GNP, including one population in the Absaroka-Beartooth Wilderness in southwestern Montana and three populations in Grand Teton National Park, Wyoming. This distribution represents a large range expansion (500 km southward) for western glacier stonefly compared to the range previously known for the species. However, because we received this information too late in the status review process to be able to incorporate it in time to meet the settlement agreement deadline of September 30, 2016, we have not yet fully evaluated this information, or incorporated it into our analysis or this proposed rule. We intend to reopen the comment period on the proposed listing rule when this information has been fully incorporated and analyzed.

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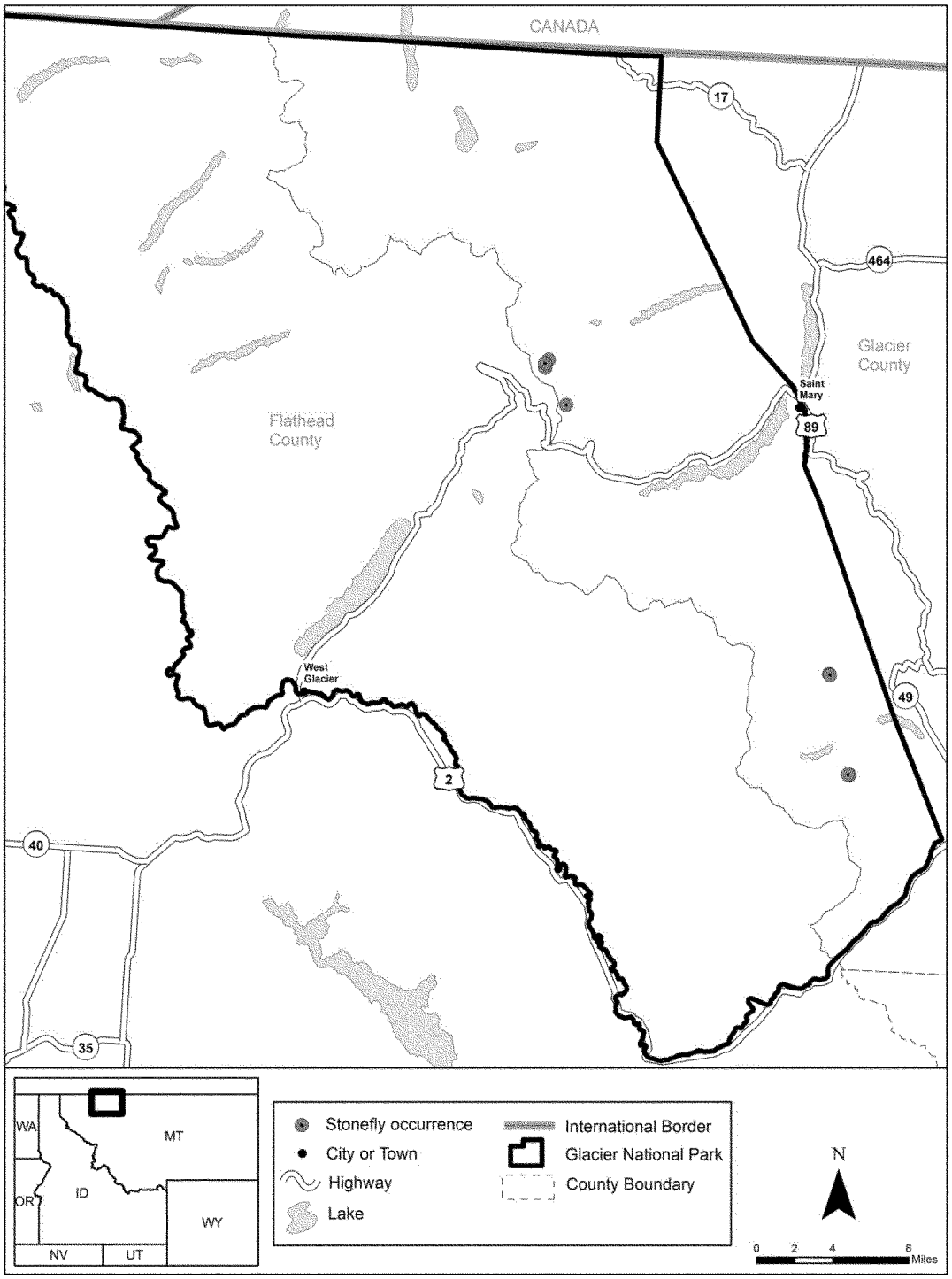

Figure 2. Documented occurrence of the western glacier stonefly (*Zapada glacier*) from 2010 to 2015 in Glacier National Park. Number of populations was determined in a separate analysis.

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The northern distributional limits of the meltwater lednian stonefly and the western glacier stonefly are not known. Potential habitat for meltwater lednian and western glacier stoneflies, similar to what both species are currently occupying, exists in the area of Banff and Jasper National Parks, Alberta, Canada. Aquatic invertebrate surveys have been conducted in this area, and no specimens of either species were found, although it is likely that sampling did not occur close enough to glaciers or icefields to detect either meltwater lednian or western glacier stonefly, if indeed they were present (Hirose 2016, pers. comm.). Sampling in this area for both meltwater lednian and western glacier stoneflies is planned for the future and would help fill in an

important data gap with regard to northern distributional limits of both species.

Habitat

Meltwater Lednian Stonefly

The meltwater lednian stonefly is found in high-elevation, fishless, alpine streams (Baumann and Stewart 1980, p. 658; MNHP 2010a) originating from meltwater sources, including glaciers and small icefields, permanent and seasonal snowpack, alpine springs, and glacial lake outlets (Hauer *et al.* 2007, p. 107; Giersch and Muhlfeld 2015, in progress). Meltwater lednian stonefly are known from alpine streams where mean and maximum water temperatures do not exceed 10 °C (50 °F) and 18 °C (64 °F), respectively (Muhlfeld *et al.* 2011, p. 342), although the species can withstand higher water temperatures (~20 °C; 68 °F) for short periods of time (Treanor *et al.* 2013, p. 602). In general, the alpine streams inhabited by the meltwater lednian stonefly are presumed to have very low nutrient concentrations (low nitrogen and phosphorus), reflecting the nutrient content of the glacial or snowmelt source (Hauer *et al.* 2007, pp. 107–108). During the daytime, meltwater lednian stonefly nymphs prefer to occupy the underside of rocks or larger pieces of bark or wood (Baumann and Stewart 1980, p. 658; Giersch and Muhlfeld 2015, in progress).

Western Glacier Stonefly

Western glacier stoneflies are found in high-elevation, fishless, alpine streams closely linked to the same meltwater sources as the meltwater lednian stonefly (Giersch and Muhlfeld 2015, in progress). The specific thermal tolerances of the western glacier stonefly are not known. However, all recent collections of the western glacier stonefly in GNP have occurred in habitats with daily maximum water temperatures less than 6.3 °C (43 °F) (Giersch *et al.* 2015, p. 61). Further, abundance patterns for other species in the *Zapada* genus in GNP indicate preferences for the coolest environmental temperatures, such as those found at high elevation in proximity to headwater sources (Hauer *et al.* 2007, p. 110). Daytime microhabitat preferences of the western glacier stonefly appear similar to those for the meltwater lednian stonefly (Giersch and Muhlfeld 2015, in progress).

Biology

Little information is available on the biology of the meltwater lednian and western glacier stoneflies. However, we assume that both species are likely to be similar to other closely related stoneflies in the Nemouridae family in terms of habitat needs and life-history traits. In general, Nemouridae stoneflies are primarily associated with clean, cool or cold, flowing waters (Baumann 1979, pp. 242–243; Stewart and Harper 1996, p. 217). Eggs and nymphs of Nemouridae stoneflies are aquatic (Stewart and Harper 1996, p. 217), and nymphs rely on perennial water sources to breathe through gills, similar to fish. Nemouridae nymphs are typically herbivores or detritivores, and their feeding mode is generally that of a shredder or collector-gatherer (Baumann 1975, p. 1; Stewart and Harper 1996, pp. 218, 262). Typically, Nemouridae stoneflies complete their life cycles within a single year (univoltine) or in 2 to 3 years (semivoltine) (Stewart and Harper 1996, pp. 217–218).

Mature stonefly nymphs emerge from the water and complete their development in the terrestrial environment as short-lived adults on and around streamside vegetation or other structures (Hynes 1976, pp. 135–136; Stewart and Harper 1996, p. 217). It is unknown if adult stoneflies select for particular features in the terrestrial environment. Timing of stonefly emergence is influenced by temperature and amount of daylight (Nebeker 1971 cited in Hynes 1976, p. 137). Adult meltwater lednian stoneflies are believed to emerge and breed in August and September (Baumann and Stewart 1980, p. 658; Giersch 2010b, pers. comm.; MNHP 2010a). Adult western glacier stoneflies have been collected from land in early July through mid-August (Baumann and Gaufin 1971, p. 277), almost immediately after snow has melted and exposed streams.

Nemouridae stoneflies disperse longitudinally (up or down stream) or laterally to the stream bank from their benthic (nymphal) source (Hynes 1976, p. 138; Griffith *et al.* 1998, p. 195; Petersen *et al.* 2004, pp. 944–945). Generally, adult stoneflies stay close to the channel of their source stream (Petersen *et al.* 2004, p. 946), and lateral movement into neighboring uplands is confined to less than 80 meters (262 feet) from the stream (Griffith *et al.* 1998, p. 197). Thus, Nemouridae stoneflies, and likely meltwater lednian and western glacier stoneflies, have limited dispersal capabilities.

Adult male and female stoneflies are mutually attracted by a drumming sound produced by tapping their abdomens on a substrate (Hynes 1976, p. 140). After mating, females deposit a mass of fertilized eggs in water where they are widely dispersed or attached to substrates by sticky coverings or specialized anchoring devices (Hynes 1976, p. 141; Stewart and Harper 1996, p. 217). Eggs may hatch within a few weeks or remain in diapause (dormancy) for much longer periods if environmental conditions, such as temperature, are not conducive to development (Hynes 1976, p. 142). Environmental conditions also may affect the growth and development of hatchlings (Stewart and Harper 1996, p. 217).

Summary of Biological Status and Threats

The Act directs us to determine whether any species is an endangered species or a threatened species because of any factors affecting its continued existence. In this section, we summarize the biological condition of these species and their resources, and the influences on such to assess both species' overall viability and the risks to that viability.

In considering what factors might constitute threats to a species, we must look beyond the exposure of the species to a factor to evaluate whether the species may respond to the factor in a way that causes actual impacts to the species. If there is exposure to a factor and the species responds negatively, the factor may be a threat and we attempt to determine how significant a threat it is. The threat is significant if it drives, or contributes to, the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined in the Act.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Meltwater lednian and western glacier stoneflies occupy remote, high-elevation alpine habitats in GNP and several proximate watersheds. The remoteness of these habitats largely precludes overlap with human uses and typical land management activities (*e.g.,* forestry, mining, irrigation) that have historically modified habitats of many species. However, these relatively pristine, remote habitats are not expected to be immune to the effects of climate change. Thus, our analysis under Factor A focuses on the expected effects of climate change on meltwater lednian and western glacier stonefly habitat and populations.

Climate Change

Our analyses under the Endangered Species Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and

''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). The term ''climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2014, pp. 119–120). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (*e.g.,* temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2014, p. 120).

Scientific measurements spanning several decades demonstrate that changes in climate are occurring; since the 1950s many of the observed changes are unprecedented over decades to millennia (IPCC 2014, p. 40). Examples include warming of the global climate system, and substantial increases in precipitation in some regions of the world and decreases in other regions. (For these and other examples, see IPCC 2014, pp. 40–44; and Solomon *et al.* 2007, pp. 35–54, 82–85). Results of scientific analyses presented by the IPCC show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate, and is ''extremely likely'' (defined by the IPCC as 95 percent or higher probability) due to the observed increase in greenhouse gas (GHG) concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from use of fossil fuels (IPCC 2014, p. 48 and figures 1.9 and 1.10; Solomon *et al.* 2007, pp. 21–35).

Scientists use a variety of climate models, which include consideration of natural processes and variability, as well as various scenarios of potential levels and timing of GHG emissions, to evaluate the causes of changes already observed and to project future changes in temperature and other climate conditions (*e.g.,* Meehl *et al.* 2007, entire; Ganguly *et al.* 2009, pp. 11555, 15558; Prinn *et al.* 2011, pp. 527, 529). All combinations of models and emissions scenarios yield very similar projections of increases in the most common measure of climate change, average global surface temperature (commonly known as global warming), until about 2050 (IPCC 2014, p. 11; Ray *et al.* 2010, p. 11). Although projections of the magnitude and rate of warming differ after about 2050, the overall trajectory of all the projections is one of increased global warming through the end of this century, even for the projections based on scenarios that assume that GHG emissions will stabilize or decline. Thus, there is strong scientific support for projections that warming will continue through the 21st century, and that the magnitude and rate of change will be influenced substantially by the extent of GHG emissions (IPCC 2014, p. 57; Meehl *et al.* 2007, pp. 760–764 and 797–811; Ganguly *et al.* 2009, pp. 15555–15558; Prinn *et al.* 2011, pp. 527, 529). (See IPCC 2014, pp. 9–13, for a summary of other global projections of climate-related changes, such as frequency of heat waves and changes in precipitation.)

Various changes in climate may have direct or indirect effects on species. These effects may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as interactions of climate with other variables (*e.g.,* habitat fragmentation) (IPCC 2014, pp. 6–7; 10–14). Identifying likely effects often involves aspects of climate change vulnerability analysis. Vulnerability refers to the degree to which a species (or system) is susceptible to, and unable to cope with, adverse effects of climate change, including climate variability and extremes. Vulnerability is a function of the type, magnitude, and rate of climate change and variation to which a species is exposed, its sensitivity, and its adaptive capacity (IPCC 2014, pp. 70, 72; see also Glick *et al.* 2011, pp. 19–22). There is no single method for conducting such analyses that applies to all situations (Glick *et al.* 2011, p. 3). We use our expert judgment and appropriate analytical approaches to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

As is the case with all stressors that we assess, even if we conclude that a species is currently affected or is likely to be affected in a negative way by one or more climate-related impacts, it does not necessarily follow that the species meets the definition of an ''endangered species'' or a ''threatened species'' under the Act. If a species is listed as endangered or threatened, knowledge regarding the vulnerability of the species to, and known or anticipated impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

Global climate projections are informative, and, in some cases, the only or the best scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (*e.g.,* IPCC 2014, pp. 12, 14). Therefore, we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling). With regard to our analysis for the meltwater lednian stonefly and western glacier stonefly, downscaled projections are available.

Regional climate—The western United States appears to be warming faster than the global average. In the Pacific Northwest, regionally averaged temperatures have risen 0.8 °C (1.5 °F) over the last century and as much as 2 °C (4 °F) in some areas. Since 1900, the mean annual air temperature for GNP and the surrounding region has increased 1.3 °C (2.3 °F), which is 1.8 times the global mean increase (U.S. Geological Survey (USGS) 2010, p. 1). Mean annual air temperatures are projected to increase by another 1.5 to 5.5 °C (3 to 10 °F) over the next 100 years (Karl *et al.* 2009, p. 135). Warming also appears to be pronounced in alpine regions globally (*e.g.,* Hall and Fagre 2003, p. 134 and references therein). For the purposes of this finding, we consider the foreseeable future for anticipated effects of climate change on the alpine environment to be approximately 35 years (~year 2050) based on two factors. First, various global climate models (GCMs) and emissions scenarios provide consistent predictions within that timeframe (IPCC 2014, p. 11). Second, the effect of climate change on glaciers in GNP has been modeled within that timeframe (*e.g.,* Hall and Fagre 2003, entire; Brown *et al.* 2010, entire).

Habitats for both the meltwater lednian stonefly and the western glacier stonefly originate from meltwater sources that will be impacted by any projected warming, including glaciers and small icefields, permanent and seasonal snowpack, alpine springs, and glacial lake outlets (Hauer *et al.* 2007, p. 107; Giersch and Muhlfeld 2015, in progress). The alteration or loss of these meltwater sources and perennial habitat has direct consequences on both meltwater lednian stonefly and western glacier stonefly populations. Below, we provide an overview of expected rate of loss of meltwater sources in GNP as a result of climate change, followed by the predicted effects to stonefly habitat and populations from altered stream flows and water temperatures.

Glacier loss—Glacier loss in GNP is directly influenced by climate change (*e.g.,* Hall and Fagre 2003, entire; Fagre 2005, entire). When established in 1910, GNP contained approximately 150 glaciers larger than 0.1 square kilometer (25 acres) in size, but presently only 25 glaciers larger than this size remain (Fagre 2005, pp. 1–3; USGS 2005, 2010). Hall and Fagre (2003, entire) modeled the effects of climate change on glaciers in GNP's Blackfoot-Jackson basin using then-current climate assumptions (*i.e.,* doubling of atmospheric carbon dioxide by 2030). Under this scenario, glaciers were predicted to completely melt in GNP by 2030, and predicted increases in winter precipitation due to climate change were not expected to buffer glacial shrinking (Hall and Fagre 2003, pp. 137–138). A more recent analysis of Sperry Glacier in GNP estimates this particular glacier may persist through 2080, in part due to annual avalanche inputs from an adjacent cirque wall (Brown *et al.* 2010, p. 5). We are not aware of any other published studies using more recent climate scenarios that speak directly to anticipated conditions of remaining glaciers in GNP. Thus, we largely rely on Hall and Fagre's 2003 predictions in our analysis, supplemented with more recent glacier-specific studies where appropriate (*e.g.,* Brown *et al.* 2010, entire). However, we note that most climate scenarios developed since 2003 predict higher carbon dioxide concentrations (and thus greater warming and predicted effects) than those used in Hall and Fagre (2003).

Loss of other meltwater sources—Meltwater in meltwater lednian stonefly and western glacier stonefly habitat is supplied by glaciers, as well as by four other sources: (1) Seasonal snow; (2) permanent snow; (3) alpine springs; and (4) ice masses (Giersch and Muhlfeld 2015, in progress). Seasonal snow is that which accumulates and melts seasonally, with the amount varying year to year depending on annual weather events. Permanent snow is some portion of a snowfield that does not generally melt on an annual basis, the volume of which can change over time. Alpine springs originate from some combination of meltwater from snow, ice masses or glaciers, and groundwater. Ice masses are smaller than glaciers and do not actively move as glaciers do.

The sources of meltwater that supply meltwater lednian and western glacier stonefly habitat are expected to persist under a changing climate for varying durations. In general, we expect all meltwater sources to decline under a changing climate, given the relationship between climate and glacial melting (Hall and Fagre 2003, entire; Fagre 2005, entire) and recent climate observations and modeling (IPCC 2014, entire). It is likely that seasonal snowpack levels will be most immediately affected by climate change, as the frequency of more extreme weather events increases (IPCC 2014, p. 8). These extremes may result in increased seasonal snowpack in some years and reduced snowpack in others.

It is also expected that permanent snowpack and ice masses will decline and completely melt within the near future. The timing of their disappearance is expected to be before the majority of glacial melting (*i.e.,* 2030), because permanent snowpack and ice masses are less dense than glaciers and typically have smaller volumes of snow and ice. However, alpine springs, at least those supplemented with groundwater, may continue to be present after complete glacial melting. We discuss the probable effects of declining meltwater from all sources on meltwater lednian stonefly and western glacier stonefly habitat and populations in more detail below. Our analysis primarily focuses on effects to meltwater lednian stonefly and western glacier stonefly populations within GNP. However, effects to meltwater lednian stonefly populations south of GNP are expected to be similar in magnitude and will likely occur sooner in time than those discussed for GNP, because the glaciers and ice/snow fields feeding occupied meltwater stonefly habitat in those areas are smaller in size, and thus likely to melt sooner than those in GNP.

Streamflows

Meltwater streams—Declines in meltwater sources are expected to affect flows in meltwater streams in GNP. Glaciers and other meltwater sources act as water banks, whose continual melt maintains streamflows during late summer or drought periods (Hauer *et al.* 2007, p. 107). Following glacier loss, declines in streamflow and periodic dewatering events are expected to occur in meltwater streams in the northern Rocky Mountains (Hauer *et al.* 1997, p. 909). In similarly glaciated regions, intermittent stream flows have been documented following glacial recession and loss (Robinson *et al.* 2015, p. 8). By 2030, the modeled distribution of habitat with the highest likelihood of supporting meltwater lednian stonefly populations is predicted to decline by 81 percent in GNP, compared to present (Muhlfeld *et al.* 2011, p. 342). Desiccation (drying) of these habitats, even periodically, could eliminate entire populations of the meltwater lednian stonefly and the western glacier stonefly because nymphs need perennial flowing water to breathe and to mature before reproducing. Given that both stonefly species are believed to be poor dispersers, recolonization of previously occupied habitats is not expected following dewatering and extirpation events. Lack of recolonization by either stonefly species is expected to lead to further isolation between extant populations.

Fifty-three (of 58) meltwater lednian stonefly populations and one (of four) western glacier stonefly population occupy habitats supplied by seasonal snowpack, permanent snowpack, and ice masses, and some glaciers. Meltwater from these sources is expected to become inconsistent by 2030 (Hall and Fagre 2003, p. 137; Giersch and Muhlfeld 2015, in progress). Although the rate at which flows will be reduced or at which dewatering events will occur in these habitats is unclear, we expect, at a minimum, to see decreases in abundance and distribution of both species in those populations. By 2030, the remaining populations are expected to be further isolated and occupying marginal habitat.

Alpine springs—Declines in meltwater sources are also expected to affect flows in alpine springs, although likely on a longer time scale than for meltwater streams. Flow from alpine springs in the northern Rocky Mountains originates from glacial or snow meltwater in part, sometimes supplemented with groundwater (Hauer *et al.* 2007, p. 107). For this reason, some alpine springs are expected to be more climate-resilient and persist longer than meltwater streams and may serve as refugia areas for meltwater lednian and western glacier stoneflies, at least in the near-term (Ward 1994, p. 283). However, small aquifers feeding alpine springs are ultimately replenished by glacial and other meltwater sources in alpine environments (Hauer *et al.* 1997, p. 908).

Once glaciers in GNP melt, small aquifer volumes and the groundwater influence they provide to alpine springs are expected to decline. Thus by 2030, even flows from alpine springs supplemented with groundwater are expected to decline (Hauer *et al.* 1997, p. 910). This expected pattern of decline is consistent with observed patterns of low flow from alpine springs in the Rocky mountain region and other glaciated regions during years with little snowpack (Hauer *et al.* 1997, p. 910; Robinson *et al.* 2015, p. 9). Further, following complete melting of glaciers,

drying of alpine springs in GNP might be expected if annual precipitation fails to recharge groundwater supplies. Changes in future precipitation levels due to climate change in the GNP region are predicted to range from relatively unchanged to a small (~10 percent) annual increase (IPCC 2014, pp. 20–21).

Only four populations of the meltwater lednian stonefly and two of the western glacier stonefly reside in streams originating from alpine springs. Thus, despite the potential for some alpine springs to provide refugia for both stonefly species even after glaciers melt, only a few populations may benefit from these potential refugia.

Glacial lake outlets—Similar to alpine springs, flow from glacial lake outlets is expected to diminish gradually following the complete melting of most glaciers around 2030. Glacial lakes are expected to receive annual inflow from melting snow from the preceding winter, although the amount by which it may be reduced after complete glacial melting is unknown. Reductions in flow from glacial lakes are expected to, at a minimum, decrease the amount of available habitat for both meltwater lednian and western glacier stoneflies.

One population each of the meltwater lednian stonefly and the western glacier stonefly occupies a glacial lake outlet (Upper Grinnell Lake; Giersch *et al.* 2015, p. 58, Giersch and Muhlfeld 2015, in progress). Thus, despite the fact that this habitat type may continue to provide refugia for both stonefly species even after the complete loss of glaciers, few populations may benefit from this potential refugia.

As such, we conclude that habitat degradation in the form of reduced streamflows due to the effects of climate change is a threat to the persistence of 89 percent of meltwater lednian stonefly and 25 percent of western glacier stonefly populations now and into the future.

Water Temperature

Meltwater streams—Glaciers act as water banks, whose continual melting maintains suitable water temperatures for meltwater lednian stonefly and western glacier stonefly during late summer or drought periods (Hauer *et al.* 2007, p. 107; USGS 2010). As glaciers melt and contribute less volume of meltwater to streams, water temperatures are expected to rise (Hauer *et al.* 1997, p. 909). Aquatic invertebrates have specific temperature needs that influence their distribution (Fagre *et al.* 1997, p. 763; Lowe and Hauer 1999, pp. 1637, 1640, 1642; Hauer *et al.* 2007, p. 110); complete glacial melting may result in an increase in water temperatures above the physiological limits for survival or optimal growth for the meltwater lednian and western glacier stoneflies. As a result of melting glaciers and a lower volume of meltwater input into streams, we expect upward elevational shifts of meltwater lednian stonefly and western glacier stonefly populations, as they track their optimal thermal preferences. However, both meltwater lednian stonefly and western glacier stonefly already occupy the most upstream portions of these habitats and can move upstream only to the extent of the receding glacier/snowfield. Once the glaciers and snowfields completely melt, meltwater lednian stonefly and western glacier stonefly will have no physical habitat left to which to migrate upstream. The likely result of this scenario would be the extirpation of these populations. If meltwater from seasonal precipitation accumulation remained after the complete loss of glaciers, displacement or extirpation of populations of both stonefly species could still occur due to thermal conditions that become unsuitable, encroaching aquatic invertebrate species that may be superior competitors, or changed thermal conditions that may favor the encroaching species in competitive interactions between the species (condition-specific competition).

The majority of meltwater lednian stonefly populations and one western glacier stonefly population occupy habitats that may warm significantly by 2030, due to the predicted complete melting of glaciers and snow/ice fields. Increasing water temperatures may be related to recent distributional declines of western glacier stoneflies within GNP (Giersch *et al.* 2015, p. 61). Thus, it is plausible that only those populations [6 meltwater lednian (11 percent of total known populations) and 3 western glacier stonefly (75 percent of total known populations)] occupying more climate-resilient habitat (*e.g.,* springs, lake outlets, Sperry Glacier) may persist through 2030.

Alpine springs—Although meltwater contributions to alpine springs are expected to decline as glaciers and permanent snow melt, water temperature at the springhead may remain relatively consistent due to the influence of groundwater, at least in the short term. The springhead itself may provide refugia for both meltwater lednian and western glacier stoneflies, although stream reaches below the actual springhead are expected to exhibit similar increases in water temperature in response to loss of glacial meltwater as those described for meltwater streams. However, as described above, some alpine springs may eventually dry up after glacier and snowpack loss, if annual precipitation fails to recharge groundwater supplies (Hauer *et al.* 1997, p. 910; Robinson *et al.* 2015, p. 9).

Only four populations of the meltwater lednian stonefly (7 percent of total known populations) and two of the western glacier stonefly (50 percent of total known populations) reside in streams originating from alpine springs. Thus, despite the fact that alpine springs may be more thermally stable than meltwater streams and provide thermal refugia to both the meltwater lednian stonefly and the western glacier stonefly, only a few populations may benefit from this potential refugia.

Glacial lake outlets—Similar to alpine springs, glacial lake outlets are more thermally stable habitats than meltwater streams. This situation is likely due to the buffering effect of large volumes of glacial lake water supplying these habitats. It is anticipated that the buffering effects of glacial lakes will continue to limit increases in water temperature to outlet stream habitats, even after loss of glaciers. However, water temperatures are still expected to increase over time following complete glacial loss in GNP. It is unknown whether water temperature increases in glacial lake outlets will exceed presumed temperature thresholds for meltwater lednian and western glacier stonefly in the near future. However, given the low water temperatures recorded in habitats where both species have been collected, even small increases in water temperature of glacial lake outlets may be biologically significant and detrimental to the persistence of both species.

One population each of the meltwater lednian stonefly and the western glacier stonefly occupies a glacial lake outlet (Upper Grinnell Lake; Giersch *et al.* 2015, p. 58, Giersch and Muhlfeld 2015, in progress). Thus, despite the fact that glacial lake outlets may be more thermally stable than meltwater streams and provide thermal refugia to both the meltwater lednian stonefly and the western glacier stonefly, a small percentage of the overall population of each species may benefit from these potential refugia. Consequently, we conclude that changes in water temperature from climate change are a threat to most populations of both stonefly species now and into the future.

Maintenance and Improvement of Glacier National Park Infrastructure

Glacier National Park is managed to protect natural and cultural resources, and the landscape within the park is relatively pristine. However, the GNP does include a number of human-built facilities and structures that support visitor services, recreation, and access, such as the Going-to-the-Sun Road (which bisects GNP) and numerous visitor centers, trailheads, overlooks, and lodges (*e.g.,* NPS 2003a, pp. S3, 11). Maintenance and improvement of these facilities and structures could conceivably lead to disturbance of the natural environment.

We are aware of one water diversion on Logan Creek that supplies water to the Logan Pass Visitor Center. This diversion is located several feet under the streambed in a segment of Logan Creek in which meltwater lednian stonefly is found. While the diversion has been operated for decades, recent surveys indicate relatively high densities of meltwater lednian stonefly in Logan Creek, particularly upstream of the diversion (NPS 2009, entire; Giersch 2016, pers. comm.). The diversion is scheduled to be retrofitted in 2017, in part to decrease instream withdrawals and increase efficiency. The diversion retrofit will likely include dewatering a short section of stream surrounding the intake structure, by diverting streamflow around the construction site. Minimization measures expected to be implemented as part of the diversion retrofit include relocation of meltwater lednian stoneflies out of the construction zone and using appropriate sedimentation control measures. Given the recent survey information indicating high densities of meltwater lednian stonefly in Logan Creek and the use of appropriate minimization measures, we have no evidence that the existing water diversion or retrofit project are a threat to meltwater lednian stonefly at the population level.

We do not have any information indicating that maintenance and improvement of other GNP facilities and structures is affecting either meltwater lednian or western glacier stoneflies or their habitat. While roads and trails provide avenues for recreationists (primarily hikers) to access backcountry areas, most habitats for both the meltwater lednian stonefly and the western glacier stonefly are located in steep, rocky areas that are not easily accessible, even from backcountry trails. Most documented occurrences of both species are in remote locations upstream from human-built structures, thereby precluding any impacts to stonefly habitat from maintenance or improvement of these structures. Given the above information, we conclude that maintenance and improvement of GNP facilities and structures, and the resulting improved access into the backcountry for recreationists, does not constitute a threat to the meltwater lednian or western glacier stonefly or their habitat now or in the near future.

Glacier National Park Visitor Impacts

In 2015, GNP hosted 2.3 million visitors (NPS 2015). Many of the recent collection sites for the meltwater lednian stonefly (*e.g.,* Logan and Reynolds Creeks) are near visitor centers or adjacent to popular hiking trails. Theoretically, human activity (wading) in streams by anglers or hikers could disturb meltwater lednian stonefly habitat. However, we consider it unlikely that many GNP visitors would actually wade in stream habitats where the species has been collected, because the sites are in small, high-elevation streams situated in rugged terrain, and most would not be suitable for angling due to the absence of fish. In addition, the sites are typically snow covered into late July or August (Giersch 2010a, pers. comm.), making them accessible for only a few months annually. We also note that the most accessible collection sites in Logan Creek near the Logan Pass Visitor Center and the Going-to-the-Sun Road are currently closed to public use and entry to protect resident vegetation (NPS 2010, pp. J5, J24). We conclude that impacts to the meltwater lednian and western glacier stonefly and their habitat from visitors to GNP do not constitute a threat now or in the near future.

Wilderness Area Visitor Impacts

Three populations of meltwater lednian stonefly are located in wilderness areas adjacent to GNP. Visitor activities in wilderness areas are similar to those described for GNP, namely hiking and angling. No recreational hiking trails are present near the two populations of meltwater lednian stonefly in the Bob Marshall wilderness and Great Bear wilderness (USFS 2015, p. 1) or near the population occurring in the Mission Mountain Tribal Wilderness. Similar to GNP, stream reaches that harbor the meltwater lednian stonefly in these wilderness areas are fishless, so wade anglers are not expected to disturb stonefly habitat. Given the remote nature of and limited access to meltwater stonefly habitat in wilderness areas adjacent to GNP, we do not anticipate any current or future threats to meltwater lednian stoneflies or their habitat from visitor use.

Summary of Factor A

In summary, we expect climate change to fragment or degrade all habitat types that are currently occupied by meltwater lednian and western glacier stoneflies, albeit at different rates. Flows in meltwater streams are expected to be affected first, by becoming periodically intermittent and warmer. Drying of meltwater streams and water temperature increases, even periodically, are expected to reduce available habitat for the meltwater lednian stonefly by 81 percent by 2030. After 2030, flow reductions and water temperature increases due to continued warming are expected to further reduce or degrade remaining refugia habitat (alpine springs and glacial lake outlets) for both meltwater lednian and western glacier stoneflies. Predicted habitat changes are based on observed patterns of flow and water temperature in similar watersheds within GNP and elsewhere where glaciers have already melted.

In addition, we have observed a declining trend in western glacier stonefly distribution over the last 50 years, as air temperatures have warmed in GNP. We expect the meltwater lednian stonefly to follow a similar trajectory, given the similarities between the two stonefly species and their meltwater habitats. Consequently, we conclude that habitat fragmentation and degradation resulting from climate change is a threat to both the meltwater lednian and western glacier stoneflies now and into the near future. Given the minimal overlap between stonefly habitat and most existing infrastructure or backcountry activities (*e.g.,* hiking), we conclude any impacts from these activities do not constitute a threat to either the meltwater lednian stonefly or the western glacier stonefly. The sole water diversion present on Logan Creek and the upcoming retrofit project also do not appear to be threats to meltwater lednian stonefly, given that recent surveys have documented high densities of meltwater lednian stonefly near the diversion, and the expected use of appropriate minimization measures for the retrofit project.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We are not aware of any threats involving the overutilization or collection of the meltwater lednian or western glacier stonefly for any commercial, recreational, or educational purposes at this time. We are aware that specimens of both species are

occasionally collected for scientific purposes to determine their distribution and abundance (*e.g.,* Baumann and Stewart 1980, pp. 655, 658; NPS 2009; Muhlfeld *et al.* 2011, entire; Giersch *et al.* 2015, entire). However both species are comparatively abundant in remaining habitats (*e.g.,* NPS 2009; Giersch 2016, pers. comm.), and we have no information to suggest that past, current, or any collections in the near future will result in population-level effects to either species. Consequently, we do not consider overutilization for commercial, recreational, scientific, or educational purposes to be a threat to the meltwater lednian or western glacier stonefly now or in the near future.

Factor C. Disease or Predation

We are not aware of any diseases that affect the meltwater lednian or western glacier stonefly. Therefore, we do not consider disease to be a threat to these species now or in the near future.

We presume that nymph and adult meltwater lednian and western glacier stoneflies may occasionally be subject to predation by bird species such as American dipper (*Cinclus mexicanus*) or predatory aquatic insects. Fish and amphibians are not potential predators because these species do not occur in the stream reaches containing the meltwater lednian stonefly and the western glacier stonefly. The American dipper prefers to feed on aquatic invertebrates in fast-moving, clear alpine streams (MNHP 2010b), and the species is native to GNP. As such, predation by American dipper on these species would represent a natural ecological interaction in the GNP (see Synergistic Effects section below for analysis on potential predation/habitat fragmentation synergy). Similarly, predation by other aquatic insects would represent a natural ecological interaction between the species. We have no evidence that the extent of such predation, if it occurs, represents any population-level threat to either meltwater lednian or western glacier stonefly, especially given that densities of individuals within many of these populations are high. Therefore, we do not consider predation to be a threat to these species now or in the near future.

In summary, the best available scientific and commercial information does not indicate that the meltwater lednian or western glacier stonefly is affected by any diseases, or that natural predation occurs at levels likely to negatively affect either species at the population level. Therefore, we do not find disease or predation to be threats to the meltwater lednian or western glacier stonefly now or in the near future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Section 4(b)(1)(A) of the Endangered Species Act requires the Service to take into account ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species....'' We consider relevant Federal, State, and Tribal laws and regulations when evaluating the status of the species. Only existing ordinances, regulations, and laws that have a direct connection to a law are enforceable and permitted are discussed in this section. No local, State, or Federal laws specifically protect the meltwater lednian or western glacier stonefly.

National Environmental Policy Act

All Federal agencies are required to adhere to the National Environmental Policy Act (NEPA) of 1970 (42 U.S.C. 4321 *et seq.*) for projects they fund, authorize, or carry out. NEPA is a procedural statute, which requires Federal agencies to formally document and publicly disclose the environmental impacts of their actions and management decisions. Documentation for NEPA is provided in an environmental impact statement, an environmental assessment, or a categorical exclusion. NEPA does not require that adverse impacts be mitigated. Our review finds that it is likely that there would be very few activities that would trigger NEPA's disclosure requirements. However, NEPA does not require protection of a species or its habitat, and does not require the selection of a particular course of action.

National Park Service Organic Act

The NPS Organic Act of 1916 54 U.S.C. 100101 (*et seq.*), as amended, states that the NPS ''shall promote and regulate the use of the National Park System by means and measures that conform to the fundamental purpose of the System units, which purpose is to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.'' Given that the vast majority of occurrences of the meltwater lednian stonefly (>90 percent) and all occurrences of the western glacier stonefly are within the boundaries of GNP, the NPS Organic Act is one Federal law of particular relevance to both species. Although the GNP does not have a management plan specific to either stonefly species, the habitats occupied by the species remain relatively pristine and generally free from direct human impacts from Park visitors (see Threat Factor A). We also note that the most accessible meltwater lednian stonefly collection sites in Logan Creek near the Logan Pass Visitor Center and the Going-to-the-Sun Road are currently closed to public use and entry to protect resident vegetation pursuant to GNP management regulations (NPS 2010, pp. J5, J24).

Regulatory Mechanisms To Limit Glacier Loss

National and international regulatory mechanisms to comprehensively address the causes of climate change are continuing to be developed. Domestic U.S. efforts relative to climate change focus on implementation of the Clean Air Act, and continued studies, programs, support for developing new technologies, and use of incentives for supporting reductions in emissions. While not regulatory, international efforts to address climate change globally began with the United Nations Framework Convention on Climate Change (UNFCCC), adopted in May 1992. The stated objective of the UNFCCC is the stabilization of GHG concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system. However, we note that greenhouse gas loading in the atmosphere can have a considerable lag effect on climate, so that what has already been emitted will have impacts out to 2100 and beyond (IPCC 2014, pp. 56–57).

National Forest Management Act

The National Forest Management Act (NFMA; 16 U.S.C. 1600–1614, as amended) requires the Secretary of the Department of Agriculture to develop and implement resource management plans for each unit of the National Forest System. The Forest Service has developed a land management plan for the Flathead National Forest, including the wilderness portions containing meltwater stonefly populations, that designates conservation of sensitive, endangered and threatened species as a high priority (USFS 2001, p. III–109). In addition, only natural agents (fire, wind, insects, etc.) are permitted to alter the vegetation or habitat within the wilderness portions of the Flathead National Forest (USFS 2001, p. III–109). As such, the wilderness areas on Flathead National Forest are managed for natural ecological processes to maintain wilderness character.

Wilderness Act

The Wilderness Act of 1964 (16 U.S.C. 1131–1136, 78 Stat. 890) provides that areas designated by Congress as ''wilderness areas'' ''shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness. . . .'' The Act also directed the Secretary of the Interior to review and make recommendations to the President about the suitability of particular lands for preservation as wilderness, with the final decision being made by Congress (16 U.S.C. 1132(c)). These lands are managed under the nonimpairment standard to ensure that they retain their wilderness character until Congress makes a decision. Areas where the meltwater lednian stonefly occurs within Flathead National Forest are designated as wilderness. Areas where the meltwater lednian and western glacier stoneflies occur within GNP were nominated for protection as wilderness in 1974, but Congress has not rendered a decision. Pursuant to NPS policy, the proposed wilderness lands are managed as wilderness (NPS Management Policy § 6.3 (2006)).

The Wilderness Act establishes restrictions on land use activities that can be undertaken on a designated area. In particular, such lands are managed to preserve their wilderness character, and many activities that might otherwise be permitted are prohibited on lands designated as wilderness (*e.g.,* commercial enterprise, roads, logging, mining, oil/gas exploration) (16 U.S.C. 1133(c)).

Flathead Indian Reservation Fishing, Bird Hunting, and Recreation Regulations

The Confederated Kootenai Salish Tribes manage land on the Flathead Reservation and are currently implementing ''Flathead Indian Reservation Fishing, Bird Hunting, and Recreation Regulations,'' which, in part, regulate recreation in the Mission Mountain Tribal Wilderness Area (MMTW), where one population of the meltwater lednian stonefly occurs. Some relevant regulations preclude the removal of natural items from the MMTW and restrict certain activities within 30 m (100 ft) of water sources.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Small Population Size

A principle of conservation biology is that the presence of larger and more productive (resilient) populations can reduce overall extinction risk. To minimize extinction risk, genetic diversity should be maintained (Fausch *et al.* 2006, p. 23; Allendorf *et al.* 1997, entire). Both meltwater lednian and western glacier stonefly populations exist as presumably isolated populations, given that most populations are separated by considerable distances (*i.e.,* miles) and stoneflies in general are poor dispersers (on the order of tens of meters). Population isolation can limit or preclude genetic exchange between populations (Fausch *et al.* 2006, p. 8). However, densities within many of these populations are high (Giersch 2016, pers. comm.), which may offset or delay, at least in part, deleterious genetic effects from population isolation. Given the lack of genetic information for both meltwater lednian and western glacier stonefly, and the relatively high densities observed in many of the populations, we conclude that the effects of small population size (as a standalone issue) is not a threat now or in the near future.

Restricted Range and Stochastic (Random) Events

Narrow endemic species, such as the meltwater lednian stonefly and the western glacier stonefly, can be at risk of extirpation from random events such as fire, flooding, or drought. Random events occurring within the narrow range of endemic species have the potential to disproportionately affect large numbers of individuals or populations, relative to a more widely dispersed species. The risk to meltwater lednian and western glacier stonefly populations from fire appears low, given that most alpine environments in GNP have few trees and little vegetation to burn. The risk to both species from flooding also appears low, given the relatively small watershed areas available to capture and channel precipitation upslope of most stonefly populations.

The risk to the meltwater lednian stonefly from drought appears moderate in the near term because 20 of the 58 known populations occupy habitats supplied by seasonal snowmelt, which would be expected to decline during drought. For the western glacier stonefly, the threat of drought is also moderate because one of the four known populations is likely to be affected by variations in seasonal precipitation and snowpack. The risk of drought in the longer term (after 2030 and when complete loss of glaciers is predicted) appears high for both stonefly species. Once glaciers melt, drought or extended drought could result in dewatering events in some habitats. Dewatering events would likely extirpate entire populations almost instantaneously. Natural recolonization of habitats affected by drought is unlikely, given the poor dispersal abilities of both stonefly species and general isolation of populations relative to one another (Hauer *et al.* 2007, pp. 108–110). Thus, we conclude that drought (a stochastic event) will be a threat to both the meltwater lednian stonefly and the western glacier stonefly in the near future.

Summary of Factor E

The effect of small population size does not appear to be a current or future threat to the meltwater lednian stonefly or the western glacier stonefly, given the high densities of individuals within most populations. However, the restricted range of the meltwater lednian and western glacier stonefly make both species vulnerable to the stochastic threat of drought. Although not considered a current threat, drought will likely affect both species negatively within the near future. There is potential for extirpation of entire populations of both species as a result of dewatering events caused by drought, after the complete loss of glaciers predicted by 2030. Thus, drought is considered a threat to both the meltwater lednian stonefly and the western glacier stonefly within the near future.

Synergistic Effects

Climate change may interact with other potential stressors and compound negative effects on meltwater lednian stonefly and western glacier stonefly populations. We limit our discussion here to factors that are not implicitly linked, and whose effects are not accounted for, in our previous analysis regarding climate change.

Climate Change and Predation

Previously, we presumed that nymph and adult meltwater lednian and western glacier stoneflies may occasionally be subject to predation by bird species such as American dipper or predatory aquatic insects. As such, predation by American dipper or predatory aquatic insects on these species would represent a natural ecological interaction in the GNP and surrounding areas. However, habitat fragmentation and degradation resulting from climate change may create different scenarios where populations of the meltwater lednian stonefly and the western glacier stonefly remain in isolated pockets of habitat, in thermally marginal habitat, or both, and are

exposed to relative increased levels of predation. In such cases, the ability of the meltwater lednian stonefly or the western glacier stonefly to persist could theoretically be compromised by the cumulative effects resulting from the two pressures acting synergistically. Below, we evaluate the possibility of these scenarios in more detail.

In the first scenario, the meltwater lednian stonefly or the western glacier stonefly may occupy small, isolated pockets (or pools) of habitat resulting from fragmentation (*e.g.,* springheads). Under this scenario, predation from both American dippers and aquatic predatory insects could result in population-level effects of either species in these habitats. However, this situation appears unlikely for several reasons. First, the microhabitat features (rocks, bark) present that allow the meltwater lednian stonefly and the western glacier stonefly to evade predation would likely still be present, albeit in smaller quantities. Thus, even with increased predation pressure within a confined stream pool, both species would likely still utilize available habitat features to survive and fulfill life-history needs. Second, assuming thermal regimes are still within physiological limits, both stonefly species would likely use the same behavioral strategies they currently use to persist (*e.g.,* timing of foraging, resting, and reproducing). In this scenario, population densities could potentially be reduced beyond what would be expected in more contiguous habitat, but population-level effects from predation appear unlikely, especially given the high densities of individuals within many of these populations.

In a second scenario, physical habitat extent may remain intact, but thermal conditions may be altered (*e.g.,* water temperature has increased significantly). In this case, increased water temperatures may interfere with the ability of the meltwater lednian stonefly or the western glacier stonefly to rely on behavioral strategies to evade predation effectively. Individuals may be forced to forage or move at inopportune times, resulting in higher predation levels and likely lower reproductive success. However, increases in water temperature may also affect the behavioral strategies (foraging) of aquatic predatory insects similar to that of the meltwater lednian and western glacier stonefly. It appears unlikely that the predatory abilities of American dipper would be affected by increased water temperature. However, it is unclear how efficient American dippers are as stonefly predators and whether they could exert enough predation pressure to rise to a population-level effect for the meltwater lednian and western glacier stonefly.

If both fragmented habitat and thermally modified habitat are present in tandem, the resulting effects of predation would likely be greater than those described for either previous scenario. The intensity of predation would be expected to increase as a result of more fragmented habitat, and from behavioral changes potentially increasing the vulnerability of meltwater lednian and western glacier stoneflies to predators. Mortality of individual stoneflies would likely be higher in this scenario than for either previous scenario. However, it is still unclear what the effects of increased water temperatures would be on aquatic predators and whether the efficiency of avian predators would increase to the point where a population-level effect would be observed in meltwater lednian stonefly or western glacier stonefly populations. While the narrow range of the species and the small areas they inhabit make entire populations vulnerable to extirpation due to the effects of climate change, the high densities of individuals found within many of these populations make the effects of predation less likely to have population-level impacts. Therefore, cumulative effects resulting from climate change and predation are not considered a threat to any population of meltwater lednian and western glacier stoneflies now or in the near future.

Climate Change, Habitat Fragmentation, Stochastic Events, and Small Population Size

Meltwater habitats used by meltwater lednian stonefly and western glacier stonefly are expected to become increasingly fragmented due to climate change. One consequence of increasing habitat fragmentation is increasing isolation of existing stonefly populations, relative to one another. As isolation among stonefly populations increases, smaller populations may become more vulnerable to extirpation due to stochastic events such as drought. In the event of local extirpations from stochastic events, recolonization of previously occupied habitat appears unlikely, given the poor dispersal capabilities of stoneflies and isolation of populations in increasingly fragmented habitat. However, while interactions between and among these factors are likely, it appears more evident that habitat degradation in the form of reduced flows and increased water temperatures will play a larger and more immediate role in determining the persistence of meltwater lednian and western glacier stonefly populations. With the potential to extirpate entire populations almost instantaneously, dewatering events resulting from loss of meltwater sources is likely to be the primary driver affecting populations of both stonefly species in the near future. While the interactions between climate change, habitat fragmentation, stochastic events, and small population size are likely to occur, the timescale at which we would expect population-level threats to occur is far beyond the timescale that habitat degradation (dewatering in particular) is expected to act on both species at the population level. Thus, at this time, we do not consider the interactions between and among climate change, habitat fragmentation, stochastic events, and small population size to be a threat.

Determination

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the meltwater lednian stonefly and the western glacier stonefly. Habitat fragmentation and degradation in the form of declining streamflows and increasing water temperatures resulting from climate change are currently affecting habitat for the meltwater lednian stonefly and the western glacier stonefly (Factor A). Habitat with a high probability of occupancy for the meltwater lednian stonefly is modeled to decrease 81 percent by 2030 (Muhlfeld *et al.* 2011, p. 342). Due to the anticipated near-term reduction of meltwater from seasonal snowpack and future reduction of flow from other meltwater sources in the foreseeable future, drought is expected to affect meltwater lednian stonefly and western glacier stonefly populations occupying habitat supplied by those meltwater sources (Factor E). As a result of this anticipated loss of habitat and

populations, only a few refugia populations are expected to persist in the longer term. Recolonization of habitats where known populations of either species are extirpated is not anticipated, given the poor dispersal abilities of both species. Threats to meltwater lednian stonefly and western glacier stonefly habitat are currently occurring rangewide and are expected to continue into the foreseeable future.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the meltwater lednian stonefly is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.

The meltwater lednian stonefly occupies a relatively narrow range of alpine habitats that are expected to become fragmented and degraded by climate change. Meltwater lednian stonefly habitat and populations are threatened by several factors that are expected to reduce the overall viability of the species. Therefore, on the basis of the best available scientific and commercial information, we propose listing the meltwater lednian stonefly as threatened in accordance with sections 3(6) and 4(a)(1) of the Act. We find that an endangered species status is not appropriate for the meltwater lednian stonefly because the species is not currently in danger of extinction because it faces relatively low near-term risk of extinction. Although the effects of climate change and drought are currently affecting, and expected to continue affecting, the alpine habitats occupied by the meltwater lednian stonefly, meltwater sources are expected to persist in the form of alpine springs and glacial lake outlets after the predicted melting of most glaciers in GNP by 2030. Densities and estimated abundance of the meltwater lednian stonefly are currently relatively high. In addition, some meltwater lednian stonefly populations continue to persist in meltwater habitats supplied by seasonal snowpack. These findings suggest that as climate change continues to impact stonefly habitat, some populations will likely persist in refugia areas at least through the foreseeable future. Thus, we find that the definition of threatened better characterizes the current status of the meltwater lednian stonefly and the likelihood that they will become in danger of extinction in the foreseeable future.

We also find that the western glacier stonefly is likely to become endangered throughout all or a significant portion of its range within the foreseeable future. Similar to meltwater lednian stonefly, the western glacier stonefly occupies a relatively narrow range of alpine habitats that are expected to become fragmented and degraded by climate change. Western glacier stonefly habitat and populations are threatened by several factors that are expected to reduce the overall viability of the species. Therefore, on the basis of the best available scientific and commercial information, we propose listing the western glacier stonefly as threatened in accordance with sections 3(6) and 4(a)(1) of the Act. We find that an endangered species status is not appropriate for the western glacier stonefly because the species is not currently in danger of extinction because it faces relatively low near-term risk of extinction. Although the effects of climate change and drought are currently affecting, and expected to continue affecting, the alpine habitats occupied by the western glacier stonefly, meltwater sources are expected to persist in the form of alpine springs and glacial lake outlets after the predicted melting of most glaciers in GNP by 2030. Although only four populations of western glacier stonefly are known, densities and estimated abundance of the western glacier stonefly within those populations are currently relatively high. These findings suggest that as climate change continues to impact stonefly habitat, some populations will likely persist in refugia areas at least through the foreseeable future. Thus, we find that the definition of threatened better characterizes the current status of the western glacier stonefly and the likelihood that they will become in danger of extinction in the foreseeable future.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that the meltwater lednian stonefly and the western glacier stonefly are threatened throughout all of their range, no portion of their range can be ''significant'' for purposes of the definitions of ''endangered species'' and ''threatened species.'' A detailed explanation of ''significance'' is included in our Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37577, July 1, 2014).

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site

(*http://www.fws.gov/endangered*), or from our Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands. If these species are listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Montana would be eligible for Federal funds to implement management actions that promote the protection or recovery of the meltwater lednian stonefly and the western glacier stonefly. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the meltwater lednian and the western glacier stonefly are only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for these species. Additionally, we invite you to submit any new information on these species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management, any other landscape-altering activities, or research permit applications on Federal lands administered by the National Park Service and U.S. Forest Service.

Under section 4(d) of the Act, the Service has discretion to issue regulations that we find necessary and advisable to provide for the conservation of threatened species. The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to threatened wildlife. The prohibitions of section 9(a)(1) of the Act, as applied to threatened wildlife and codified at 50 CFR 17.31, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) threatened wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing.

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species;

(2) Destruction/alteration of the species' habitat, whether aquatic or riparian.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Critical Habitat

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as: An area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement,

habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist:

(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or

(2) such designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Service may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of ''critical habitat.''

As discussed above, there is currently no imminent threat of take attributed to collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, we next determine whether such designation of critical habitat would not be beneficial to the species. In our analysis above, we determined that there are habitat-based threats to the meltwater lednian stonefly and the western glacier stonefly identified under Factor A. Therefore, we find that the designation of critical habitat would be beneficial to the meltwater lednian stonefly and the western glacier stonefly through the provisions of section 7 of the Act. Because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and would be beneficial, we find that designation of critical habitat is prudent for the meltwater lednian stonefly and the western glacier stonefly.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for meltwater lednian stonefly and western glacier stonefly is determinable. Our regulations (50 CFR 424.12(a)(2)) further state that critical habitat is not determinable when one or both of the following situations exists:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)). In this instance, we find that critical habitat is not determinable at this time because data sufficient to perform the required analyses are lacking, as explained below.

New information on western glacier stonefly was received late in the status review process (see *Distribution and Abundance* above), and this information has not yet been analyzed or incorporated. Consequently, a careful assessment of the new biological information is still ongoing. In the near future, we will begin reassessing which specific features and areas are essential for the conservation of the species and, therefore, meet the definition of critical habitat. This evaluation is needed in order to determine where to designate critical habitat for the western glacier stonefly. Once we have determined where to designate critical habitat for both species, we must also analyze the economic impacts of our proposed designation. The Service has conducted an economic analysis but that data may now be incomplete given the new information. The information sufficient to perform a required analysis of the impacts of the designation is lacking, and, therefore, we find designation of critical habitat to be not determinable at this time. Accordingly, we will publish a proposed critical habitat rule for both species in the near future when we finish our assessment of the new biological information.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. As part of our responsibilities to communicate meaningfully and work directly with Tribal Governments, we informed the Confederated Kootenai Salish Tribe (CKST) of our intent to conduct a status review on meltwater

lednian stonefly, and solicited any information the Tribe may have regarding the sole population of meltwater lednian stonefly occurring in Tribal wilderness on CKST land.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* at Docket No. FWS–R6–ES–2016–0086 and upon request from the Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Montana Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; unless otherwise noted.

■ 2. In § 17.11(h), add an entry for ''Stonefly, meltwater lednian '' and an entry for ''Stonefly, western glacier '' to the List of Endangered and Threatened Wildlife in alphabetical order under INSECTS to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
INSECTS				
*	*	*	*	*
Stonefly, meltwater lednian	*Lednia tumana*	Wherever found	T	[Insert **Federal Register** citation when published as a final rule]
Stonefly, western glacier	*Zapada glacier*	Wherever found	T	[Insert **Federal Register** citation when published as a final rule]
*	*	*	*	*

Dated: September 12, 2016

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–23710 Filed 10–3–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 81, No. 192
Tuesday, October 4, 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 AGRICULTURE

Economic Research Service

Submission for OMB Review; Comment Request

September 28, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; 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, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 3, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Economic Research Service

Title: National Food Study Pilot.

OMB Control Number: 0536–NEW.

Summary of Collection: The Economic Research Service (ERS) will be conducting the National Alternative Data Collection Method (ADCM) for Collecting FoodAPS-Like Data Study (aka National Food Study Pilot). The mission of ERS is to provide timely research and analysis to public and private decision makers on topics related to agriculture, food, the environment, and rural America. To achieve this mission, ERS requires a variety of data that describe agricultural production, food distribution channels, availability and price of food at the point of sale, and household demand for food products. Section 17 (U.S.C. 2026) (a) (1) of the Food and Nutrition Act of 2008 provides legislative authority for the planned data collection. .

Need and Use of the Information: The main objective of the National Food Study Pilot (NSF) is to test an alternative method of collecting data on the food acquired by American households that leads to more complete and accurate information about patterns of food acquisitions. The NSF Pilot will make use of the latest computer technologies to collect data on foods acquired and to monitor data. The data collection will provide information that is critical to ERS' plans for the next round of FoodAPS data collection. The NSF Pilot findings will be used to improve the sampling design and data collection methodology for the next FoodAPS Study.

Description of Respondents: Individuals or household.

Number of Respondents: 2,500.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 6,575.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–23869 Filed 10–3–16; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Child Nutrition Program Operations Study II (CN–OPS–II)

AGENCY: Food and Nutrition Service, United States Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of a currently approved collection for the Child Nutrition Program Operations Study II (CN–OPS–II) (OMB Number 0584–0607, Expiration Date: 04/30/2019).

DATES: Written comments must be received on or before December 5, 2016.

ADDRESSES: Comments are invited on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Devin Wallace-Williams, Ph.D., Social Science Research Analyst, Office of Policy Support, Food and Nutrition Service, USDA, 3101 Park Center Drive, VA 22302. Comments may also be submitted via fax to the attention of Devin Wallace-Williams at 703–305–2576 or via email to *Devin.Wallace-Williams@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, contact Devin Wallace-Williams, Ph.D., Social Science Research Analyst, Office of Policy Support, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, VA 22302; Fax: 703–305–2576; Email: *Devin.Wallace-Williams@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Child Nutrition Program Operations Study II (CN–OPS–II).

Form Number: N/A. *OMB Number:* 0584–0607.

Expiration Date: 04/30/2019.

Type of Request: Revision of a currently approved collection.

Abstract: The objective of the Child Nutrition Program Operations Study II (CN–OPS–II) is to collect timely data on policies, administrative, and operational issues on the Child Nutrition Programs (CNP). The ultimate goal is to analyze these data and to provide input for new legislation on Child Nutrition Programs, as well as to provide pertinent technical assistance and training to program implementation staff.

CN–OPS–II will help the Food and Nutrition Service (FNS) better understand and address current policy issues related to CNP operations. The policy and operational issues include, but are not limited to, the preparation of the program budget, development and implementation of program policy and regulations, and identification of areas for technical assistance and training. Specifically, this study will help FNS obtain:

- General descriptive data on the CN program characteristics to help FNS respond to questions about the nutrition programs in schools;
- Data related to program administration for designing and revising program regulations, managing resources, and reporting requirements; and
- Data related to program operations to help FNS develop and provide training and technical assistance for School Food Authorities (SFAs) and State Agencies responsible for administering the CN programs.

The activities to be undertaken subject to this notice include:

- Conducting a multi-modal (*e.g.* paper, web, and telephone) survey of approximately 1,750 SFA Directors in School Year (SY) 2016–17, SY 2017–18, and SY 2018–19; and
- Conducting a multi-modal (*e.g.* paper, web, and telephone) survey of all 55 State Agency CN Directors in SY 2016–17, SY 2017–18, and SY 2018–19.

Affected Public: State, Local and Tribal Governments.

Type of Respondents: SFA Directors and State CN Directors.

Estimated Total Number of Respondents: 2,251 annually, including 1,813 respondents and 438 non-respondents.

Frequency of Responses per Respondent: 3.

Estimated Total Annual Responses: 6737 responses across the entire collection. This includes 5,423 for the respondents and 1,314 for the non-respondents.

Estimate of Time per Respondent and Annual Burden: The average time across all respondents is 42 minutes (0.70 hours). This includes 3.5 minutes (0.06 hours) for non-respondents and 51 minutes (0.85 hours) for respondents. The total annual reporting burden is estimated at 4,699 (see Exhibit 1. Estimates of Respondent Burden). The estimates presented are expected to be typical of the burden in each year of data collection. FNS will submit amended estimates if burden deviates significantly for a particular year.

Dated: September 20, 2016.

Telora T. Dean,

Acting Administrator, Food and Nutrition Service.

BILLING CODE 3410–30–P

[FR Doc. 2016–23859 Filed 10–3–16; 8:45 am]
BILLING CODE 3410–30–C

Exhibit 1. Estimates of Respondent Burden

			Responsive					Non-Responsive					
Type of Respondents	Data Collection Activity	Sample Size	Number of Respondents	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (hours)	Number of Nonrespondents	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (hours)	Total Annual Hour Burden
State CN Directors	Hard Copy Pretest	2	2	1	2	2	4	0	1	0	0.50	0	4.00
State CN Directors	Self-Administered Web/Telephone Survey	55	55	1	55	2	110	0	1	0	0.083	0	110.00
State CN Directors	Pre-Survey Notification Emails/FAQ/Letters	55	55	1	55	0.05	2.75	0	1	0	0.05	0	2.75
State CN Directors	Post-Survey Follow-up Reminder Emails, Phone Calls, Thank-you Emails	55	55	1	55	0.50	27.5	0	1	0	0.05	0	27.50
SFA Directors	Hard Copy Pretest	6	6	1	6	2	12	0	1	0	0.50	0	12.00
SFA Directors	Self-Administered Web/Telephone Survey	2,188	1,750	1	1,750	2	3,500	438	1	438	0.083	36.50	3,536.50
SFA Directors	Pre-Survey Notification Emails/FAQ/Letters	2,188	1,750	1	1,750	0.05	87.50	438	1	438	0.05	22	109.40
SFA Directors	Post-Survey Follow-up Reminder Emails, Phone Calls, Thank-you Emails	2,188	1,750	1	1,750	0.50	875.00	438	1	438	0.05	22	896.90
TOTAL		**2,251**	**1,813**	**2.99**	**5,423**	**0.852**	**4,618.75**	**438**	**3.00**	**1,314**	**0.061**	**80.30**	**4,699.05**

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Request for an Information Collection; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: National Institute of Food and Agriculture.

ACTION: Notice and request for comments.

SUMMARY: The National Institute of Food and Agriculture, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' for approval under the Paperwork Reduction Act (PRA). This collection was developed to create a vehicle for obtaining stakeholder feedback. This notice announces our intent to submit this collection to Office of Management and Budget for approval and solicits comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by December 5, 2016. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments may be submitted by any of the following methods: Email: *rmartin@nifa.usda.gov;* Fax: 202–720–0857; Mail: Office of Information Technology (OIT), NIFA, USDA, STOP 2216, 1400 Independence Avenue SW., Washington, DC 20250–2216.

FOR FURTHER INFORMATION CONTACT: Robert Martin, Records Officer; email: *rmartin@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The National Institute of Food and Agriculture (NIFA), U.S. Department of Agriculture, oversees roughly $1.5 billion to fund research, education, and extension efforts in a wide range of scientific fields related to agricultural and behavioral sciences. NIFA achieves its mission through partnerships with Land-Grant Universities (LGU), non-profit organizations, private sector firms, and other government agencies. These partners, through research, education, and extension activities, help NIFA and USDA address highly complex and multidimensional challenges in food and agriculture. To ensure that our programs address the Nation's food and agricultural priorities and our processes minimize burden without jeopardizing accountability, NIFA seeks OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback, we mean information that provides insights on perceptions and opinions, but are not statistical surveys or quantitative results that can be generalized to the population of study.

This collection of information is necessary to enable NIFA, herein ''the Agency,'' to garner feedback from customers, stakeholders, and partners (herein ''stakeholders'') in an efficient and timely manner, and in accordance with our commitment to providing the highest quality service delivery. The information collected from our stakeholders will help NIFA identify emerging and significant priorities in food and agriculture; refine NIFA's business processes; and promote inclusiveness and diversity to ensure that NIFA drives outcomes that meets the needs of all Americans.

Improving agency programs requires ongoing assessment of NIFA's programs and processes, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards. NIFA will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements based on stakeholder feedback. If this information is not collected, NIFA's ability to respond to stakeholders' needs and continuously improve programs and services will be greatly diminished.

The solicitation of feedback will target areas in: Strategic, portfolio, and programmatic planning; competitive and non-competitive awards processes; post-award management; information technology systems and Web sites; and, grants management training. Responses will inform efforts to improve or maintain the quality of service offered to the public.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Request for approval for a new collection of information.

Type of Review: New.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: 11,250.

Below we provide projected average estimates for the next three years:

Average Expected Annual Number of activities: 15.

Average number of Respondents per Activity: 750.

Annual responses: 11,250.

Frequency of Response: Once per request.

Average minutes per response: 30.

Burden hours: 5,625.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection on *Regulations.gov.*

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 Office of Management and Budget control number.

Done at Washington, DC, this 23rd day of September, 2016.

Catherine E. Woteki,

Under Secretary, Research, Education, and Economics.

[FR Doc. 2016–23956 Filed 10–3–16; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed collection; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's intention to request an extension for a currently approved information collection in support of the Rural Economic Development Loan and Grant Program.

DATES: Comments on this notice must be received by December 5, 2016, to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Director, Specialty Programs Division, Rural Business-Cooperative Service, U.S. Department of Agriculture, STOP 3226, 1400 Independence Avenue SW., Washington, DC 20250–3226, Telephone (202) 720–1400.

SUPPLEMENTARY INFORMATION:

Title: Rural Economic Development Loan and Grant Program.

OMB Number: 0570–0035.

Expiration Date of Approval: February 28, 2017.

Type of Request: Extension of a currently approved information collection.

Abstract: Under this program, loans and grants are provided to electric and telecommunications utilities that have borrowed funds from the Agency. The purpose of the program is to encourage these electric and telecommunications utilities to promote rural economic development and job creation projects such as business start-up costs, business expansion, community development, and business incubator projects. The utilities must use program loan funds to make a pass-through loan to an ultimate recipient such as a business. The utility is responsible for fully repaying its loan to the Government, even if the ultimate recipient does not repay its loan. The intermediary must use program grant funds, along with its required contribution, to create a revolving loan fund that the utility will operate and administer. Loans to the ultimate recipient are made from the revolving loan fund for a variety of community development projects. The information requested is necessary and vital in order for the Agency to be able to make prudent and financial analysis decisions.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Rural Utilities Service Electric and Telecommunications Borrowers.

Estimated Number of Respondents: 120.

Estimated Number of Responses per Respondent: 17.

Estimated Number of Responses: 2,075.

Estimated Total Annual Burden on Respondents: 4,728.

Copies of this information collection can be obtained from Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division at (202) 692–0040.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of USDA, including whether the information will have practical utility; (b) the accuracy of USDA's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Avenue SW., Washington, DC 20250–0742. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: September 28, 2016.

Justin Hatmaker,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2016–23914 Filed 10–3–16; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, Department of Agriculture.

ACTION: Proposed Collection; Comments Requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this Notice announces the Rural Business-Cooperative Service intention to request an extension for to a currently approved information collection for the Rural Microentrepreneur Assistance Program (RMAP).

DATES: Comments on this notice must be received by December 5, 2016 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Director, Specialty Programs Division, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–3226, Telephone (202) 720–1400,

SUPPLEMENTARY INFORMATION:

Title: Rural Microentrepreneur Assistance Program.

OMB Number: 0570–0062.

Expiration Date of Approval: February 28, 2017.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The purpose of the RMAP program is to support the development and ongoing success of rural microentrepreneurs and microenterprises. Direct loans and grants are made to selected Microenterprise Development Organizations (MDOs).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Nonprofits, Indian Tribes, and Public Institutions of Higher Education.

Estimated Number of Respondents: 75.

Estimated Number of Responses per Respondent: 20.

Estimated Number of Responses: 1506.

Estimated Total Annual Burden Hours on Respondents: 3,254 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Jeanne Jacobs, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, 1400 Independence Avenue SW., STOP 0742, Washington, DC 20250. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record.

Dated: September 28, 2016.

Justin Hatmaker,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2016–23915 Filed 10–3–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Utility Service

Submission for OMB Review; Comment Request

September 29, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 3, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Broadband Grant Program.

OMB Control Number: 0572–0127.

Summary of Collection: Congress has recognized the need to facilitate the deployment of broadband service to unserved rural areas. The provision to broadband transmission service is vital to the economic development, education, health, and safety of rural Americans.

The Consolidated Appropriations Act, 2004 (Title III, Pub. L. 108–199, Stat.3), 7 CFR 1739 Subpart A, as amended, authorizes the Rural Development, Rural Utilities Service (RUS) to administer the Community Connect Grant Program for the provision of broadband transmission service in rural America. Grant authority is utilized to deploy broadband infrastructure to extremely rural, lower income communities on a ''community-oriented connectivity'' basis.

Need and Use of the Information: RUS gives priority to rural areas that it believes have the greatest need for broadband transmission services. This broadband access is intended to promote economic development and provide enhanced educational and health care opportunities. RUS will provide financial assistance to eligible entities that are proposing to deploy broadband transmission service in rural communities where such service does not currently exist and who will connect the critical community facilities including the local schools, libraries, hospitals, police, fire and rescue services and who will operate a community center that provides free and open access to residents.

Description of Respondents: Business or other for-profit; Not-for-profit institutions; State, Local and Tribal Governments.

Number of Respondents: 70.
Frequency of Responses: Reporting; On occasion.
Total Burden Hours: 11,380.

Charlene Parker,
Departmental Information Collection Clearance Officer.
[FR Doc. 2016–23932 Filed 10–3–16; 8:45 am]
BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–65–2016]

Foreign-Trade Zone (FTZ) 158—Vicksburg/Jackson, Mississippi; Notification of Proposed Production Activity; MTD Consumer Group, Inc. (Lawn and Garden Equipment); Verona, Mississippi

MTD Consumer Group, Inc. (MTD), submitted a notification of proposed production activity to the FTZ Board for its facility in Verona, Mississippi, within FTZ 158. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on September 13, 2016.

The MTD facility is located within Site 17 of FTZ 158. The facility is used for the production of lawn and garden equipment. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt MTD from customs duty payments on the foreign-status components used in export production. On its domestic sales, MTD would be able to choose the duty rates during customs entry procedures that apply to water pumps; blowers; power washers; tillers; de-thatchers; aerators; snow throwers; walk behind mowers; mower attachments; edgers; wheeled string trimmers; chippers; shredders; chipper/shredder/vacuums (CSVs); log splitters; and, 2-wheel tractors (duty rates range between free and 2.4%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: polyvinyl chloride tubes; plastic flexible hoses/adhesive labels/bagger cover panels; rubber v-belts/tire inner tubes/0-rings/oil seals/water seals/plugs; cardboard retail cartons; textile grass catcher bags; steel hydraulic fittings/control cables/screw rings/hexagonal head bolts/nuts/washers/pins/springs/mower blades; metal frame brackets; gasoline-powered engines; engine shrouds; hydraulic cylinders; reciprocating positive displacement pumps; hydraulic fluid power pumps; pump parts (ports, bodies and cores); wheels for leaf blowers; hydraulic fluid inlet filters; air cleaners; pressure washer spray gun/nozzle fittings/nozzle extension tubes; snow thrower wheels; block joint assemblies for snow throwers; tiller parts (tine/handle assemblies, handle covers, tines, bails, drive handles, handle height adjuster plates); lawn mower wheels; water nozzle adapters for lawn mower decks; blower chutes for lawn mowers; wheeled string trimmer bodies; string trimmer handles; log splitter wheels; hitch coupling assemblies for log splitters; steel screens for wood chippers; wedges for wood chippers; edger wheels; manual directional valves for hydraulic fluid on log splitters; valve parts for log splitters; radial ball bearings; transmission shafts/cranks/assemblies; worm gears; gearbox housings; metal magnets; motor starters; axles for 2-wheel tractors; and, wheel barrow/cart wheels with tires (duty rates range from free to 9%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is November 14, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: September 27, 2016.

Andrew McGilvray,
Executive Secretary.
[FR Doc. 2016–23965 Filed 10–3–16; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Initiation of Expedited Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is initiating an expedited review of the countervailing duty order on certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea) with respect to POSCO and Hyundai Steel Company (Hyundai).

DATES: Effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–2371.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2016, the Department published the countervailing duty order on CORE from Korea.[1] On August 24, 2016, the Department received requests from POSCO and Hyundai to conduct an expedited review of this countervailing duty order.[2] POSCO and Hyundai were not selected for individual examination during the investigation and made these requests pursuant to 19 CFR 351.214(k).

Initiation of Expedited Review

In accordance with 19 CFR 351.214(k)(1)(i)–(iii), POSCO and Hyundai each certified that it exported the subject merchandise to the United States during the period of investigation; that it was not affiliated with an exporter or producer that the Department individually examined in the investigation; and that it informed the Government of Korea, as the government of the exporting country, that the government will be required to

[1] *See Certain Corrosion-Resistant Steel Products From India, Italy, Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016).

[2] *See* letter from POSCO, ''Corrosion-Resistant Steel Products from South Korea, Case No. C–580–879: Request for Expedited Review Pursuant to 19 CFR 351.214(k),'' (August 24, 2016). *See also* letter from Hyundai, ''Corrosion-Resistant Steel Products from South Korea, Case No. C–580–879: Request for Expedited Review Pursuant to 19 CFR 351.214(k),'' (August 24, 2016).

provide a full response to the Department's questionnaire.

Therefore, in accordance with 19 CFR 351.214(k), we are initiating an expedited review of the countervailing duty order on CORE from Korea. Pursuant to 19 CFR 351.214(i)(1) and (k)(3), we intend to issue the preliminary results of this expedited review not later than 180 days from the date of initiation of this review.[3] As specified by 19 CFR 351.214(k)(3)(i), the period of review will be the same as the original period of investigation, *i.e.,* January 1, 2014, through December 31, 2014.

Pursuant to 19 CFR 351.214(k)(3)(iii), the final results of this expedited review will not be the basis for the assessment of countervailing duties. Instead, this expedited review is intended to establish individual cash deposit rates for POSCO and Hyundai, or to exclude from the countervailing duty order a company for which the final results of review are zero or *de minimis,* as provided in 19 CFR 351.214(k)(3)(iv) .

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305 and 351.306.

Dated: September 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–23967 Filed 10–3–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC901

Endangered and Threatened Species; Announcement of a Recovery Planning Workshop and Request for Information

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

ACTION: Notice; request for information.

SUMMARY: We, NMFS, are convening a workshop to solicit facts and information from experts to inform recovery planning for the Main Hawaiian Islands (MHI) insular false killer whale (*Pseudorca crassidens*) Distinct Population Segment (DPS). This workshop will be open to the public. We also request information that might inform the development of the recovery plan. On October 2, 2013, we published a Notice of Intent to prepare a Recovery Plan and Request for Information for this DPS. We received seven public comments in response to that notice, which remain relevant and will be considered in the recovery planning process. Because significant time has elapsed since this last request, we are requesting any additional information that has become available in the interim.

DATES:

• *Workshop dates and information:* The four-day recovery planning workshop for the MHI insular false killer whale DPS will be held Tuesday, October 25 through Friday, October 28, 2016, at the Ohana Waikiki East Hotel, 150 Kaiulani Ave., Honolulu, HI 96815. The workshop will begin each day at 9 a.m. and end each day at 5:30 p.m. or as necessary to complete business for the day.

RSVP date: If you plan to attend the workshop as an interested member of the public, please contact Krista Graham, NMFS, Pacific Islands Regional Office, *krista.graham@noaa.gov,* 808–725–5152 no later than October 21, 2016.

• *Date for information submission:* Please submit information to inform recovery planning via the methods listed below in the **ADDRESSES** section by December 5, 2016.

ADDRESSES: You may submit information by either of the following methods:

• *Mail:* Krista Graham, NMFS Pacific Islands Regional Office, Protected Resources Division, 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

• *Electronic Submissions:* Submit all electronic information that may inform the development of recovery criteria and actions via email to *NMFS.PIR.FKWRecoveryPlan@noaa.gov* (No files larger than 5MB can be accepted).

FOR FURTHER INFORMATION CONTACT: Krista Graham, NMFS, Pacific Islands Regional Office, 808–725–5152. You may also visit our Web site at: *http://www.fpir.noaa.gov/PRD/prd_mhi_false_killer_whale.html#fwk_esa_listing.*

SUPPLEMENTARY INFORMATION:

Background

On November 28, 2012, we published a final rule listing the MHI insular false killer whale DPS as endangered under the Endangered Species Act (ESA) (77 FR 70915). The final listing rule describes the background of the listing action for this DPS and provides a summary of our conclusions regarding its status. For additional background and a summary of natural history and threats to the species, the reader is referred to the status review report and final listing rule (available at *http://www.fpir.noaa.gov/PRD/prd_mhi_false_killer_whale.html*).

NMFS is required by section 4(f) of the ESA to develop and implement recovery plans for the conservation and survival of federally listed species unless the Secretary finds that such a plan will not promote the conservation of the species. Recovery means that listed species and their ecosystems are restored, and their future secured, so that the protections of the ESA are no longer necessary. The ESA specifies that recovery plans are to include (1) a description of site-specific management actions necessary to achieve the plan's goals for the conservation and survival of the species; (2) objective, measurable criteria which, when met, would result in the species being removed from the list; and (3) estimates of the time and costs required to carry out the actions and achieve the plan's conservation goals. Under Section 4(f) of the ESA, public notice and an opportunity for public review and comment are also provided during recovery plan development. We published a Notice of Intent and Request for Information to Prepare a Recovery Plan for this DPS in October of 2013 (78 FR 60850). We received seven substantive public comments in response to that notice, which remain relevant and will be considered in the recovery planning process. Because significant time has elapsed since the last request, we are requesting any relevant information that may have become available.

This notice and request for information serves as a second public notice and opportunity for public input early in the process. Once a recovery plan has been drafted, it will be announced in the **Federal Register** and available on our Web site (see **ADDRESSES** section) for public review and comment before being finalized.

Recovery Planning Workshop Announcement

From October 25 through 28, 2016, NMFS will hold a workshop at the Ohana Waikiki East Hotel in Honolulu, HI to help inform our recovery planning for the MHI insular false killer whale DPS (see **DATES** section). We are inviting experts in specific topic areas, including the species' biology/ecology, threats to the species and the species' habitat, and the recovery planning process itself. These experts will help us to update the threats analysis from the listing rule, and identify potential actions to address the threats. Identified experts include representatives of Federal and state

[3] Under 19 CFR 351.214(k)(i)(2), this period may be extended to 300 days.

agencies, scientific experts, individuals from conservation partners and non-governmental organizations, and commercial and recreational fishermen. Information received at the workshop may be used to inform the development of other conservation decisions and actions, including the designation of critical habitat.

NMFS will provide a moderator to manage the workshop as well as a notetaker to document input received. We are seeking only individual analysis, facts, and opinions from participants. Questions to the participants will be limited to those necessary to clarify the expert's presentation and questions seeking consensus among panelists or experts will not be entertained. NMFS also will provide a time-limited question and answer period during which attendees may ask NMFS about information presented. NMFS will prepare a summary of the workshop, noting the main points raised by the panelists and registered speakers.

This workshop will be open to the public, and a public comment period will be provided at the end of each session. If you plan to attend the workshop as an interested member of the public, please contact Krista Graham at the address listed above by October 21, 2016, so we can ensure sufficient space for all participants and interested parties during our logistics planning.

Agenda

○ October 25–26 will focus on recovery actions and criteria related to non-longline commercial and recreational fisheries interactions;

○ October 27 will focus on recovery actions and criteria related to nutrition, *i.e.,* prey size/biomass, distribution, and competition with fisheries;

○ October 28 will focus on recovery actions and criteria related to other threats to both the species itself and its habitat including noise and contaminants.

Request for Information

We also invite the public to submit scientific or commercial information that may help to inform the recovery criteria and actions for the MHI insular false killer whale DPS. We are soliciting relevant information related to the MHI insular false killer whale and its habitat, including the following:

1. Criteria for removing the MHI insular false killer whale from the list of threatened and endangered species (this could be either threats-based or abundance/trends based);

2. Human activities that contribute to threats to the species;

3. Physical, biological or chemical features of the environment that limit the recovery of the MHI insular false killer whale;

4. Recovery strategies addressing threats to physical and biological features that are essential to species conservation;

5. Strategies and/or actions to recover the MHI insular false killer whale;

6. Estimates of the time and cost to implement recovery actions;

7. Critical knowledge gaps and/or uncertainties that need to be resolved to better inform recovery efforts; and

8. Research, monitoring, and evaluation needs to address knowledge gaps and uncertainties, or to assess the species' status, limiting factors, and threats relative to recovery goals.

Information may be submitted via the methods listed above in the **ADDRESSES** section.

The workshop is accessible to persons with disabilities. Send requests for sign language interpretation or other auxiliary aids at least five business days in advance to Krista Graham at 808–725–5152.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: September 28, 2016.

Nicole R. LeBoeuf,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–23857 Filed 10–3–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE913

Marine Mammals; File No. 20452

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that SMRU Consulting North America, LLC, P.O. Box 764, Friday Harbor, WA 98250, has applied in due form for a permit to conduct research on harbor porpoises and harbor seals in Admiralty Inlet and the San Juan Islands, Washington.

DATES: Written, telefaxed, or email comments must be received on or before November 3, 2016.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 20452 from the list of available applications.

These documents are also available 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.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Sara Young or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to characterize the behavioral responses of harbor porpoise (*Phocoena phocoena*) and harbor seal (*Phoca vitulina*) to marine renewable energy devices, and to characterize the fine scale habitat use of marine mammals in tidal inlets to inform collision risk with tidal turbines. Behavioral responses to tidal turbine noise will be addressed with an experimental playback approach. The playback studies will be undertaken in the inland waters of Washington State using a combination of land-based surveys and passive acoustic monitoring methods. Studies to characterize the fine scale habitat use of harbor porpoise and pinnipeds in tidal inlets will use a combination of land-based and unmanned aerial system surveys, and will also be carried out in the inland waters of Washington State during 2016–2021. The applicant requests 244 Level B takes of harbor porpoise between two study areas, 416 takes of harbor seals, 154 Steller sea lions (*Eumetopias jubatus*), and 7 California sea lions (*Zalophus californianus*) by means of acoustic playbacks and UAS.

In compliance with the National Environmental Policy Act of 1969 (42

U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 28, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–23933 Filed 10–3–16; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2016–0045]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (The Bureau) is proposing to renew the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Truth in Savings Act (Regulation DD) 12 CFR 1030.''

DATES: Written comments are encouraged and must be received on or before November 3, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OMB:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 or fax to (202) 395–5806. Mailed or faxed comments to OMB should be to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review, use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *CFPB_PRA@cfpb.gov. Please do not submit comments to this email box.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Truth in Savings Act (Regulation DD) 12 CFR 1030.

OMB Control Number: 3170–0004.

Type of Review: Extension without change of a currently approved information collection.

Affected Public: Private sector (non-credit union depository institutions).

Estimated Number of Respondents: 129.

Estimated Total Annual Burden Hours: 573,008.

Abstract: Consumers rely on the disclosures required by The Truth in Savings Act (TISA) and Regulation DD to facilitate informed decision-making regarding deposit accounts offered at depository institutions. Without this information, consumers would be severely hindered in their ability to assess the true costs and terms of the deposit accounts offered. Federal agencies and private litigants use the records to ascertain whether accurate and complete disclosures of depository accounts have been provided to consumers. This information also provides the primary evidence of law violations in TISA enforcement actions brought by the Bureau. Without the Regulation DD recordkeeping requirement, the Bureau's ability to enforce the TISA would be significantly impaired.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on June 14, 2016, 81 FR 38691, Docket Number: CFPB–2016–0031. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: September 28, 2016.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2016–23860 Filed 10–3–16; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed use of the AmeriCorps NCCC Project Completion Report. The report is used to collect project assessment and implementation information. Organizations that are awarded and sponsor an AmeriCorps NCCC team will be required to complete this collection instrument.

Copies of the information collection request can be obtained by contacting

the office listed in the Addresses section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by December 5, 2016.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, AmeriCorps NCCC; Attention Terry D. Grant, Program Analyst, 3238–C; 250 E Street SW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Terry D. Grant, 202–606–6899, or by email at *tgrant@cns.gov.*

SUPPLEMENTARY INFORMATION:

CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Background

Organizations that sponsor an AmeriCorps NCCC team provide the information collected on this form in order to report on the project's implementation and assess the project's scope and community impact.

Current Action

This is a new information collection request. The AmeriCorps NCCC Project Completion Report is distributed to organizations that have hosted an NCCC team within 30 days of the end of each project and should be completed within 60 days of the end of each project. Reports are submitted via PDF by email to NCCC staff.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: AmeriCorps NCCC Project Completion Report.

OMB Number: None.

Agency Number: None.

Affected Public: AmeriCorps NCCC Project Sponsoring Organizations.

Total Respondents: Approximately 1,000 per year.

Frequency: Once per project.

Average Time per Response: Averages 15 minutes.

Estimated Total Burden Hours: Approximately 300 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: September 28, 2016.

Jacob Sgambati,

Director of Operations, NCCC.

[FR Doc. 2016–23963 Filed 10–3–16; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2015–0005]

Proposed Collection; Comment Request

AGENCY: Department of Navy (DON), DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Naval Sea Systems Command (NAVSEA), Cost Engineering and Industrial Analysis Group (SEA 05C) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 5, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Naval Sea Systems Command (SEA 05C), 1333 Isaac Hull Avenue SE., STOP 1340, Washington Navy Yard, ATTN: Denitra Carter, Washington, DC 20376–1340, at (202) 781–5069.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Facilities Available for the Construction or Repair of Ships; Standard Form 17; OMB Control Number 0703–0006.

Needs and Uses: This information collection is part of a joint effort between the Naval Sea Systems Command (NAVSEA) and the U.S. Maritime Administration (MARAD), to maintain a working data set on active U.S. Shipyards. The information collected is required by the Merchant

Marine Act of 1936 as amended and is critical in providing both organizations with a comprehensive list of U.S. commercial shipyards and their capabilities and capacities. These shipyards play a crucial role in national defense, the economy and the U.S. transportation infrastructure and as such, are of considerable interest to the U.S. Government. The data collected is used to assess the capabilities and capacities of U.S. commercial shipyards in the areas of ship repair and ship construction. The data is also used to monitor employment numbers for labor forecasting for future build projects as well as providing information on the ability to raise labor to meet national industrial mobilization requirements during times of national emergency. The data collected is the main source of information on these shipyards and is used to these ends.

Affected Public: Business or other for profit.

Annual Burden Hours: 800.

Number of Respondents: 200.

Responses per Respondent: 1.

Annual Responses: 200.

Average Burden per Response: 4 hours.

Frequency: Annual.

Respondents are businesses involved in shipbuilding and/or ship repair who provide NAVSEA and MARAD with information and a list of facilities available for the construction or repair of ships that is utilized in a database for assessing the production capacity of the individual shipyards.

Dated: September 28, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–23861 Filed 10–3–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2675–000]

AltaGas Pomona Energy Storage Inc.; 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 AltaGas Pomona Energy Storage Inc.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 October 18, 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: September 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–23923 Filed 10–3–16; 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: EC16–193–000.

Applicants: Pioneer Wind Park I LLC.

Description: Application for Authorization under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Pioneer Wind Park I, LLC.

Filed Date: 9/27/16.

Accession Number: 20160927–5154.

Comments Due: 5 p.m. ET 10/18/16.

Docket Numbers: EC16–194–000.

Applicants: Brady Wind, LLC, Brady Wind II, LLC, Brady Interconnection, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action of Brady Wind, LLC, et al.

Filed Date: 9/27/16.

Accession Number: 20160927–5159.

Comments Due: 5 p.m. ET 10/18/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–569–012; ER16–2453–001; ER16–2190–001; ER16–2191–001; ER15–1925–005; ER15–2676–004; ER16–1672–001; ER13–712–013; ER10–1849–011; ER11–2037–011; ER12–2227–011; ER10–1887–011; ER10–1920–013; ER10–1928–013; ER10–1952–011; ER10–1961–011; ER12–1228–013; ER16–2275–001; ER16–2276–001; ER14–2707–008; ER12–895–011; ER10–2720–013; ER11–4428–013; ER12–1880–012; ER16–2241–001; ER16–2297–001; ER15–58–006; ER14–2710–008; ER16–1440–002; ER16–2240–001; ER15–30–006; ER14–2708–009; ER14–2709–008; ER13–2474–007; ER11–4462–021; ER10–1971–030.

Applicants: Blackwell Wind, LLC, Brady Interconnection, LLC, Brady Wind, LLC, Brady Wind II, LLC, Breckinridge Wind Project, LLC, Cedar Bluff Wind, LLC, Chaves County Solar, LLC, Cimarron Wind Energy, LLC, Elk City Wind, LLC, Elk City II Wind, LLC, Ensign Wind, LLC, FPL Energy Cowboy Wind, LLC, FPL Energy Oklahoma Wind, LLC, FPL Energy Sooner Wind, LLC, Gray County Wind Energy, LLC, High Majestic Wind Energy Center, LLC, High Majestic Wind II, LLC, Kingman Wind Energy I, LLC, Kingman Wind Energy II, LLC, Mammoth Plains Wind Project, LLC, Minco Wind

Interconnection Services, LLC, Minco Wind, LLC, Minco Wind II, LLC, Minco Wind III, LLC, Ninnescah Wind Energy, LLC, Osborn Wind Energy, LLC, Palo Duro Wind Interconnection Services, LLC, Palo Duro Wind Energy, LLC, Roswell Solar, LLC, Rush Springs Wind Energy, LLC, Seiling Wind Interconnection Services, LLC, Seiling Wind, LLC, Seiling Wind II, LLC, Steele Flats Wind Project, LLC, NEPM II, LLC, NextEra Energy Power Marketing, LLC.

Description: Notification of Non-material Change in Status of the NextEra Resources Entities, et al.

Filed Date: 9/27/16.

Accession Number: 20160927–5161.

Comments Due: 5 p.m. ET 10/18/16.

Docket Numbers: ER16–1363–001.

Applicants: Arizona Public Service Company.

Description: Compliance filing: Compliance Filing of Arizona Public Service Company to be effective 9/30/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5097.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2023–001.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2016–09–28 Waiver Petition Delay Implementation of Flexible Ramping Product to be effective. N/A.

Filed Date: 9/28/16.

Accession Number: 20160928–5146.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2467–001.

Applicants: NSTAR Electric Company.

Description: Tariff Amendment: Amendment—Notice of Cancellation of Exelon West Medway Design-Engineering Agmt to be effective 6/14/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5113.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2676–000.

Applicants: PacifiCorp.

Description: Notice of Termination of LGIA SA 309 of PacifiCorp.

Filed Date: 9/27/16.

Accession Number: 20160927–5158.

Comments Due: 5 p.m. ET 10/18/16.

Docket Numbers: ER16–2677–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3215R1 People's Electric Cooperative NITSA NOA to be effective 8/1/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5051.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2678–000.

Applicants: Nevada Power Company.

Description: § 205(d) Rate Filing: OATT Revisions TOC, Definitions and Attachment P to be effective 11/1/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5057.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2679–000.

Applicants: Terrapin Energy LLC.

Description: § 205(d) Rate Filing: Certificate of Concurrence Filing to be effective 9/20/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5059.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2680–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: OATT Revisions (Flexible Ramping Requirement) to be effective 11/1/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5067.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2681–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment AE to Remove Interim TCR Process to be effective 11/28/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5149.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2682–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Second Revised ISA No. 3669, Queue No. Y3–046/Y3–051/Z1–058/Z2–059/Z2–002 to be effective 8/29/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5150.

Comments Due: 5 p.m. ET 10/19/16.

Docket Numbers: ER16–2683–000.

Applicants: El Paso Electric Company.

Description: Compliance filing: OATT Order No. 827 and 828 Compliance Filing to be effective 10/14/2016.

Filed Date: 9/28/16.

Accession Number: 20160928–5155.

Comments Due: 5 p.m. ET 10/19/16.

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: September 28, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–23921 Filed 10–3–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–1244–000.

Applicants: Enable Mississippi River Transmission, L.

Description: § 4(d) Rate Filing: 2016 Fuel Adjustment Filing to be effective 11/1/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5124.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1245–000.

Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Fuel Tracker Filing Effective November 1 2016 to be effective 11/1/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5138.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1246–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2016 Misc Updates Orig Vol 1A to be effective 10/24/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5159.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1247–000.

Applicants: Trunkline Gas Company, LLC.

Description: Compliance filing Annual Report of Flow Through filed 9–23–16.

Filed Date: 9/23/16.

Accession Number: 20160923–5171.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1248–000.

Applicants: Alliance Pipeline L.P.

Description: § 4(d) Rate Filing: Fuel Requirement Nov 2016 to be effective 11/1/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5172.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1249–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) Rate Filing: Imbalance Calculations to be effective 11/1/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5198.

Comments Due: 5 p.m. ET 10/5/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP16–618–001.

Applicants: Algonquin Gas Transmission, LLC.

Description: Compliance filing Capacity Release Bidding Exemption—Compliance Filing to be effective 9/1/2016.

Filed Date: 9/23/16.

Accession Number: 20160923–5153.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: RP16–1178–001.

Applicants: Equitrans, L.P.

Description: Compliance filing Ohio Valley Connector Errata Filing to be effective 12/31/9998.

Filed Date: 9/26/16.

Accession Number: 20160926–5085.

Comments Due: 5 p.m. ET 10/11/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, 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: September 26, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–23922 Filed 10–3–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2010–0505; FRL–9953–57–OAR]

Clarification of Reconsideration of the Oil and Natural Gas Sector: New Source Performance Standards; Final Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of supplemental action denying petitions for reconsideration.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is providing notice that it has clarified the scope of its July 29, 2016, response to petitions for reconsideration of the 2012 final rule titled ''Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews'' and the subsequent amendments published in the **Federal Register** on September 23, 2013, and December 31, 2014. The EPA has sent a letter to each of the petitioners clarifying that the July 29, 2016, action denied the above mentioned petitions only with respect to the issues related to the new source performance standards (NSPS), and was not intended to include denial of reconsideration of any issue relative to the 2012 action on the national emission standards for hazardous air Pollutants (''2012 NESHAP''). The letters further state that, to the extent the July 29, 2016, action may be construed to have denied reconsideration of issues relative to the 2012 NESHAP, the follow-up letters supersede that previous action on NESHAP-related matters.

DATES: Effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Thompson, Sector Policies and Programs Division (E143–05), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–9775; fax number: (919) 541–3470; email address: *thompson.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Where can I get a copy of this document and other related information?

A copy of this **Federal Register** notice, the supplemental letters, and the revised supporting document describing the full basis for the July 29, 2016, action are available in the docket the EPA established under Docket ID No. EPA–HQ–OAR–2010–0505. In addition, following signature, all relevant documents will be available on the World Wide Web (WWW) at the following address: *https://www3.epa.gov/airquality/oilandgas/actions.html.*

II. Description of Action

On August 16, 2012, the EPA published the final rule titled ''Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews.'' See 77 FR 49490. The rule contains final actions on two different national standards for the oil and natural gas sector: (1) NSPS, promulgated under section 111 of the Clean Air Act (CAA) and (2) NESHAP, promulgated under section 112 of the CAA. The 2012 rule was followed by a series of reconsideration actions and amendments to the 2012 NSPS. 78 FR 58416 (September 23, 2013); 79 FR 79018 (December 31, 2014); 80 FR 48262 (August 12, 2015); and 81 FR 35824 (June 3, 2016) (''2016 Final Rule''). The EPA received administrative petitions for reconsideration of the 2012 rules (on both the NSPS and the NESHAP), as well as for reconsideration of the 2013 and 2014 NSPS amendments. On July 29, 2016, the Administrator took final action denying these petitions with respect to NSPS issues not otherwise addressed in prior reconsideration actions. That action was announced in a **Federal Register** notice published on August 10, 2016 (81 FR 52778). Although several of the reconsideration petitions identified in the July 29, 2016, action also include NESHAP issues, and one petition pertains only to the 2012 NESHAP,[1] the EPA did not address the substance of any NESHAP related issues in that action.

The EPA is providing notice that it has issued a supplemental letter to clarify the scope of its July 29, 2016, action. The supplemental letter further clarifies that the July 29, 2016, action was not intended to include denial of reconsideration of any issue relative to the 2012 NESHAP and that the EPA continues to evaluate reconsideration issues relative to the 2012 NESHAP. The letter also states that, to the extent the July 29, 2016, letter may be construed to have denied reconsideration of issues relative to the 2012 NESHAP, the

[1] Petition for Reconsideration of Oil and Natural Gas Sector: National Emission Standards for Hazardous Air Pollutants Reviews; Final Rule, 77 FR 49490 (August 16, 2012), 40 CFR part 63, subparts HH and HHH, submitted by Earthjustice on behalf of California Communities Against Toxics, California Safe Schools, Clean Air Council, Coalition For A Safe Environment, Desert Citizens Against Pollution, Natural Resources Defense Council, and Sierra Club (October 15, 2012).

supplemental letter supersedes that action on NESHAP-related issues.

Enclosed with the supplemental letter is a revised document titled ''Denial of Petitions for Reconsideration of Certain Issues: Oil and Natural Gas New Source Performance Standards (40 CFR part 60, subpart OOOO).'' The document sets forth the EPA's reasons for denying the above mentioned petitions with respect to NSPS issues not otherwise addressed in previous reconsideration actions. The NSPS reconsideration denial supporting document that accompanied the July 29, 2016 letters has been revised to remove two erroneous references: (1) Replaced No. 4591 with No. 4575 as the Petitioner for Issue 26; and (2) removed No. 4591 from the list of NSPS Petitioners in Appendix A.

Dated: September 26, 2016.

Janet G. McCabe,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2016–23972 Filed 10–3–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2007–0468; ER–FRL–9029–4]

Proposed Information Collection Request; Comment Request; Final Rule at 40 CFR Part 8: Environmental Impact Assessment of Nongovernmental Activities in Antarctica (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Final Rule at 40 CFR part 8: Environmental Impact Assessment of Nongovernmental Activities in Antarctica'' (EPA ICR No. 1808.07, OMB Control No. 2020–0007) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2017. 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.

DATES: Comments must be submitted on or before Monday, December 5, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OECA–2007–0468 online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Julie Roemele, Office of Federal Activities, Mail Code 2252A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–5632; fax number: (202) 564–0072; email address: *roemele.julie@epa.gov.*

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The Environmental Protection Agency's (EPA's) regulations at 40 CFR part 8, Environmental Impact Assessment of Nongovernmental Activities in Antarctica (Rule), were promulgated pursuant to the Antarctic Science, Tourism, and Conservation Act of 1996 (Act), 16 U.S.C. 2401 *et seq.,* as amended, 16 U.S.C. 2403a, which implements the Protocol on Environmental Protection (Protocol) to the Antarctic Treaty of 1959 (Treaty). The Rule provides for assessment of the environmental impacts of nongovernmental activities in Antarctica, including tourism, for which the United States is required to give advance notice under Paragraph 5 of Article VII of the Treaty, and for coordination of the review of information regarding environmental impact assessments received from other Parties under the Protocol. The requirements of the Rule apply to operators of nongovernmental expeditions organized or proceeding from the territory of the United States to Antarctica and include commercial and non-commercial expeditions. Expeditions may include ship-based tours; yacht, skiing or mountaineering expeditions; privately funded research expeditions; and other nongovernmental activities. The Rule does not apply to individual U.S. citizens or groups of citizens planning travel to Antarctica on an expedition for which they are not acting as an operator. (Operators, for example, typically acquire use of vessels or aircraft, hire expedition staff, plan itineraries, and undertake other organizational responsibilities.) The rule provides nongovernmental operators with the specific requirements they need to meet in order to comply with the requirements of Article 8 and Annex I to the Protocol. The provisions of the Rule are intended to ensure that potential environmental effects of nongovernmental activities undertaken in Antarctica are appropriately identified and considered by the operator during the planning process and that to the extent practicable appropriate environmental safeguards which would mitigate or prevent adverse impacts on the Antarctic environment are identified by the operator.

Environmental Documentation. Persons subject to the Rule must prepare environmental documentation to support the operator's determination regarding the level of environmental impact of the proposed expedition.

Environmental documentation includes a Preliminary Environmental Review Memorandum (PERM), an Initial Environmental Evaluation (IEE), or a Comprehensive Environmental Evaluation (CEE). The environmental document is submitted to the Office of Federal Activities (OFA). If the operator determines that an expedition may have: (1) Less than a minor or transitory impact, a PERM needs to be submitted no later than 180 days before the proposed departure to Antarctica; (2) no more than minor or transitory impacts, an IEE needs to be submitted no later than 90 days before the proposed departure; or (3) more than minor or transitory impacts, a CEE needs to be submitted. Operators who anticipate such activities are encouraged to consult with EPA as soon as possible regarding the date for submittal of the CEE. (Article 3(4), of Annex I of the Protocol requires that draft CEEs be distributed to all Parties and the Committee for Environmental Protection 120 days in advance of the next Antarctic Treaty Consultative Meeting (ATCM) at which the CEE may be addressed.)

The Protocol and the Rule also require an operator to employ procedures to assess and provide a regular and verifiable record of the actual impacts of an activity which proceeds on the basis of an IEE or CEE. The record developed through these measures needs to be designed to: (a) Enable assessments to be made of the extent to which environmental impacts of nongovernmental expeditions are consistent with the Protocol; and (b) provide information useful for minimizing and mitigating those impacts and, where appropriate, on the need for suspension, cancellation, or modification of the activity. Moreover, an operator needs to monitor key environmental indicators for an activity proceeding on the basis of a CEE. An operator may also need to carry out monitoring in order to assess and verify the impact of an activity for which an IEE would be prepared. For activities that require an IEE, an operator should be able to use procedures currently being voluntarily utilized by operators to provide the required information. Should an activity require a CEE, the operator should consult with EPA to: (a) Identify the monitoring regime appropriate to that activity, and (b) determine whether and how the operator might utilize relevant monitoring data collected by the U.S. Antarctic Program. The Office of Federal Activities (OFA) would consult with the National Science Foundation and other interested Federal agencies regarding the monitoring regime.

In cases of emergency related to the safety of human life or of ships, aircraft, equipment and facilities of high value, or the protection of the environment which would require an activity to be undertaken without completion of the documentation procedures set out in the Rule, the operator would need to notify the Department of State within 15 days of any activities which would have otherwise required preparation of a CEE, and provide a full explanation of the activities carried out within 45 days of those activities. (During the time the Interim Final and Final Rules have been in effect, there were no emergencies requiring notification by U.S. operators. An Interim Final Rule was in effect from April 30, 1997, until replaced on December 6, 2001, by the Final Rule).

Environmental documents (*e.g.,* PERM, IEE, CEE) are submitted to OFA. Environmental documents are reviewed by OFA, in consultation with the National Science Foundation and other interested Federal agencies, and also made available to other Parties and the public as required under the Protocol or otherwise requested. OFA notifies the public of document availability via the World Wide Web at: *https://www.epa.gov/international-cooperation/receipt-environmental-impact-assessments-eias-regarding-nongovernmental.*

The types of nongovernmental activities currently being carried out (*e.g.,* ship-based tours, land-based tours, flights, and privately funded research expeditions) are typically unlikely to have impacts that are more than minor or transitory, thus an IEE is the typical level of environmental documentation submitted. For the 1997–1998 through 2015–2016 austral summer seasons during the time the Rule has been in effect, all respondents submitted IEEs with the exception of three PERMs. Paperwork reduction provisions in the Rule that are used by the operators include: (a) Incorporation of material in the environmental document by referring to it in the IEE, (b) inclusion of all proposed expeditions by one operator within one IEE; (c) use of one IEE to address expeditions being carried out by more than one operator; and (d) use of multi-year environmental documentation to address proposed expeditions for a period of up to five consecutive austral summer seasons.

Coordination of Review of Information Received from Other Parties to the Treaty. The Rule also provides for the coordination of review of information received from other Parties and the public availability of that information including: (1) A description of national procedures for considering the environmental impacts of proposed activities; (2) an annual list of any IEEs and any decisions taken in consequence thereof; (3) significant information obtained and any action taken in consequence thereof with regard to monitoring from IEEs to CEEs; and (4) information in a final CEE. This provision fulfills the United States' obligation to meet the requirements of Article 6 of Annex I to the Protocol. The Department of State is responsible for coordination of these reviews of drafts with interested Federal agencies, and for public availability of documents and information. This portion of the Rule does not impose paperwork requirements on any nongovernmental person subject to U.S. regulation.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are all nongovernmental operators with activities in Antarctica, including tour operators, for which the United States is required to give advance notice under paragraph 5 of Article VII of the Antarctic Treaty of 1959; this includes all nongovernmental expeditions to and within Antarctica organized in or proceeding from the territory of the United States.

Respondent's obligation to respond: Mandatory (40 CFR part 8).

Estimated number of respondents: 19.

Frequency of response: Annual.

Total estimated burden: 1,273 hours.

Total estimated cost: $103,891 includes $3,353 annualized capital or operation & maintenance costs.

Changes in Estimates: There is an increase of 19 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is the result of a change to the level of environmental documentation EPA anticipates the operators will submit as well as an anticipated increase in the number of operators submitting documentation.

Dated: September 29, 2016.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–23982 Filed 10–3–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–9953–67–OA]

Notification of a Public Meeting of the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen Primary NAAQS Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public meeting of the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQS) Review Panel to peer review EPA's *Policy Assessment for the Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (External Review Draft—September 2016).*

DATES: The CASAC Oxides of Nitrogen Primary NAAQS Review Panel meeting will be on Wednesday, November 9, 2016 from 9:00 a.m. to 5:00 p.m. (Eastern Time) and on Thursday, November 10, 2016 from 8:30 a.m. to 12:30 p.m. (Eastern Time).

LOCATION: The public meeting will be held at the Embassy Suites by Hilton Alexandria Old Town, 1900 Diagonal Road, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain information concerning the public meeting may contact Mr. Aaron Yeow, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; by telephone at (202) 564–2050 or via email at *yeow.aaron@epa.gov.* General information about the CASAC, as well as any updates concerning the meeting announced in this notice, may be found on the CASAC Web site at *http://www.epa.gov/casac.*

SUPPLEMENTARY INFORMATION: The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409(d)(2), to review air quality criteria and NAAQS and recommend any new NAAQS and revisions of existing criteria and NAAQS as may be appropriate. The CASAC shall also provide advice, information, and recommendations to the Administrator on the scientific and technical aspects of issues related to the criteria for air quality standards, research related to air quality, sources of air pollution, and of adverse effects which may result from various strategies to attain and maintain air quality standards. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six ''criteria'' air pollutants, including oxides of nitrogen. EPA is currently reviewing the primary (health-based) NAAQS for nitrogen dioxide (NO_2) as an indicator for health effects caused by the presence of oxides of nitrogen in the ambient air.

Pursuant to FACA and EPA policy, notice is hereby given that the CASAC Oxides of Nitrogen Primary NAAQS Review Panel will hold a public meeting to peer review EPA's *Policy Assessment for the Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (External Review Draft—September 2016).* The CASAC Oxides of Nitrogen Primary NAAQS Review Panel and the CASAC will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Technical Contacts: Any technical questions concerning the *Policy Assessment for the Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (External Review Draft—September 2016)* should be directed to Dr. Jennifer Nichols (*nichols.jennifer@epa.gov*), EPA Office of Air and Radiation.

Availability of Meeting Materials: Prior to the meeting, the review documents, agenda and other materials will be accessible on the CASAC Web site at *http://www.epa.gov/casac/.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit relevant comments on the topic of this advisory activity, including the charge to the panel and the EPA review documents, and/or the group conducting the activity, for the CASAC to consider during the advisory process. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Interested parties should contact Mr. Aaron Yeow, DFO, in writing (preferably via email) at the contact information noted above by November 2, 2016, to be placed on the list of public speakers. *Written Statements:* Written statements will be accepted throughout the advisory process; however, for timely consideration by Panel members, statements should be supplied to the DFO (preferably via email) at the contact information noted above by November 2, 2016. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the CASAC Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Aaron Yeow at the contact information provided above. To request accommodation of a disability, please contact Mr. Yeow preferably at least ten days prior to each meeting to give EPA as much time as possible to process your request.

Dated: September 28, 2016.

Khanna Johnston,

Acting Deputy Director, EPA Science Advisory Staff Office.

[FR Doc. 2016–23974 Filed 10–3–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9953–70–ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

DATES: A public virtual meeting will be held on October 19–20, 2016, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate, subsequent teleconference meeting is planned for Tuesday, December 13, 2016, from 2:00 p.m. to approximately 3:30 p.m. for the HSRB to finalize its Final Report of the October 19–20, 2016 meeting.

ADDRESSES: Both of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information visit the HSRB Web site: *http://www2.epa.gov/osa/human-studies-review-board.*

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to receive further information should contact the HSRB Designated Federal Official, Jim Downing on telephone number (202) 564–2468; fax number: (202) 564–2070; email address: *downing.jim@epa.gov;* or mailing address: Environmental Protection Agency, Office of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Meeting access: These meetings are open to the public. Meeting materials are available at the HSRB Web site: *http://www2.epa.gov/osa/human-studies-review-board* for questions on document availability, or if you do not have access to the Internet, consult with Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact Jim Downing listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

How may I participate in this meeting?

The HSRB encourages the public's input. You may participate in these meetings by following the instructions in this section.

1. *Oral comments.* Requests to present oral comments during either conference call will be accepted up to Noon Eastern Time on Wednesday, October 12, 2016, for the October 19–20, 2016 meeting and up to Noon Eastern Time on Thursday, December 8, 2016 for the December 13, 2016 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during either call at the designated time on the agenda. Oral comments before the HSRB are generally limited to five minutes per individual or organization. If additional time is available, further public comments may be possible.

2. *Written comments.* Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Wednesday, October 12, 2016, for the October 19–20, 2016 conference call, and by noon Eastern Time on Thursday, December 8, 2016 for the December 13, 2016 teleconference. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments to Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App. 2 § 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research that are submitted to the Office of Pesticide Programs to be used for regulatory purposes. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research.

Topics for discussion. On Wednesday, October 19, 2016, EPA's Human Studies Review Board will consider a Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings. On Thursday, October 20, 2016 the HSRB will consider: A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial. Meeting materials for these two topics will be available in advance of the meeting at *http://www2.epa.gov/osa/human-studies-review-board.*

On December 13, 2016, the Human Studies Review Board will review and finalize their draft Final Report from the October 19–20, 2016 meeting. The draft report will be available prior to the conference call at *http://www2.epa.gov/osa/human-studies-review-board.*

Meeting minutes and final reports. Minutes of these meetings, summarizing the matters discussed and recommendations made by the HSRB, will be released within 90 calendar days of the meeting. These minutes will be available at *http://www2.epa.gov/osa/human-studies-review-board.* In addition, information regarding the HSRB's Final Report, will be found at *http://www2.epa.gov/osa/human-studies-review-board* or from Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

Thomas A. Burke,

EPA Science Advisor.

[FR Doc. 2016–23987 Filed 10–3–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1079]

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 Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. 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 OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before December 5, 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 Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1079.

Title: Section 15.240, Radio Frequency Identification Equipment.

Type of Review: Extension of a currently approved collection.

Form No.: N/A.

Respondents: Business or other for-profit and not-for-profit institutions.

Number of Respondents and Responses: 10 respondents; 20 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirements.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r).

Total Annual Burden: 200 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period in order to obtain the three year clearance. Section 15.240 requires each grantee of certification for Radio Frequency Identification (RFID) Equipment to register the location of the equipment/devices its markets with the Commission. The information that the grantee must supply to the Commission when registering the device(s) shall include the name, address and other pertinent contact information of users, the geographic coordinates of the operating location, and the FCC identification number(s) of the equipment. The improved RFID equipment could benefit commercial shippers and have significant homeland security benefits by enabling the entire contents of shipping containers to be easily and immediately identified, and by allowing a determination of whether tampering with their contents has occurred during shipping.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–23916 Filed 10–3–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, September 29, 2016 at the conclusion of the open meeting.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting was closed to the public.

ITEMS DISCUSSED: Matters concerning participation in civil actions or proceeding, or arbitration. Internal personnel rules and internal rules and practices.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary.

[FR Doc. 2016–24040 Filed 9–30–16; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 28, 2016.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *NSB Holdings, Inc., and NSB Mutual Holding Company, both of Newtown, Connecticut;* to become bank holding companies by acquiring 100 percent of the voting shares of Newtown Savings Bank, Newtown, Connecticut.

Board of Governors of the Federal Reserve System, September 29, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–23959 Filed 10–3–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0136]; [Docket 2016–0053; Sequence 28]

Submission for OMB Review; Commercial Item Acquisitions

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review

and approve an extension of a previously approved information collection requirement concerning the clauses and provisions required for use in commercial item acquisitions. A notice was published in the **Federal Register** at 81 FR 43201 on July 1, 2016. No comments were received.

DATES: Submit comments on or before November 3, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0136, Commercial Item Acquisitions, by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0136, Commercial Item Acquisitions''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0136, Commercial Item Acquisitions'' on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0136, Commercial Item Acquisitions.

Instructions: Please submit comments only and cite Information Collection 9000–0136, Commercial Item Acquisitions, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, at 202–208–4949, or email at *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Acquisition Streamlining Act of 1994 reformed Federal acquisition statutes to encourage and facilitate the acquisition of commercial items and services by the Federal Government. Accordingly, DoD, NASA, and GSA amended the Federal Acquisition Regulation (FAR) to include streamlined/simplified procedures for the acquisition of commercial items.

Pertinent to this information collection, FAR Provision 52.212–3, ''Offeror Representations and Certifications—Commercial Items,'' was implemented to combine the multitude of individual provisions used in Government solicitations into a single provision for use in commercial acquisitions. The provision is among the representations and certifications that are available for completion in the System for Award Management (SAM).

B. Annual Reporting Burden

Respondents: 397,000.

Responses per Respondent: 1.46.

Total Responses: 579,620.

Hours per Response: .500.

Total Burden Hours: 289,810.

Frequency: On Occasion.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0136 regarding Commercial Item Acquisitions in all correspondence.

Dated: September 28, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–23868 Filed 10–3–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16BFQ; Docket No. CDC–2016–0096]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed study project entitled ''Survey of Sexually Transmitted Disease (STD) Provider Practices in the United States''. The primary goal of this study is to better understand policies and practices for STD care delivery among medical providers who typically see patients for STDs. Another goal is to assess awareness and use of CDC's STD treatment guidelines.

DATES: Written comments must be received on or before December 5, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0096 by any of the following methods:

• *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.

• *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Survey of Sexually Transmitted Disease (STD) Provider Practices in the United States—NEW—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year, 19.7 million sexually transmitted diseases (STDs) occur in the U.S., half of which strike youth 15 – 24 years of age.—The public health burden of STDs is compounded by their economic impact. In 2010, an estimated $15.6 billion in direct medical costs were attributed to STDs. Undiagnosed and untreated STDs can lead to serious long-term health consequences, especially for adolescent girls and young adult women. For example, every year, about 24,000 young women become infertile as a result of undiagnosed and untreated STDs. The STD Provider Survey will collect much needed data from U.S. health care providers in specialties that typically see STD patients, including physician specialties such as obstetrics/gynecology, internal medicine, general or family practice, emergency medicine, or pediatrics. Knowledge of provider practices relative to guidelines and state-level laws and policies will provide information useful to stakeholders at all levels regarding the delivery of STD preventive services and treatment by health care providers in the U.S. As providers are one of the few professionals who have face-to-face contact with persons infected with STDs, they are also a potential intervention point for attempts to reduce re-infection and halt the further transmission of STDs. There is no national survey that collects detailed information on STD practices of physicians who typically see STD patients.

The purpose of this survey is to conduct a nationally representative survey of physicians who typically see STD patients (*e.g.,* primary care—including internal medicine, general or family practice, obstetrics/gynecology, emergency medicine, and pediatrics) that would allow for national estimates and comparisons among specialties. Additionally, the survey will provide national estimates for comparisons between providers in the public and private sectors. Information collected will also be used to determine STD prevention activities needed by type of providers (by specialty or public/private) based on findings related to screening and treatment practices for STDs including EPT.

The survey contains sections on the physician's specialty areas, primary practice setting, primacy practice policies, patient demographics, STD testing and diagnosis, STD care and treatment, and respondent demographics.

In an effort to better understand policies and practices for STD care delivery among medical providers who typically see patients for STDs, the surveys will be sent to a random sample of 5,000 U.S. physicians across several specialties using the American Medical Association Master file. Using a multimode design (mail and web), multiple reminders will be sent to non-responders in order to reach the target of 3,000 completed surveys.

There is no cost to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Physicians responding via Mail	STD Provider Survey	2,250	1	20/60	750
Physicians responding via Web	STD Provider Survey	750	1	32/60	400
Total					1,150

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–23925 Filed 10–3–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; CMS Computer Match No. 2016–15; HHS Computer Match No. 1609

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of Computer Matching Program.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a Computer Matching Program that CMS plans to conduct with the Peace Corps (PC).

DATES: Comments are invited on all portions of this notice. Public comments are due within 30 days after publication. The matching program will become effective no sooner than 40 days after the report of the matching program is sent to the Office of Management and Budget (OMB) and Congress, or 30 days after publication in the **Federal Register**, whichever is later.

ADDRESSES: The public should send comments to: CMS Privacy Act Officer, Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Enterprise Information, CMS, Room N l–24–08, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9:00 a.m.–3:00 p.m., Eastern Time zone.

FOR FURTHER INFORMATION CONTACT: Lindsey Murtagh, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, Phone: (301) 492–4106, Email: *lindsey.murtagh@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, state, or local government records. It requires Federal agencies involved in a CMP to:

1. Negotiate written agreements with the other agencies participating in the matching programs;
2. Obtain the Data Integrity Board approval of the match agreements;
3. Furnish detailed reports about matching programs to Congress and OMB;
4. Notify applicants and beneficiaries that the records are subject to matching; and,
5. Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

This matching program meets the requirements of the Privacy Act of 1974, as amended.

Walter Stone,

CMS Privacy Act Officer, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2016–15
HHS Computer Match No.1609

NAME:

Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Peace Corps for the ''Verification of Eligibility for Minimum Essential Coverage Under the Patient Protection and Affordable Care Act Through a Peace Corps Health Benefits Plan.''

SECURITY CLASSIFICATION:

Unclassified

PARTICIPATING AGENCIES:

Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and the Peace Corps (PC).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

Sections 1411 and 1413 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ACA) require the Secretary of HHS to establish a program for applying for and determining eligibility for advance payments of the premium tax credit and cost-sharing reductions and authorize use of secure, electronic interfaces and an on-line system for the verification of eligibility.

The Computer Matching and Privacy Protection Act of 1988 (CMPPA) (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) and requires the parties participating in a matching program to execute a written agreement specifying the terms and conditions under which the matching will be conducted. CMS has determined that status verification checks to be conducted through the CMS Data Services Hub (Hub) by agencies administering insurance affordability programs using data provided in bulk by PC through a security transfer data protocol to CMS constitute a ''computer matching program'' as defined in the CMPPA.

PURPOSE(S) OF THE MATCHING PROGRAM:

The purpose of the Computer Matching Agreement is to establish the terms, conditions, safeguards, and procedures under which the Peace Corps will provide records, information, or data to CMS for verifying eligibility for Minimum Essential Coverage through a Peace Corps Health Benefits Plan. The data will be used by CMS in its capacity as a Federally-facilitated Exchange, and agencies administering insurance affordability programs that will receive the results of verifications using PC data obtained through the CMS Data Services Hub.

Data will be matched for the purpose of verifying an Applicant or Enrollee's eligibility for PC Health Benefit Plans that constitute minimum essential coverage as defined in § 5000A(f) of the Internal Revenue Code of 1986, 26 U.S.C. 5000A, as amended by § 1501 of the ACA.

DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:

The Peace Corps maintains the following SORN to support this data matching program: ''Peace Corps Manual Section 897, Attachment B, PC–17 Volunteer Applicant and Service Records System.'' Routine Use (i) is used ''to verify active or former Volunteer service''—supports disclosure to CMS.

CMS maintains the following SORN to support this data to support this data matching program: ''Health Insurance Exchanges Program (HIX)'', CMS System No. 09–70–0560, originally published at 78 Fed. Reg. 8538 (Feb. 6, 2013), and last amended at 78 **Federal Register**, 63211 (October 23, 2013).

INCLUSIVE DATES OF THE MATCH:

The CMP will become effective no sooner than 40 days after the report of

the matching program is sent to 0MB, 30 days after a copy of the matching agreement is transmitted to Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 2016–23866 Filed 10–3–16; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA NUMBER: 93.658]

Announcement of a Single-Source Supplement Grant to the National Child Welfare Capacity Building Center for Tribes

AGENCY: Children's Bureau, ACYF, ACF, HHS.

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF), Administration for Children Youth and Families (ACYF), Children's Bureau announces the award of a single-source supplement grant in the amount of $547,000 to the National Child Welfare Capacity Building Center for Tribes (CBCT), operated by the University of Denver (Colorado Seminary). The primary goal of this grant is to provide capacity-building services to title IV–E and IV–B American Indian and Alaska Native Nations (AI/AN), and to promote intergovernmental collaboration between tribes and state child welfare agencies in system improvement work.

DATES: Supplemental funding will support activities and costs from September 30, 2016, through September 29, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Roshanda Shoulders, Children's Bureau, 330 C Street SW., Washington, DC 20024. Telephone: 202–401–5323; email: *roshanda.shoulders@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Supplemental funds would be used to enhance the development and delivery of high-quality products and services designed to build the capacities of child welfare systems to improve outcomes for AI/AN children, youth, and families and their communities. These enhanced services will build on CBCT's existing engagement and partnerships with state and tribal child welfare agencies to further address the needs of, and reduce disparities for, native children and families (*e.g.,* rates of removal and placement in out-of-home care, access to effective and culturally appropriate services, well-being outcomes), and improve overall child welfare services delivery and outcomes for AI/AN children youth and families.

The supplemental funding will afford CBCT the opportunity to provide expanded universal and tailored technical assistance to tribes across the nation and allow for expanded and enhanced collaboration and coordination with the other capacity building providers.

The programmatic components targeted under this supplement will be for CBCT expansion activities to better meet the national need for universal and tailored services to tribal child welfare agencies. Over 180 tribes are eligible to receive capacity-building services through CBCT based on their management of title IV–B and tribal title IV–E funded programs. There has been a concerted outreach effort to encourage a maximum number of tribes to access services through CBCT.

Statutory Authority: Section 426(a)(1)(A) of the Social Security Act (42 U.S.C. 626(a)(1)(A)).

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–23909 Filed 10–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Updating the Immigration Judge with information about the unaccompanied minor's case and reunification with a sponsor.

Title: Unaccompanied Children Case Summary Form.

OMB No.: New.

Description: Following the passage of the 2002 Homeland Security Act (Pub. L. 107–296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of unaccompanied children in Federal custody. Unaccompanied children attend immigration court hearings while in ORR care if the length of stay is more than sixty days. The form in question was created with input from immigration judges at the Executive Office for Immigration Review (EOIR).

The proposed information collection requests information to be utilized by EOIR for determining the best course of action to take in the UC's case in immigration court. The proposed instrument is the Unaccompanied Children Case Summary Form.

Respondents: Case Managers who are employees of social service agencies receiving grants from ORR to vet potential sponsors and to help advance the UC's case by providing updates to the Immigration Judge hearing the UC's case requesting legal relief from deportation.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UAC Case Summary	100	10	.10	100

Estimated Total Annual Burden Hours: In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests

should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–23951 Filed 10–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Interstate Administrative Subpoena and Notice of Interstate Lien.

OMB No.: 0970–0152.

Description: Section 452(a)(11) of the Social Security Act requires the Secretary of the Department of Health and Human Services to promulgate a form for administrative subpoenas and imposition of liens used by State child support enforcement (Title IV–D) agencies. The Interstate Administrative Subpoena is used to collect information for the establishment, modification and enforcement of child support orders in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the federal form for issuance of administrative subpoenas and imposition of liens in interstate child support cases. Tribal IV–D agencies are not required to use this form but may choose to do so. OMB approval of these forms is expiring in December 2016 and the Administration for Children and Families is requesting an extension of this form.

Respondents: State, local or Tribal agencies administering a child support enforcement program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Administrative Subpoena	31,344	1	0.50	15,672
Notice of Lien	1,916,891	1	0.25	479,223

Estimated Total Annual Burden Hours: 494,895.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–23950 Filed 10–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Income Withholding Order/Notice for Support (IWO).

OMB No.: 0970–0154.

Description: The Income Withholding Order/Notice for Support (IWO) is the standard form that must be used to order and notify employers and income providers to withhold child support payments from an obligor's income. It also indicates where employers and other income providers must remit the payments and other information needed to withhold correctly.

Child support agencies, courts, private attorneys, custodial parties, and others must use the IWO form to initiate an income withholding order for support and give notice of income withholding. State child support agencies are required to have automated data processing systems containing current order and case information. State child support agencies providing services to custodial and/or noncustodial parties enter the terms of a child support order established by a tribunal into the state's automated system, which automatically populates the order information into the IWO form.

Employers and income providers also use the form to respond to the order/notice with termination or income status information. Employers and other income providers may choose to receive the IWO form from child support agencies on paper or electronically, and may respond on paper or electronically to notify the sender of termination of employment or change in the income status.

The information collection activities pertaining to the IWO form are authorized by 42 U.S.C. 666(a)(1), (a)(8) and 666(b)(6), which require the use of the Income Withholding for Support (IWO) form to order income withholding for all child support orders.

Respondents: Courts, private attorneys, custodial parties or their

representatives, employers, and other parties that provide income to noncustodial parents.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Income withholding order/notice (Courts, private attorneys, custodial parties or their representatives).	3,699,790	1.00	5 minutes	308,316
Income withholding orders/termination of employment/income status (Employers and other income providers).	1,207,484	9.694	2 minutes	390,178
Electronic income withholding orders/termination of employment/income status (Employers and other income providers).	9,596	136.38	3 seconds	1,090
Estimated Total Annual Burden Hours	.....	.....	.....	699,585

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–23865 Filed 10–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2655]

Center for Devices and Radiological Health Veteran Amputee Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Center for Devices and Radiological Health Veteran Amputee Devices.'' The purpose of this workshop is to engage all stakeholders involved in the research, development, and marketing of prosthetic limb medical devices used by veteran amputees. A specific goal is to engage veteran amputees who use prosthetic limb medical devices and hear their views on these devices so that these perspectives may be considered in the total product life cycle of prosthetic limb devices.

DATES: The public workshop will be held on October 31, 2016, from 9 a.m. to 4 p.m. Submit either electronic or written comments on the public workshop by November 30, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2655 for ''Center for Devices and Radiological Health Veteran Amputee Devices.'' 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: Fabienne Santel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3502, Silver Spring, MD 20993, 301–796–9644, email: *Fabienne.santel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) is committed to including views of patients on the total product life cycle of medical devices. To better understand their needs, CDRH plans to engage patients throughout our regulatory process. CDRH is interested in patients contributing their views, data, and resources to improve the total product life cycle for medical devices, reduce adverse events, and improve communication about the risks and benefits that matter most to them.

Together with other centers and offices across FDA, we are testing and developing ways to engage patients and capture their views through public workshops. The CDRH Veteran Amputee Devices is one such workshop intended to engage veteran amputees, such as those patients from the Walter Reed National Military Medical Center, Warrior Clinic, who use prosthetic limb medical devices.

II. Topics for Discussion at the CDRH Veteran Amputee Devices Public Workshop

Topics to be discussed at the public workshop include, but are not limited to the following:

• Introduce the CDRH Total Product life Cycle (TPLC) for prosthetic limb devices.

• A focus group to obtain information on priorities for upper-limb prosthetics from the perspective of upper-limb amputees.

• Presentations from prosthetic limb device manufacturer.

• Question and answer session where patients, their caregivers and other interested parties have an opportunity to present their views and ask questions about the total product life cycle of medical devices.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the CDRH Veteran Amputee Devices public workshop must register online by October 24, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be begin at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication, Education (OCE), 301–796–5661 email: *Susan.Monahan@fda.hhs.gov* no later than October 17, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Fabienne Santel to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after October 21, 2016. Organizations are requested to view using one connection per location. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments or give presentations during the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 17, 2016. All requests to make oral presentations must be received by October 10, 2016. If selected for presentation, any presentation materials must be emailed to Fabienne Santel (see **FOR FURTHER INFORMATION CONTACT**) no later than October 28, 2016. If you are a manufacturer and wish to have a display table, please submit this

request by October 17, 2016. Space is limited; therefore, FDA will select and notify manufacturers by October 24, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain views from patients on prosthetic limb devices so that these perspectives may be considered in the total product life cycle of prosthetic limb medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this patient workshop is November 30, 2016.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23924 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2976]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Firms and Processors That Export to the European Union

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 reporting requirements in implementing the lists of United States (U.S.) firms/processors exporting shell eggs, game meat and game meat products, gelatin, and collagen to the European Union (the EU).

DATES: Submit either electronic or written comments on the collection of information by December 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2976 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Information From United States Firms and Processors That Export to the European Union.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown

St., North Bethesda, MD 20852, *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.

Information From U.S. Firms and Processors That Export to the EU (OMB Control Number 0910–0320)—Extension

The EU is a group of 28 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. For certain food products, including those listed in this document, EU legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements. Regulation (EC) No 854/2004 of the European Parliament and of the European Council states that products of animal origin may only be imported from establishments that appear on a list of establishments for which the competent authority of the exporting country has guaranteed compliance with applicable regulatory requirements and that shipments of these products must be accompanied by documents that certify the products' compliance with applicable regulatory standards. Section 801(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)) authorizes FDA to provide the certification described in this document. As stated in the notice published in the **Federal Register** of April 4, 1996 (61 FR 15077), we established a list of U.S. firms and processors eligible to export shell eggs, dairy products, and game meat and game meat products to the EU. In response to changing EU requirements, we revised this information collection and lists of eligible exporters in order to facilitate U.S. exports of gelatin and collagen to the EU. In 2001, we revised this collection to include firms and processors intending to export gelatin products to the EU (66 FR 12802, February 28, 2001) and in 2010, we revised the collection again to include firms and processors intending to export collagen products to the EU (75 FR 51077, August 18, 2010).

We request the following information from each firm or processor seeking to be included on the lists of eligible exporters for shell eggs, and game meat and game meat products (dairy products will be covered under OMB control number 0910–0509):

- Business name and address;
- Name and telephone number of person designated as business contact;
- Lists of products presently being shipped to the EU and those intended to be shipped in the next 6 months;
- Name and address of manufacturing plants for each product; and
- Names and affiliations of any Federal, State, or local governmental Agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection.

We request the following information from each firm or processor seeking to be included on the list of eligible exporters for gelatin and collagen products:

- Food Facility Registration Number and Pin Number (if applicable);
- Business name and address;
- Name, telephone number, facsimile number, and email address of main business contact person;
- List of products presently shipped to the EU and those intended to be shipped within the next 2 years;
- Name and address of the manufacturing and processing plant for each product (manufacturer type for primary producer);
- Names and affiliations of any Federal, State, and local governmental Agencies that inspect the plant, government assigned plant identifier, such as plant number and last date of inspection; and
- A copy of the most recent (within 1 year of the date of application) inspection report issued by a State, local or Federal public health regulatory Agency and a copy of a recent laboratory analysis as required by the EU of the finished product including: Total aerobic bacteria, coliforms (30 degrees C), coliforms (44.5 degrees C), anaerobic sulphite-reducing bacteria (no gas production), *Clostridium perfringens, Staphylococcus aureus, Salmonella,* arsenic, lead, cadmium, mercury, chromium, copper, zinc, moisture (105 degrees C), ash (550 degrees C), sulfur dioxide, and hydrogen peroxide.

We use the information to maintain lists of firms and processors that have demonstrated current compliance with U.S. requirements. We make the lists available on our Web site. We include on the lists only firms and processors that are not the subject of an unresolved regulatory enforcement action or unresolved warning letter. If a listed firm or processor subsequently becomes the subject of a regulatory enforcement action or an unresolved warning letter, we will view such a circumstance as evidence that the firm or processor is no longer in compliance with applicable U.S. laws and regulations. Should this occur, we will take steps to remove that firm or processor from the list and send a revised list to the EU authorities, usually within 48 to 72 hours after the relevant regulatory enforcement action. If a firm or processor has been delisted as a result of a regulatory enforcement action or unresolved warning letter, the firm or processor will have to reapply for inclusion on the list once the regulatory action has been resolved.

We update the lists of firms and processors eligible to export products of animal origin to the EU quarterly. Firms and processors placed on lists of eligible exporters are subject to audit by FDA and EU officials. Complete requests for inclusion must be submitted to us every 12 months to remain on these lists. Inclusion on the lists is voluntary. However, products of animal origin from firms or processors not on lists of eligible exporters for these products are not eligible for export certificates for these products, and these products may be detained at EU ports of entry.

Description of Respondents: The respondents to this collection of information include U.S. producers of

shell eggs, game meat and game meat products, gelatin, and collagen.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Shell Eggs	10	1	10	0.25 (15 minutes)	3
Game Meat and Game Meat Products	5	1	5	0.25 (15 minutes)	1
Gelatin	7	1	7	0.25 (15 minutes)	2
Collagen	18	1	18	0.25 (15 minutes)	5
Total					11

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates of the number of respondents and total annual responses on the submissions that we have received in the past 3 years for each product type. To calculate the estimate for the hours per response values, we assumed that the information requested is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission. We believe that this effort should take no longer than 15 minutes (0.25 hour) per response. We estimate that we will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3 hours. This collection has previously covered information collected to maintain lists of eligible exporters of dairy products; dairy products will be covered under OMB control number 0910–0509, so the estimated burden has been removed from this collection. We estimate that we will receive one submission from five game meat and game meat product producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. We estimate that we will receive one submission from seven gelatin producers annually, for a total of seven annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.75 hours, rounded to 2 hours. We estimate that we will receive one submission from 18 collagen producers annually, for a total of 18 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 4.5 hours, rounded to 5 hours. The estimated burden for collagen producers includes animal casings, which have been listed separately in previous notices. Therefore, the proposed annual burden for this information collection is 11 hours.

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23930 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0115; FDA–2013–N–0717]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have 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, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Manufactured Food Regulatory Program Standards	0910–0601	9/30/2019
Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign	0910–0753	9/30/2019

Dated: September 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23898 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0002]

Hospira, Inc. et al.; Withdrawal of Approval of 44 New Drug Applications and 158 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 44 new drug applications (NDAs) and 158 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: *Effective Date:* November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
NDA 005264	Heparin Sodium Injection	Hospira, Inc., 275 North Field Dr., Bldg. H2–2, Lake Forest, IL 60045–5046.
NDA 009470	Xylocaine Viscous (lidocaine hydrochloride (HCl)) Solution	Fresenius Kabi USA LLC, Three Corporate Dr., Lake Zurich, IL 60047.
NDA 009698	Miltown (meprobamate) Tablets, 200 milligrams (mg) and 400 mg.	Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 300, Somerset, NJ 08873–4120.
NDA 009939	Senokot Granules (sennosides), 15 mg	Purdue Products, L.P., One Stamford Forum, Stamford, CT 06901.
NDA 010382	Tempra (acetaminophen) Syrup, 160 mg/5 milliliters (mL)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 88543–4000.
NDA 011228	Liquamar (phenprocoumon) Tablets	Organon USA Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 011613	Ionamin (phentermine resin complex) Capsules, 15 mg and 30 mg.	UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080.
NDA 011738	Numorphan (oxymorphone HCl) Suppositories, 5 mg	Endo Pharmaceuticals, Inc., 100 Endo Blvd., Chadds Ford, PA 19317.
NDA 012365	Soma Compound (carisoprodol and aspirin) Tablets	Meda Pharmaceuticals, Inc.
NDA 012940	Isordil (isosorbide dinitrate) Sublingual Tablets, 2.5 mg, 5 mg, and 10 mg.	Valeant International Bermuda, c/o Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 013483	Drixoral/Disophrol (dexbrompheniramine maleate and pseudoephedrine sulfate) Extended-Release Tablets, 6 mg/120 mg.	Merck Consumer Care, 556 Morris, Ave., Summit, NJ 07901.
NDA 014005	Maxibolin (ethylestrenol) Tablets	Organon USA Inc.
NDA 017087	Ethrane (enflurane USP)	Baxter Healthcare Corp., 32650 N. Wilson Rd., Round Lake, IL 60073.
NDA 017689	Methadone HCl Syrup	Sandoz, Inc., 4700 Sandoz, Dr., Wilson, NC 27893.
NDA 018766	Ansaid (flurbiprofen) Tablets, 50 mg and 100 mg	Pharmacia & Upjohn Co., c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 018812	Sulfamethoxazole and Trimethoprim Oral Suspension USP, 200 mg/5 mL and 40 mg/5 mL.	Teva Pharmaceuticals USA, Inc., 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454.
NDA 019304	Tricor (fenofibrate) Micronized Capsules, 67 mg, 134 mg, and 200 mg.	AbbVie Inc., 1 N. Waukegan Rd., Dept. PA77/Bldg. AP30, North Chicago, IL 60064.
NDA 019384	Noroxin (norfloxacin) Tablets, 400 mg	Merck Sharp & Dohme Corp., 351 North Sumneytown Pike, P.O. Box 1000, North Wales, PA 19454.
NDA 020005	Cardene SR (nicardipine HCl) Extended-Release Capsules, 30 mg, 45 mg, and 60 mg.	Chiesi USA, Inc., 1255 Crescent Green Dr., Suite 250, Cary, NC 27518.
NDA 020073	Romazicon (flumazenil) Injection	Hoffman-LaRoche, Inc., c/o Genetech, Inc., 1 DNA Way MS #241B, South San Francisco, CA 94080–4900.
NDA 020084	Iobenguane Sulfate I–131 Injection, 2.3 millicuries	Pharmalucence, 10 DeAngelo Dr., Bedford, MA 01730.
NDA 020107	Novamine (amino acids) Injection	Baxter Healthcare Corp.
NDA 020229	Leustatin (cladribine) Injection, 1 mg/mL	Janssen Pharmaceuticals Inc., 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 020251	Zantac (ranitidine HCl) Effervescent Tablets, 25 mg and 150 mg Zantac (ranitidine HCl) Effervescent Granules, 150 mg.	Glaxo Group Limited, England d/b/a GlaxoSmithKline, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 020312	Univasc (moexipril HCl) Tablets, 7.5 mg and 15 mg	UCB, Inc.
NDA 020346	Zyrtec (cetirizine HCl) Syrup, 1 mg/mL	Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
NDA 020410	Gastromark (ferumoxsil) Oral Suspension	AMAG Pharmaceuticals, 100 Haydon Ave., Lexington, MA 02421.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020416	Feridex I.V. (ferumoxides) Injection	Do.
NDA 020460	Cytovene (ganciclovir) Capsules, 250 mg and 500 mg	Roche Palo Alto LLC, c/o Genentech, Inc., 1 DNA Way, MS#241B, South San Francisco, CA 94080–4990.
NDA 020575	DentiPatch (lidocaine)	Noven Pharmaceuticals, Inc., 11960 SW. 144th St., Miami, FL 33186.
NDA 020638	Vistide (cidofovir) Injection, Equivalent to (EQ) 75 mg base/mL.	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.
NDA 020729	Uniretic (moexipril HCl and hydrochlorothiazide) Tablets, 7.5 mg/12.5 mg, 15 mg/12.5 mg, and 15 mg/25 mg.	UCB, Inc.
NDA 021044	Palladone (hydromorphone HCl) Extended-Release Capsules	Rhodes Pharmaceuticals L.P., 498 Washington St., Coventry, RI 02816.
NDA 021046	Celexa (citalopram hydrobromide) EQ 10 mg base/5 mL Oral Solution.	Forest Laboratories, Inc., Harborside Financial Center, Plaza V, Suite 1900, Jersey, City, NJ 07311.
NDA 021378	Combunox (Oxycodone HCl and Ibuprofen) Tablets	Do.
NDA 021671	DepoDur (morphine sulfate) Extended-Release Injection	Pacira Pharmaceuticals, Inc., 10450 Science Center Dr., San Diego, CA 92121.
NDA 021693	Rybix ODT (tramadol HCl) Orally Disintegrating Tablets	Shionogi, Inc., 300 Campus Dr., Suite 300, Florham Park, NJ 07932.
NDA 021768	Fludeoxyglucose F18 (FDG) Injection	Weill Medical College of Cornell University, c/o Citigroup Biomedical Imaging Center, 516 East 72nd St., New York, NY 10021.
NDA 022244	Lusedra (fospropofol disodium) Injection	Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07677.
NDA 022312	Docetaxel Injection	Apotex Inc., c/o Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326.
ANDA 040223	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg, 300 mg/30 mg, and 300 mg/60 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040297	Estradiol Tablets USP, 0.5 mg, 1 mg, and 2 mg	Upsher-Smith Laboratories, Inc., 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 040311	Medroxyprogesterone Acetate Tablets USP, 2.5 mg, 5 mg, and 10 mg.	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040318	Meperidine HCl Tablets USP, 50 mg and 100 mg	Do.
ANDA 040472	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 050143	Chloromycetin (chloramphenicol ophthalmic solution USP) Ophthalmic Solution.	Parkedale Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 050156	Chloromycetin (chloramphenicol ophthalmic ointment USP) Ophthalmic Ointment, 1%.	Do.
NDA 050443	Blenoxane (bleomycin sulfate) for Injection, EQ 15 units base/vial and 30 units base/vial.	Bristol-Myers Squibb Co.
NDA 050630	Primaxin (imipenem and cilastatin sodium) Powder, EQ 500 mg base/vial; 500 mg/vial and EQ 750 mg base/vial; 750 mg/vial.	Merck, Sharp & Dohme Corp.
ANDA 060306	Penicillin G Potassium Tablets USP	Teva Pharmaceuticals USA, Inc.
ANDA 060307	Penicillin G Potassium for Oral Solution USP	Do.
ANDA 061969	Cephalexin Capsules USP, EQ 250 mg base and EQ 500 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062240	Cloxacillin Sodium Capsules USP, EQ 250 mg base and EQ 500 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 062252	Oxacillin Sodium for Oral Solution USP, EQ 250 mg base/5 mL.	Teva Pharmaceuticals USA, Inc.
ANDA 062268	Cloxacillin Sodium for Oral Solution USP, EQ 125 mg base/5 mL.	Do.
ANDA 062653	Doryx (doxycycline hyclate) Delayed-Release Capsules, EQ 100 mg base.	Warner Chilcott Co., LLC, c/o Warner Chilcott (US), LLC, 100 Enterprise Dr., Rockaway, NJ 07866.
ANDA 062670	Nystatin Oral Suspension USP, 100,000 units/mL	Teva Pharmaceuticals USA, Inc.
ANDA 062683	Cephradine Capsules USP, 250 mg and 500 mg	Do.
ANDA 062695	Cefadroxil Capsules USP, EQ 500 mg base	Do.
ANDA 062751	Erythromycin Pledgets USP, 2%	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062760	Cephalexin Capsules USP, EQ 250 mg base	Teva Pharmaceuticals USA, Inc.
ANDA 062761	Cephalexin Capsules USP, EQ 500 mg base	Do.
ANDA 062766	Cefadroxil Capsules USP, EQ 500 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062767	Cephalexin for Oral Suspension USP, EQ 125 mg base/5 mL	Teva Pharmaceuticals USA, Inc.
ANDA 062768	Cephalexin for Oral Suspension USP, EQ 250 mg base/5 mL	Do.
ANDA 062775	Cephalexin Capsules USP, EQ 500 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062853	Amoxicillin Capsules USP, 250 mg	Teva Pharmaceuticals USA, Inc.
ANDA 062854	Amoxicillin Capsules USP, 500 mg	Do.
ANDA 062946	Amoxicillin for Oral Suspension USP, 125 mg/5 mL	Do.
ANDA 063001	Amoxicillin for Oral Suspension USP, 250 mg/5 mL	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 063018	Cefazolin Sodium for Injection USP, EQ 5 grams (g) base/vial and EQ 10 g base/vial.	Do.
ANDA 063027	Clindamycin HCl Capsules USP, EQ 75 mg base	Do.
ANDA 063030	Amoxicillin Capsules USP, 250 mg	Do.
ANDA 063031	Amoxicillin Capsules USP, 500 mg	Do.
ANDA 064031	Amoxicillin Chewable Tablets, 125 mg and 250 mg	Do.
ANDA 064081	Cefaclor Capsules USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 064145	Cefaclor Capsules USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 065137	Clarithromycin Tablets USP, 250 mg and 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070006	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg/80 mg.	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124.
ANDA 070007	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg/160 mg.	Do.
ANDA 070232	Propranolol HCl Tablets USP, 10 mg	Teva Pharmaceuticals USA, Inc.
ANDA 070234	Propranolol HCl Tablets USP, 40 mg	Do.
ANDA 070266	Indo-Lemmon (Indomethacin Capsules USP), 25 mg	Do.
ANDA 070267	Indo-Lemmon (Indomethacin Capsules USP), 50 mg	Do.
ANDA 070469	Ibuprohn (Ibuprofen Tablets USP), 400 mg	Ohm Laboratories, Inc., c/o Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 070618	Potassium Chloride Extended-Release Tablets USP, 8 milliequivalents.	Copley Pharmaceutical, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070660	Metoclopramide HCl Tablets USP, EQ 10 mg base	Mutual Pharmaceutical Co., Inc.
ANDA 071145	Ibuprofen Tablets USP	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071146	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 071184	Thiothixene HCl Oral Solution USP, EQ 5 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 071342	Indomethacin Capsules USP, 25 mg	Do.
ANDA 071343	Indomethacin Capsules USP, 50 mg	Do.
ANDA 072438	Fenoprofen Calcium Capsules USP, EQ 300 mg base	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 072522	Fluocinonide Topical Solution USP, 0.05%	Teva Pharmaceuticals USA, Inc.
ANDA 072600	Clofibrate Capsules USP, 500 mg	Do.
ANDA 072692	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals, USA, Inc.
ANDA 072999	Dopamine HCl Injection USP, 200 mg/5 mL	Teva Parenteral Medicines, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 073005	Cinoxacin Capsules USP, 250 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073006	Cinoxacin Capsules USP, 500 mg	Do.
ANDA 073043	Baclofen Tablets USP, 10 mg	Do.
ANDA 073044	Baclofen Tablets USP, 20 mg	Do.
ANDA 073099	Leucovorin Calcium Tablets USP, EQ 5 mg base	Pharmachemie B.V., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 073101	Leucovorin Calcium Tablets USP, EQ 25 mg base	Do.
ANDA 073141	Ibuprofen Tablets USP, 200 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073315	Atenolol Tablets USP, 50 mg	Do.
ANDA 073316	Atenolol Tablets USP, 100 mg	Do.
ANDA 073343	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 073344	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 073345	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 073515	Ketoprofen Capsules USP, 25 mg	Do.
ANDA 073679	Diflunisal Tablets USP, 250 mg	Do.
ANDA 074067	Diltiazem HCl Tablets USP, 30 mg, 60 mg, 90 mg, and 120 mg.	Do.
ANDA 074107	Atenolol and Chlorthalidone Tablets USP, 50 mg/25 mg and 100 mg/25 mg.	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074120	Atenolol Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074123	Pindolol Tablets USP, 5 mg and 10 mg	G&W Laboratories, Inc., 111 Coolidge St., South Plainfield, NJ 07080.
ANDA 074124	Ciprofloxacin HCl Tablets, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074143	Metoprolol Tartrate Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074216	Naproxen Tablets, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074294	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, 1 mg, and 2 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074333	Metoprolol Tartrate Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074357	Trazodone HCl Tablets USP, 150 mg	Do.
ANDA 074365	Cimetidine Tablets USP, 200 mg, 300 mg, 400 mg, and 800 mg.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 074446	Terazosin HCl Tablets, EQ 1 mg base, EQ 2 mg base, EQ 5 mg base, and EQ 10 mg base.	Do.
ANDA 074459	Diclofenac Sodium Delayed-Release Tablets USP, 25 mg, 50 mg, and 75 mg.	Do.
ANDA 074476	Hydroxyurea Capsules USP, 500 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 074504	Tamoxifen Citrate Tablets USP, EQ 10 mg base and EQ 20 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 074537	Selegiline HCl Tablets USP, 5 mg	G&W Laboratories, Inc.
ANDA 074555	Cholestyramine for Oral Suspension USP	Teva Pharmaceuticals, USA, Inc.
ANDA 074674	Acyclovir Capsules USP, 200 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074745	Megestrol Acetate Tablets USP, 40 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074771	Cholestyramine for Oral Suspension USP	Do.
ANDA 074847	Etodolac Tablets USP, 400 mg and 500 mg	Do.
ANDA 074883	Etodolac Tablets USP, 400 mg and 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074895	Amiodarone HCl Tablets, 200 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074914	Acyclovir Capsules USP, 200 mg	Do.
ANDA 074989	Labetalol HCl Tablets USP, 100 mg, 200 mg, and 300 mg	Do.
ANDA 075021	Acyclovir Tablets USP, 400 mg and 800 mg	Do.
ANDA 075557	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base.	Do.
ANDA 075686	Bisoprolol Fumarate and Hydrochlorothiazide Tablets USP, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg.	Do.
ANDA 075719	Sertraline HCl Tablets USP, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Do.
ANDA 075726	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Mallinckrodt Inc., 675 McConnell Blvd., Hazelwood, MO 63042.
ANDA 075740	Tamoxifen Citrate Tablets USP, EQ 10 mg base and EQ 20 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075810	Fluoxetine HCl Tablets , EQ 10 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075823	Calcitriol Injection USP, 0.001 mg/mL and 0.002 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 075827	Gabapentin Tablets USP, 600 mg and 800 mg	Teva Pharmaceuticals USA, Inc.
ANDA 075862	Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg/0.02 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075865	Fluoxetine HCl Tablets , EQ 10 mg base and EQ 40 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075971	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075975	Metformin HCl Tablets USP, 500 mg, 625 mg, 750 mg, 850 mg, and 1 g.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076094	Pergolide Mesylate Tablets, EQ 0.05 mg base, EQ 0.25 mg base, and EQ 1 mg base.	Do.
ANDA 076184	Alendronate Sodium Tablets USP, EQ 35 mg tablets and EQ 70 mg tablets.	Teva Pharmaceuticals USA, Inc.
ANDA 076198	Balziva-21 Tablets (norethindrone and ethinyl estradiol tablets USP), 0.4 mg/0.035 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076244	Mirtazapine Tablets USP, 15 mg, 30 mg, and 45 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076251	Fluoxetine HCl Capsules, EQ 40 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076328	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Teva Pharmaceuticals USA, Inc.
ANDA 076340	Finasteride Tablets USP, 5 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076426	Ciprofloxacin HCl Tablets , EQ 100 mg base, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076496	Metformin HCl Extended-Release Tablets USP, 500 mg	Barr Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076545	Metformin HCl Extended-Release Tablets USP, 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076840	Sumatriptan Succinate Tablets, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 076880	Nicotine Polacrilex Gum USP, EQ 2 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076945	Fosinopril Sodium and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg and 20 mg/12.5 mg.	Teva Pharmaceuticals USA, Inc.
ANDA 077020	Cilostazol Tablets USP, 100 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077082	Paroxetine Tablets USP, EQ 10 mg base, EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base.	Teva Pharmaceuticals USA, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 077775	Fentanyl Extended-Release Film, 25 micrograms (mcg), 50 mcg, 75 mcg, and 100 mcg.	Noven, Pharmaceuticals, Inc.
ANDA 077850	Nicotine Polacrilex Gum USP, EQ 4 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077898	Cilostazol Tablets USP, 50 mg and 100 mg	Pliva Hrvatska DOO, c/o Teva Pharmaceuticals USA, Inc.,425 Privet Rd., Horsham, PA 19044.
ANDA 077973	Bicalutamide Tablets USP, 50 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
ANDA 077995	Bicalutamide Tablets UPS, 50 mg	Kudco Ireland Limited, c/o Kremers Urban Pharmaceuticals, Inc., 1101 C Ave. West, Seymour, IN 47274.
ANDA 078079	Ciclopirox Topical Solution USP, 8%	Teva Pharmaceuticals USA, Inc.
ANDA 078221	Granisetron HCl Tablets USP, EQ 1 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 078263	Perindopril Erbumine Tablets, 2 mg, 4 mg, and 8 mg	Lupin Limited, c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202.
ANDA 078567	Ciclopirox Topical Solution USP, 8%	Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 078666	Levonorgestrel Tablets, 0.75 mg	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
ANDA 078773	Atorvastatin Calcium Tablets, EQ 10 mg base, EQ 20 mg (base), EQ 40 mg base, and EQ 80 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 080400	Hydrocortisone Cream USP	Do.
ANDA 080828	Hydrocortisone Acetate Ophthalmic Ointment USP, 0.5%	Fera Pharmaceuticals LLC, 134 Birch Hill Rd., Locust Valley, NY 11560.
ANDA 083919	Meprobamate Tablets USP, 600 mg	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873.
ANDA 085022	Hydrochlorothiazide Tablets USP, 100 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 085855	A-Methapred (methylprednisolone sodium succinate for Injection USP), EQ 125 mg base/vial.	Hospira, Inc.
ANDA 086750	Ergotamine Tartrate Sublingual Tablets USP, 2 mg	Organon USA, Inc.
ANDA 087014	Orgatrax (hydroxyzine HCl Injection USP), 25 mg/mL and 50 mg/mL.	Do.
ANDA 087264	Thioridazine HCl Tablets USP, 25 mg	Mutual Pharmaceutical Co., Inc.
ANDA 087665	Sulfinpyrazone Tablets USP, 100 mg	Barr Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087666	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 087760	Hydroxyzine Pamoate Capsules USP, EQ 50 mg HCl	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087761	Hydroxyzine Pamoate Capsules USP, EQ 25 mg HCl	Do.
ANDA 088370	Thioridazine HCl Tablets USP, 50 mg	Mutual Pharmaceutical Co., Inc.
ANDA 088375	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088379	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088469	Dexamethasone Sodium Phosphate Injection USP, EQ 10 mg Phosphate/mL.	Fresenius Kabi USA, LLC.
ANDA 088900	Doxylamine Succinate Tablets USP, 25 mg	Copley Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088902	Chlorthalidone Tablets USP, 25 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088903	Chlorthalidone Tablets USP, 50 mg	Do.
ANDA 088974	Procainamide HCl Extended-Release Tablets USP, 500 mg	ANI Pharmaceuticals, Inc.,.
ANDA 089109	Promethazine HCl Tablets USP, 25 mg	Teva Pharmaceuticals USA, Inc.
ANDA 090299	Melphalan HCl for Injection, EQ 50 mg base/vial	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 090924	Ibutilide Fumarate Injection, 0.1 mg/mL	Do.
ANDA 091242	Anastrozole Tablets USP, 1 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 091638	Letrozole Tablets USP, 2.5 mg	Do.
ANDA 200792	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Par Pharmaceutical, Inc.
ANDA 204538	Zidovudine Injection USP, 10 mg/mL	Liaoning Chengda Biotechnology Co., Ltd., c/o Ruby Pharma, Inc., 116 Village Blvd, Suite 200, Princeton, NJ 08540.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective November 3, 2016. Introduction or delivery for introduction into interstate

commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23893 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2880]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 9 and 10, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2880 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, *aden.asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 9, 2016, during session one, the committee will

discuss and make recommendations regarding the reclassification of quantitative Cytomegalovirus (CMV) viral load devices from class III (Premarket approval) to class II (510(k)). A nucleic acid-based in vitro diagnostic device for the quantitation of CMV viral load, within the context of transplant patient management, is a post-amendment device classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)(21 U.S.C. 360c(f)(1). To date, the following product code has been established for CMV viral load devices: PAB (CMV DNA Quantitative Assay). During session two, the committee will discuss and make recommendations regarding the appropriate initial classification for qualitative or quantitative viral load devices for Epstein-Barr virus, BK virus, JC virus, Human Herpesvirus 6, and Adenovirus infections. FDA is seeking expert recommendations to assess the potential risks and benefits of these devices when used in patients following solid-organ or stem cell transplantation.

On November 10, 2016, the committee will discuss and make recommendations to FDA regarding how FDA might handle a future premarket notification (510(k)) submission for a Procalcitonin (PCT) test. One test that FDA previously reviewed and cleared was the VIDAS B·R·A·H·M·S PCT (Procalcitonin) test which is an in vitro diagnostic test for measuring procalcitonin from human serum or plasma. The test was cleared with an indication for use as follows:

- VIDAS B·R·A·H·M·S PCT (PCT) is an automated test for use on the instruments of the VIDAS family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the Enzyme-Linked Fluorescent Assay technique.
- VIDAS B·R·A·H·M·S PCT (PCT) is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.
- VIDAS B·R·A·H·M·S PCT (PCT) is also intended for use to determine the change of PCT level over time as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with severe sepsis or septic shock in the intensive care unit (ICU) or when obtained in the emergency department or other medical wards prior to ICU admission.
- Procalcitonin (PCT) is a biomarker associated with the inflammatory response to bacterial infection that aids in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock. The percent change in PCT level over time also aids in the prediction of cumulative 28-day mortality in patients with severe sepsis and septic shock.

PCT levels on the first day of ICU admission above 2.0 nanograms per milliliter (ng/mL) are associated with a higher risk for progression to severe sepsis and/or septic shock than PCT levels below 0.5 ng/mL.

- A PCT level that declines ≤80 percent from the day that severe sepsis or septic shock was clinically diagnosed (day 0) to 4 days after clinical diagnosis (day 4) is associated with higher cumulative 28-day risk of all-cause mortality than a decline >80 percent.
- The combination of the first PCT level (≤2.0 ng/mL or >2.0 ng/mL) at initial diagnosis of severe sepsis or septic shock with the patient's clinical course and the change in PCT level over time until day 4 provides important additional information about the mortality risk.
- The PCT level on day 1 (the day after severe sepsis or septic shock is first clinically diagnosed) can be used to calculate the percent change in PCT level at day 4 if the day 0 measurement is unavailable.

FDA anticipates receiving a 510(k) submission for PCT test in which the intended use could be modified to add an indication for use as an aid in the antibiotic management of patients with suspected lower respiratory tract infection, an indication for use as an aid in the antibiotic management of patients being treated with antibiotics for confirmed or documented sepsis, or both. FDA is seeking feedback from the committee and interested parties to assess the evidence in support of the hypothetical changes and the overall benefits and risks from this proposed new indication for use in clinical practice, including feedback on whether any additional mitigations are necessary.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 27, 2016. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on November 9, 2016, and between approximately 1 p.m. and 2 p.m. on November 10, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 19, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 20, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this document. The docket number is FDA–2016–N–2880. The docket will close on December 6, 2016. Comments received on or before October 26, 2016, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638, at least 7 days in advance of the meeting. For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–23895 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

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 November 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 0910–0454. 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway—21 CFR 11.2 OMB Control Number 0910–0454—Extension

We accept certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S–0251 as required by 21 CFR 11.2. Our ability to receive and process information submitted electronically is limited by our current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. Our guidance entitled ''Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA Electronic Submission Gateway (ESG). The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of April 8, 2016 (81 FR 20647), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
11.2	3538	29	1.3	38	.08 (5 minutes)	3.0

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with the submission of electronic information to us using the FDA ESG and the number of electronic registration or change requests received between January 1, 2014, and December 31, 2014.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23897 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the revised draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues,'' that appeared in the **Federal Register** of August 12, 2016. We are taking this action in response to requests to extend the comment period to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the draft guidance published August 12, 2016 (81 FR 53486). Submit either electronic or written comments by December 12, 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–2011–D–0376 for ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry.'' 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: Cara Welch, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2333.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 2016, we published a notice announcing the availability of a revised draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.'' The revised draft guidance, when finalized, will help industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient (NDI), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications (also referred to as NDI notifications). section III of the notice (81 FR 53486 at 53489), ''Other Issues for Consideration,'' listed specific issues to be addressed.

The notice provided a 60-day period for the submission of comments pertaining to the revised draft guidance, including in particular (but not limited to) section III. Comments on these issues, the revised draft guidance, and the relevant portions of the 2011 draft guidance, will contribute to our final guidance on new dietary ingredient notifications and related issues. The comment period was scheduled to end on October 11, 2016.

We received requests for 30- and 90-day extensions of the comment period. In general, the requests conveyed concern that the current 60-day comment period does not allow sufficient time for interested parties to develop a meaningful or thoughtful response to the draft guidance. Some requests mentioned that the requests for comment may necessitate indepth research and/or require supporting data to provide meaningful responses.

We considered the requests and are extending the comment period for the draft guidance for 60 days until December 12, 2016. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23931 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2873]

Workshop on Promoting Semantic Interoperability of Laboratory Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Library of Medicine (NLM) of the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC), and the Centers for Medicare and Medicaid Services (CMS) are announcing the following public workshop entitled ''CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data.'' The purpose of this public workshop is to receive and discuss input from stakeholders regarding

proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized descriptions of in vitro diagnostic tests and results.

DATES: The public workshop will be held on November 8, 2016, from 8 a.m. to 5 p.m. (EDT). Submit either electronic or written comments on the public workshop by December 9, 2016.

ADDRESSES: The public workshop will be held at the NLM NIH Bethesda Campus, 8600 Rockville Pike, NIH Building 38A, Bethesda, MD 20894. For general information, including parking and security information, please refer to: *https://www.nlm.nih.gov/about/lhcaud_gen.html.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2873 for the ''CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data.'' 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. EDT, 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: Michael Waters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4535, Silver Spring, MD 20993–0002, 301–796–4653, FAX: 301–847–2512, email: *michael.waters@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is a followup to the FDA/CDC/NLM Workshop on ''Promoting Semantic Interoperability of Laboratory Data'' held on September 28, 2015. For more information on the content of the previous public workshop, the Webcast, the transcript, and any presentations from the 2015 workshop can be found at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm453897.htm.*

The primary purpose of the current workshop is to discuss with stakeholders the means to facilitate adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized electronic health data reporting. Specifically this workshop will discuss aspects of semantic interoperability of laboratory data including the use of Logical Observation Identifiers Names and Codes (LOINC; *http://loinc.org/*) for identifying laboratory tests and the use of Uniform Systematized Nomenclature of Medicine-Clinical Terms (SNOMED–CT; *http://www.ihtsdo.org/snomed-ct*) coding sets for describing results of qualitative test results.

In order to build on the foundations of what was discussed during the 2015 workshop, discussions will begin by summarizing the previous workshop and addressing questions and concerns that were raised at the previous meeting. These conversations will be followed by a discussion on potential mechanisms for implementation of structured communication models containing device information, LOINC (*http://loinc.org/*), transmission codes, and other information that can be used to consolidate a semantically interoperable and transmittable message.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations to provide a framework and a context for a series of interactive panel discussions. Presentations will focus on mechanisms for attaining harmonized semantically interoperable information and advancing the probable functional models for information transmission, including possible challenges and solutions for implementation. Presentations and discussions will address proposals for harmonization

and communication that can facilitate practical adoption of semantically interoperable data. Following the presentations on each topic, there will be a moderated discussion where the participants and additional panelists will be asked to provide their individual perspectives.

In advance of the meeting, CDC, FDA, NLM, ONC, and CMS will place an agenda on file in the public docket (the docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* See **DATES** for the deadline for submitting comments to the agenda for the public workshop.

The agencies will use the input from this workshop and public comments to determine the appropriate next steps to advance semantic interoperability of laboratory data.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT) October 28, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. (EDT).

If you need special accommodations due to a disability, please contact Rebecca Goodwin at 301–496–4441 (*Rebecca.Goodwin@nih.gov*) and/or the Federal Relay at 1–800–877–8339. Requests should be made no later than November 3, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Michael Waters to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be videocast. Videocast access will be available at *https://videocast.nih.gov/*. The videocast link will also be available on the registration Web page. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the public comment session. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 1, 2016. All requests to make oral presentations must be received by the close of registration on 4 p.m. (EDT) October 28, 2016. If selected for presentation, any presentation materials must be emailed to Michael Waters (see **FOR FURTHER INFORMATION CONTACT**) no later than October 28, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

CDC, FDA, NLM, ONC, and CMS are holding this public workshop to obtain input from stakeholders regarding proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized electronic laboratory reporting. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. See **DATES** for the deadline for submitting comments to the agenda for the public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23894 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–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 October 27–28, 2016.

Date: October 27–28, 2016.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Suites—Rockville 1 Helen Heneghan Way, Rockville, MD 20850.

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: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23881 Filed 10–3–16; 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 Clinical and Basic Science Review Committee October 27–28, 2016.

Date: October 27–28, 2016.

Time: 10:30 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Crystal City, 1800 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Keith A. Mintzer, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892–7924, 301–594–7947, *mintzerk@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: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23879 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Subcommittee, MID–B November 2016.

Date: November 4–7, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Ellen S. Buczko, Ph.D., Scientific Review Officer Scientific Review Program Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2676, *ebuczko1@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 27, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23882 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Multi-Site Clinical Trials and Data Coordinating Center.

Date: October 28, 2016.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief, Office of Scientific Review, National Center for Complementary, & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23877 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Clinical Research on Mind-Body Interventions study section.

Date: November 3, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Hungyi Shau, Ph.D., Scientific Review Officer, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda,

MD 20892, 301–480–9504, *Hungyi.Shau@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23878 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: October 28, 2016.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Uday K. Shankar, Ph.D., MSC, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G21B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5051, *uday.shankar@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 28, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23873 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: October 21, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rita Anand, Ph.D., Scientific Review Officer, Division Of Scientific Review, National Institute of Child Health and Human Development, NIH, 6710 B Rockledge Drive, Bethesda, Maryland 20892, 301–496–1487, *anandr@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: December 8, 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: Priscah Mujuru, DRPH, COHNS, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Suite 5B01, Bethesda, MD 20892–7510, 301–435–6908, *mujurup@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23875 Filed 10–3–16; 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; Clinical Trials Review Committee.

Date: October 27–28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–435–2222, *copeka@mail.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: September 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23880 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, November 01, 2016, 01:00 p.m. to November 01, 2016, 05:00 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD, 20814 which was

published in the **Federal Register** on September 26, 2016, 81FR66043.

The meeting notice is amended to change the meeting location to the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814. The meeting is closed to the public.

Dated: September 28, 2016.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23885 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Clinical Oncology Study Section.

Date: October 17, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Reston Hotel, 11810 Sunrise Valley Dr., Reston, VA 20191.

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301–806–2515, *chatterm@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date:

October 27–28, 2016.

Time:

9:00 a.m. to 1:00 p.m.

Agenda:

To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Joanne T. Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–TW–16–002: International Fogarty Scholars.

Date: October 28, 2016.

Time: 12:00 p.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: Hilary D. Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, (301) 594–6377, *sigmonh@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Systems Science and Health in the Behavioral and Social Science.

Date: November 2, 2016.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428, *wup4@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.

Date: November 2–3, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301–435–1501, *morrisr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Bacterial Pathogenesis.

Date: November 2, 2016.

Time:

8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard G. Kostriken, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 240–519–7808, *kostrikr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13–374: Modeling Social Behavior.

Date: November 2, 2016.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428, *wup4@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Preclinical Research on Model Organisms to Predict Treatment Outcomes for Disorders Associated with Intellectual and Developmental Disabilities.

Date: November 2, 2016.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@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: September 27, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23876 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Technology Transfer Direct Phase II (SBIR–TT) (R44).

Date: November 7, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834, Rockville, MD 20852, 301–496–2550, *amir.zeituni@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 27, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23883 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Investigator Initiated Program Project Applications (P01) and NIAID Resource-Related Research Projects (R24).

Date: November 10, 2016.

Time: 9:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G41, NIAID/NIH/DHHS, 5601 Fishers Lane, Bethesda, MD 20892–7616, 240–669–5067, *pamstad@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 28, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–23874 Filed 10–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. No. 16–16]

Expansion of Global Entry to Nine Additional Airports

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: Global Entry is a voluntary program that allows pre-approved participants dedicated U.S. Customs and Border Protection (CBP) processing into the United States using Global Entry kiosks located at designated airports. CBP previously announced in the **Federal Register** thirty-nine designated Global Entry airports. This document announces the expansion of the program to include nine additional designated Global Entry airports.

DATES: Global Entry will be available at all nine airport locations on or before April 3, 2017. The exact starting date for each airport location will be announced on the CBP Global Entry Web site, *http://www.globalentry.gov.*

FOR FURTHER INFORMATION CONTACT: Garret A. Conover, Office of Field Operations, (202) 325–4062, *Garret.A.Conover@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Global Entry Program

Global Entry is a voluntary program that allows for dedicated CBP processing of pre-approved travelers arriving in the United States at Global Entry kiosks located at designated airports. In a final rule published in the **Federal Register** (77 FR 5681) on February 6, 2012, CBP promulgated the regulation (8 CFR 235.12) to establish Global Entry as an ongoing voluntary regulatory program. Section 235.12 contains a description of the program, the eligibility criteria, the application and enrollment process, and redress procedures. Travelers who wish to participate in Global Entry must apply via the Global On-Line Enrollment System (GOES) Web site, *https://goes-app.cbp.dhs.gov,* and pay the applicable fee. Applications for Global Entry must be completed and submitted electronically.

In the above-referenced final rule that established the Global Entry program, Global Entry was initially limited to twenty airports. The rule provides that any expansion of the Global Entry program to new airports will be by publication in the **Federal Register** and by posting the information at *http://www.globalentry.gov. See* 8 CFR 235.12(c).

In a notice published in the **Federal Register** (77 FR 17492) on March 26, 2012, Global Entry was expanded to include four additional designated airports. In a notice published in the **Federal Register** (78 FR 38069) on June 25, 2013, Global Entry was expanded to include eight additional designated airports. Finally, in a notice published in the **Federal Register** (80 FR 1510) on January 12, 2015, Global Entry was expanded to include an additional seven airports.

The thirty-nine airports previously designated for Global Entry, listed alphabetically by state, and then city, include:

- Ted Stevens Anchorage International Airport, Anchorage, Alaska (ANC);
- Phoenix Sky Harbor International Airport, Phoenix, Arizona (PHX);
- Los Angeles International Airport, Los Angeles, California (LAX);
- San Diego International Airport, San Diego, California (SAN);
- San Francisco International Airport, San Francisco, California (SFO);
- John Wayne Airport, Santa Ana, California (SNA);
- Denver International Airport, Denver, Colorado (DEN);
- Ft. Lauderdale Hollywood International Airport, Fort Lauderdale, Florida (FLL), including the General Aviation Facility private aircraft terminal;
- Miami International Airport, Miami, Florida (MIA);
- Orlando International Airport, Orlando, Florida (MCO);
- Sanford-Orlando International Airport, Sanford, Florida (SFB);
- Tampa International Airport, Tampa, Florida (TPA);
- Hartsfield-Jackson Atlanta International Airport, Atlanta, Georgia (ATL);
- Honolulu International Airport, Honolulu, Hawaii (HNL);
- Chicago Midway International Airport, Chicago, Illinois (MDW);
- Chicago O'Hare International Airport, Chicago, Illinois (ORD);

• Cincinnati/Northern Kentucky International Airport, Hebron, Kentucky (CVG);
• Baltimore/Washington International Thurgood Marshall Airport, Baltimore, Maryland (BWI);
• Boston-Logan International Airport, Boston, Massachusetts (BOS);
• Detroit Metropolitan Wayne County Airport, Romulus, Michigan (DTW);
• Minneapolis-St. Paul International Airport, Minneapolis, Minnesota (MSP);
• Las Vegas-McCarran International Airport, Las Vegas, Nevada (LAS);
• Newark Liberty International Airport, Newark, New Jersey (EWR);
• John F. Kennedy International Airport, Jamaica, New York (JFK);
• Charlotte Douglas International Airport, Charlotte, North Carolina (CLT);
• Raleigh-Durham International Airport, Morrisville, North Carolina (RDU);
• Cleveland Hopkins International Airport, Cleveland, Ohio (CLE);
• Portland International Airport, Portland, Oregon (PDX);
• Philadelphia International Airport, Philadelphia, Pennsylvania (PHL);
• Pittsburgh International Airport, Pittsburgh, Pennsylvania (PIT);
• San Juan-Luis Munoz Marin International Airport, San Juan, Puerto Rico (SJU);
• Austin-Bergstrom International Airport, Austin, Texas (AUS);
• Dallas Fort Worth International Airport, Dallas, Texas (DFW);
• George Bush Intercontinental Airport, Houston, Texas (IAH);
• San Antonio International Airport, San Antonio, Texas (SAT);
• Salt Lake City International Airport, Salt Lake City, Utah (SLC);
• Washington Dulles International Airport, Sterling, Virginia (IAD);
• Seattle-Tacoma International Airport-SEATAC, Seattle, Washington (SEA);
• General Mitchell International Airport, Milwaukee, Wisconsin (MKE).

Expansion of Global Entry Program to Nine Additional Airports

CBP is designating nine additional Global Entry airports. Each of these airports will have Global Entry kiosks for the use of participants. The additional airports, listed alphabetically by state, and then city, are:
• Fairbanks International Airport, Fairbanks, Alaska (FAI);
• Oakland International Airport, Oakland, California (OAK);
• Sacramento International Airport, Sacramento, California (SMF);
• Norman Y. Mineta San Jose International Airport, San Jose, California (SJC);
• Louis Armstrong New Orleans International Airport, New Orleans, Louisiana (MSY);
• Kansas City International Airport, Kansas City, Missouri (MCI);
• Lambert-St. Louis International Airport, St. Louis, Missouri (STL);
• William P. Hobby International Airport, Houston, Texas (HOU);
• Burlington International Airport, Burlington, Vermont (BTV).

Global Entry will become operational at all nine airports on or before April 3, 2017. The exact starting dates of Global Entry at each airport location will be announced on the Web site, *http://www.globalentry.gov.*

Dated: September 29, 2016.

Todd C. Owen,

Executive Assistant Commissioner, Office of Field Operations.

[FR Doc. 2016–23966 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0011]

Individuals and Households Program Unified Guidance

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of availability.

SUMMARY: This document provides notice of the availability of the final Individuals and Households Program Unified Guidance. The Federal Emergency Management Agency (FEMA) published a notice of availability and request for comment for the proposed guidance on June 15, 2016 at 81 FR 39061.

DATES: The Individuals and Households Program Unified Guidance is effective on September 30, 2016.

ADDRESSES: This final guidance is available online at *http://www.regulations.gov* and on FEMA's Web site at *http://www.fema.gov.* The proposed and final guidance, all related **Federal Register** Notices, and all public comments received during the comment period are available at *http://www.regulations.gov* under docket ID FEMA–2016–0011. You may also view a hard copy of the final guidance at the Office of Chief Counsel, Federal Emergency Management Agency, Room 8NE, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Johnathan Torres, Individual Assistance Division, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202–212–1079) or (*FEMA-IHPUG-Comments@fema.dhs.gov*).

SUPPLEMENTARY INFORMATION: FEMA is announcing its final *Individuals and Households Program Unified Guidance* which describes the policies for the Individuals and Households Program. The final guidance compiles FEMA policy for each type of assistance under the Individuals and Households Program into one comprehensive document and is intended to serve as a singular policy resource for state, local, territorial, and tribal governments, and other entities who assist disaster survivors with post-disaster recovery.

FEMA received 86 comments during the public comment period. None of the comments received were deemed ''critical'', and the majority included only minor grammatical and formatting suggestions. Several comments included requests for statement clarification, which were addressed to improve overall policy comprehension. All comments were reviewed and adjudicated, and the Individuals and Households Program Unified Guidance was updated accordingly.

The final guidance does not have the force or effect of law.

Authority: 42 U.S.C. 5174.

David Bibo,

Acting Associate Administrator, Office of Policy and Program Analysis, Federal Emergency Management Agency.

[FR Doc. 2016–23948 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0014; OMB No. 1660–0033]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Residential Basement Floodproofing Certification

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork

Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 3, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on July 5, 2016 at 81 FR 43622 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Residential Basement Floodproofing Certification.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0033.

Form Titles and Numbers: FEMA Form 086–0–24, Residential Basement Floodproofing Certificate.

Abstract: The Residential Basement Floodproofing Certification is completed by an engineer or architect and certifies that the basement floodproofing meets the minimum floodproofing specifications of FEMA. This certification is for residential structures located in non-coastal Special Flood Hazard Areas in communities that have received an exception to the requirement that structures be built at or above the Base Flood Elevation (BFE) under 44 CFR 60.6(c). Residential structures with certification showing the building is floodproofed to at least 1 foot above the BFE are eligible for lower rates on flood insurance.

Affected Public: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 100.

Estimated Total Annual Burden Hours: 325 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $18,151. The annual costs to respondents' operations and maintenance costs for technical services is $35,000. There are no annual start-up or capital costs. The cost to the Federal Government is $2,885.71.

Dated: September 28, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–23889 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0016; OMB No. 1660–0134]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; America's PrepareAthon! National Day of Action Event Registration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 3, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on July 12, 2016 at 81 FR 45172 with a 60-day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: America's PrepareAthon! National Day of Action Event Registration.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0134.

Form Titles and Numbers: FEMA Form 008–0–8, America's PrepareAthon! National Day of Action Registration.

Abstract: As part of 6 U.S.C. 742 and Presidential Policy Directive 8 (PPD–8): National Preparedness, the President tasked the Secretary of Homeland Security to:

> coordinate a comprehensive campaign to build and sustain national preparedness, including public outreach and community-based and private-sector programs to enhance national resilience.

These entities taking part in the National Day of Action register their planned events through this information collection effort.

Affected Public: Individuals or households; Farms; Business or other for-profit; Federal Government; Not-for-profit institutions; State, local or Tribal Government.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 15,000 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $487,830. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $332,361.86.

Dated: September 28, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–23946 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–27–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0014; OMB No. 1660–0033]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Residential Basement Floodproofing Certification

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 3, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on July 5, 2016 at 81 FR 43622 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Residential Basement Floodproofing Certification.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0033.

Form Titles and Numbers: FEMA Form 086–0–24, Residential Basement Floodproofing Certificate.

Abstract: The Residential Basement Floodproofing Certification is completed by an engineer or architect and certifies that the basement floodproofing meets the minimum floodproofing specifications of FEMA. This certification is for residential structures located in non-coastal Special Flood Hazard Areas in communities that have received an exception to the requirement that structures be built at or above the Base Flood Elevation (BFE) under 44 CFR 60.6(c). Residential structures with certification showing the building is floodproofed to at least 1 foot above the BFE are eligible for lower rates on flood insurance.

Affected Public: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 100.

Estimated Total Annual Burden Hours: 325 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $18,151. The annual costs to respondents' operations and maintenance costs for technical services is $35,000. There are no annual start-up or capital costs. The cost to the Federal Government is $2,885.71.

Dated: September 28, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–23888 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0015; OMB No. 1660–0080]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Application for Surplus Federal Real Property Public Benefit Conveyance and BRAC Program for Emergency Management Use

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 3, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on July 14, 2016 at 81 FR 45518 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Application for Surplus Federal Real Property Public Benefit Conveyance and BRAC Program for Emergency Management Use.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0080.

Form Titles and Numbers: FEMA Form 119–0–1, Surplus Federal Real Property Application for Public Benefit Conveyance.

Abstract: Use of the Application for Surplus Federal Real Property Public Benefit Conveyance and Base Realignment and Closure (BRAC) Program for Emergency Management Use is necessary to implement the processes and procedures for the successful, lawful, and expeditious conveyance of real property from the Federal Government to public entities such as State, local, county, city, town, or other like government bodies, as it relates to emergency management response purposes, including fire and rescue services. Utilization of this application will ensure that properties will be fully positioned for use at their highest and best potentials as required by GSA and Department of Defense regulations, public law, Executive Orders, and the Code of Federal Regulations.

Affected Public: State, local, or Tribal Government.

Estimated Number of Respondents: 20.

Estimated Total Annual Burden Hours: 100 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $6,177. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $2,398.97.

Dated: September 28, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–23947 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0045]

Agency Information Collection Activities: Petition by Entrepreneur To Remove Conditions on Permanent Resident Status, Form I–829; 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 December 5, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0045 in the subject box, the agency name and Docket ID USCIS–2006–0009. 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–2006–0009;

(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, 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–2006–0009 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:* Petition by Entrepreneur to Remove Conditions on Permanent Resident Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–829; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Alien entrepreneurs admitted to the United States under section 203(b)(5) of the Immigration and Nationality Act (INA) are required to petition for removal of the conditional residence status imposed on them and their accompanying spouse and children, within a 90-day period before the second anniversary of their conditional residence under section 216A of the INA.

(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 I–829 is 3,829 and the estimated hour burden per response is 3 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 15,967 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 469,053.

Dated: September 27, 2016.

Samantha Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–23981 Filed 10–3–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–27]

60-Day Notice of Proposed Information Collection: Energy Benchmarking

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comment Due Date:* December 5, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

FOR FURTHER INFORMATION CONTACT: Stan Houle, Office of Multifamily Housing Programs, Department of Housing and Urban Development, 451 7th Street SW., Room 6182, Washington, DC 20410, telephone 202–708–2572. (This is not a toll-free number.) Persons with hearing or speech impairments may access these numbers through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The President's Climate Action Plan

The President's Climate Action Plan calls on Federal agencies to rapidly increase investments in energy productivity, eliminate energy waste, ramp up efficiency standards, and deploy the tools and technology needed to build a new energy economy. The residential building sector is responsible for fully 21 percent of the nation's greenhouse gas emissions. Utility costs (energy and water) account for around 22 percent of public housing operating budgets and a similar share in the assisted housing sector. HUD spends an estimated $6.4 billion annually to cover the costs of utilities in its public and assisted housing programs.[1]

HUD is committed to creating energy-efficient, water-efficient, and healthy housing as part of a broader effort to foster the development of inclusive, sustainable, and resilient communities. Investments in energy-efficiency and water-efficiency pay dividends by improving occupant comfort, stabilizing operating costs, alleviating taxpayer burden, preserving affordable housing, ensuring disaster resilience, and mitigating climate change. As such, the Office of Multifamily Housing Programs in HUD's Office of Housing has taken several steps to encourage greater energy and water efficiency in multifamily housing, including:

- Updating and standardizing the utility allowance methodology for assisted properties that must submit annual documentation of utility allowances (estimated 70 percent of portfolio);[2] (See Section ''Other PRA Collections that Impact this Submission'' for more information on how other previously approved PRA collections relate to Energy Benchmarking).
- Offering incentives to multifamily owners and management agents who have joined the Better Buildings Challenge, set a goal of reducing energy and/or water use by 20 percent within 10 years, and established themselves as leaders in the field with respect to energy and/or water efficiency;[3]
- Providing access to capital to make energy improvements by implementing changes to the Federal Housing Administration's (FHA) underwriting standards in the Multifamily Accelerated Processing Guide (MAP Guide) to allow greater loan proceeds

[1] See *https://portal.hud.gov/hudportal/documents/huddoc?id=afrfy13_egyeff.pdf.*

[2] See *http://portal.hud.gov/hudportal/documents/huddoc?id=15-04hsgn.pdf.*

[3] See *https://www4.eere.energy.gov/challenge/home.*

from standard offerings, supporting products such as the Fannie Mae Green Preservation Plus loan, and affirming how owners may use reserve for replacement funds to make energy and/or water improvements; [4] (See Section ''Other PRA Collections that Impact this Submission'' for more information on how other previously approved PRA collections relate to Energy Benchmarking.)

- Lowering annual multifamily mortgage insurance premiums for energy-efficient properties (those committed to achieving an industry-recognized green building standard and to maintaining energy performance in the top 25 percent of multifamily buildings nationwide);
- Developing and implementing a standardized Capital Needs Assessment suite of online tools (CNA e-Tool) available (later in 2016) for free to assist borrowers with submitting standard information to HUD, the U.S. Department of Agriculture, and others; [5]
- Developing a ''pay for success'' demonstration program under which the Department will execute budget-neutral, performance-based agreements that result in a reduction in energy or water costs. Recent legislation authorized HUD to implement this pilot in up to 20,000 units of multifamily buildings participating in the Sec. 8 Project-Based Rental Assistance, Sec. 202 and Sec. 811 programs; and
- Publishing guidance on utilizing Property Assessed Clean Energy (PACE) financing with HUD-assisted and FHA-insured properties.

Accounting for Energy and Water Usage

While HUD has a vested interest in eliminating energy and water waste in the assisted housing stock and stabilizing operating costs in both the insured and assisted housing stocks, to ensure that taxpayer investments in multifamily housing are viable for the long-term, the Office of Multifamily Housing Programs is currently unable to effectively analyze the portfolio-wide energy and water use patterns, improvement potential, and investment needs of properties in the assisted and insured portfolios. Though the Department currently collects utility cost data through its utility allowance and annual project financial statement requirements, the collection of information on utility consumption associated with those costs has been limited to small subsets of the portfolio, such as properties participating in the Department of Energy's Better Buildings Challenge.

In 2003 and 2008, the Harvard Graduate School of Design [6] and the Government Accountability Office,[7] respectively, strongly recommended that HUD require the practice of utility benchmarking across its housing portfolios. Utility benchmarking involves tracking the utility consumption of a development on an on-going basis, calculating the energy and water efficiency of the development, and comparing its efficiency to similar developments. It is a valuable tool in the strategic management of building portfolios. As such, a growing number of municipal and state governments across the country are instituting utility benchmarking requirements across the country so that government policymakers, funding providers, and building owners alike can make data-driven decisions.

Though obstacles remain, utility benchmarking is rapidly becoming quicker, easier, more automated, and more integrated as it becomes an industry-standard best practice. In September 2014, the U.S. Environmental Protection Agency (EPA) developed a new feature for its free, web-based tool called ENERGY STAR Portfolio Manager, which allows users to calculate an energy-efficiency rating or ''benchmarking score'' for most multifamily developments. Benchmarking scores developed through ENERGY STAR Portfolio Manager are officially known as ENERGY STAR Scores. These scores are available for multifamily housing properties of 21 units or more. A score of 50 indicates energy performance consistent with the national median, while 100 represents a top performer, and a score of at least 75 may make buildings eligible for ENERGY STAR certification.[8] The EPA will release a similar benchmark score for water usage in approximately a year. With these advancements, building owners across the country now have access to a free tool for utility benchmarking that can be used without the need to hire a building professional.

A Deeper Look at Utility Benchmarking

Utility benchmarking helps building owners to understand their buildings' energy and water performance, allowing them to detect malfunctioning equipment and billing errors, prioritize operational and capital improvements, verify the return on those investments, and plan future budget needs. Indeed, the practice of utility benchmarking can lead to significant improvements in building performance. Based on analysis of more than 35,000 buildings covered by newly established local energy benchmarking laws, EPA found an average energy use reduction of seven percent between 2008 and 2011.[9]

In addition to potential benefits to building owners, the sharing of utility benchmarking data allows government policymakers and funding providers (in this case, HUD acts as both) to account for utility expenditures, plan future budget needs, develop efficiency incentive programs, offer targeted technical assistance, and verify the return on these investments. For over 30 years, HUD has been promoting energy- and water-efficiency work in the public and assisted housing stocks through financial incentives, technical assistance, and pledge programs. However, portfolio-wide utility benchmarking and data sharing will significantly enhance HUD's ability to use robust information to direct those financial incentives, technical assistance, and pledge programs to the areas of greatest need, opportunity, and success.

Utility consumption and cost tracking by a building owner is the first step of utility benchmarking, and multiple approaches to this are available. The most direct method is to request whole-building utility data directly from the utility provider(s), covering the sum of owner-paid and tenant-paid accounts. When that is not possible, building owners may collect utility data for owner-paid accounts simply by compiling the information from their electronic or paper utility bills into a spreadsheet or web-based tool like ENERGY STAR Portfolio Manager. Some utility providers offer easy downloads of this information directly from their Web sites. Building owners may then collect utility data for tenant-paid accounts either by requesting the information directly from tenants in accordance with existing lease

[4] See *http://www.fanniemae.com/portal/about-us/media/corporate-news/2014/6117.html.*

[5] See Form HUD–9001a–ORCF at *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/hudclips/forms/hud9.*

[6] See *http://portal.hud.gov/hudportal/documents/huddoc?id=DOC_9238.pdf.*

[7] See *http://www.gao.gov/products/GAO-09-46.*

[8] See *http://www.energystar.gov/buildings/facility-owners-and-managers/existing-buildings/use-portfolio-manager.* See also former HUD Secretary Shaun Donovan's July 17, 2014, letter to Property Owners and Operators participating in HUD programs encouraging the use of EPA's ENERGY STAR Portfolio Manager at *http://portal.hud.gov/hudportal/documents/huddoc?id=SOHUDSignedLetterPHAsMFH.pdf.*

[9] See *http://www.energystar.gov/sites/default/files/buildings/tools/DataTrends_Savings_20121002.pdf.*

provisions, or, in some cases, by submitting individual tenant-data release forms to the utility provider. Once received, this utility data should be added to the spreadsheet or web-based tool to offer a complete picture of the whole-building utility consumption and cost. If using ENERGY STAR Portfolio Manager (OMB 2060–0347), as is required by this information collection request, the software will then automatically calculate a variety of useful metrics, such as the Site and Source Energy Use Intensity (EUI), Site Water Use Intensity (WUI), ENERGY STAR Score for Energy, and ENERGY STAR Score for Water. With this information, building owners are empowered to make more strategic decisions.

Cities across the country have enacted utility benchmarking and data sharing ordinances that ask commercial and multifamily building owners to track and disclose energy and/or water usage. Each program has unique building size requirements and different disclosure procedures.

At this time and with this notice, HUD is proposing limited requirements for utility benchmarking and data sharing, in order to balance the need to institute contemporary best practices and strategically manage the housing portfolio with the burden presented to building owners of adopting a new reporting requirement. Whereas an increasing number of state and local laws require utility benchmarking on an annual basis, HUD is proposing ''spot-check'' utility benchmarking on a less frequent basis. And whereas state and local benchmarking laws generally require utility benchmarking based on whole-building data, HUD intends to accept metrics developed with sampled tenant-paid utility data when whole building data are not available. Together, this will allow building owners to begin practicing utility benchmarking while the market continues to build support for more integration and automation of this best practice.

Over time, the Department will use the scores, along with EUI and WUI metrics, to see if energy and water efficiency is increasing, decreasing, or staying the same in the multifamily portfolio. The Office of Multifamily Housing Programs will use the information to assess energy and/or water efficiency needs and opportunities in the portfolio. Benchmarking data may also be used to inform the development of new policy initiatives, financial incentives, technical assistance, and pledge programs. Energy benchmarking will become more valuable over time as multiple years of energy consumption data are available.

II. Proposed Information Collection

To build a foundation of awareness and data concerning the current building performance of the multifamily building stock, as well as to inform and spur energy- and water-efficiency investments in multifamily housing, HUD proposes, through this notice, to require owners of covered property types to provide HUD's Office of Multifamily Housing Programs with the following utility consumption metrics for each property when completing several types of property transactions: Site and Source Energy Use Intensities (EUI), Site Water Use Intensity (WUI), and the ENERGY STAR Score for Energy, and—when available from EPA—the Energy Star Score for Water. The Portfolio Manager software—which must be used to meet HUD benchmarking requirements—calculates and reports these metrics in a standardized report format. This report may also include property identifiers (such as address and HUD contract number), building characteristics and other summary-level data underlying the benchmarking score calculations. The ENERGY STAR Score for Water is currently pending release by EPA, and so it will not be required until it is available. HUD will provide at least 90 days advance notice before a requirement to submit water efficiency data goes into effect.

Site EUI represents a property's energy use per square foot of gross floor area, expressed in thousand British thermal units per square foot (kBTU/ft^2), a standardized measure of thermal power consumption regardless of fuel source. Source EUI includes an adjustment to reflect how the energy was produced and transmitted, and this metric is calculated by ENERGY STAR Portfolio Manager and used as the basis for the ENERGY SSTAR Score for Energy. Site WUI represents a property's water use per square foot of gross floor area, expressed in gallons per square foot (gal/ft^2). The Energy Star Score for Energy and Water each serve as a ranking of a property's Source EUI and Site WUI, respectively, compared to similar properties.

There are a few exceptions to the stated information collection requirements. Only properties that have been in existence for at least 12 months and that include 21 housing units or more are eligible to receive an Energy Star Score for Energy or Water, and so these two metrics will not be required for ineligible properties. Properties with less than 21 units are encouraged to submit EUI and WUI data, but will not be required to submit this analysis to HUD.

Additionally, for the purposes of this basic information collection effort, the Office of Multifamily Housing Programs will accept metrics calculated using either whole building data or a combination of whole owner-paid utility data and sampled tenant-paid utility data. It is important to understand, however, that metrics calculated with less than whole building data are not accepted by EPA for the purposes of Energy Star certification. If choosing to use sampled tenant-paid utility data, owners must meet or exceed the standards outlined in this document.

Finally, for the Department's purposes, the required metrics will be considered valid for three years beyond the 12-month period upon which they are based. For example, an ENERGY STAR Score based on 2015 calendar-year utility data and generated in 2016 will be accepted by HUD for any required reporting under this notice in 2016, 2017, and 2018. An ENERGY STAR Score based on 2013 calendar-year data and generated in 2016 will be accepted by HUD for any required reporting under this notice in 2016, but not in 2017. At this point, the owner would need to provide more recent data. The frequency is intended to align benchmarking with information collection efforts undertaken by HUD-assisted properties in preparing their utility allowance.

Covered property types include:

- Section 202 Project Rental Assistance Contracts (PRAC),[10]
- Section 811 PRAC and Project Rental Assistance (PRA) contracts,[11]
- Section 202/162 Project Assistance Contracts (PAC),[12]
- Section 202 Senior Preservation Rental Assistance Contracts (SPRAC),[13]

[10] Under HUD's regulations for the Section 202 and Section 811 programs at 24 CFR 891.400(d)(2) Owners are required to submit ''statements regarding project operation, financial conditions and occupancy as HUD may require to administer the PRAC and to monitor project operations

[11] *Id.*

[12] Under HUD regulations for the Section 202 PAC program at 24 CFR 891.740(d), HUD may require owners to submit other statements regarding project operations, financial conditions, and occupancy, as HUD may require to administer the contracts and monitor project operations.

[13] In the SPRAC contract between HUD and the owner, Section 2.11 Financial Requirements subsection (a)(ii) provides that the owner must submit to the contract administrator other statements as to project operations, financial conditions, and occupancy as HUD may require pertinent to the administration of the SPRAC and monitoring of project operations.

• Section 8 Housing Assistance Payment (HAP) contracts,[14]

• Multifamily Housing properties insured under Sections 223(a)(7), 223(f), 221(d)(3), 221(d)(4), 220, 231, 236, and 241(a)).[15]

HUD will evaluate properties insured under the FHA Risk Share programs—Section 542(b): Fannie Mae, Freddie Mac, and Small Building Risk Share, and Section 542(c): Housing Finance Agencies—to determine feasibility and timeframes for applying energy benchmarking requirements to those properties in the future.

Owners of covered properties are encouraged to voluntarily submit water and energy benchmarking data to HUD on an annual basis. HUD will require that owners submit benchmarking information on the following schedule, subject to revision:

• For HUD-assisted properties with a utility allowance, at the time of a triennial utility allowance baseline calculation;

• For HUD-assisted properties where there is no utility allowance, every third year at the time of financial statement submission;

• Prior to issuance of new FHA mortgage insurance under Sections 223(a)(7), 223(f), and 241(a));

• With a Capital Needs Assessment submission required by the Office of Asset Management and Portfolio Oversight in HUD's Office of Multifamily Housing Programs on a 10-year cycle;

• With a Capital Needs Assessment submission required as part of any enforcement action.

HUD is seeking feedback on the required submission points and will finalize the schedule with the issuance of an Office of Housing Notice. Note that these submission requirements are a minimum schedule and do not supersede more frequent reporting required for properties participating in certain other Multifamily Housing programs, such as the Better Buildings Challenge, FHA green buildings financing, or Multifamily PACE.

Required Format

As noted above, owners seeking a covered property transaction will be required to enter data into ENERGY STAR Portfolio Manager and electronically submit to HUD the referenced metrics created by the free web tool. ENERGY STAR Portfolio Manager has the ability to automatically generate reports from user data and offers a variety of standard formats. Prior to the requirements' effective date, HUD will specify a machine-readable report format in Portfolio Manager that HUD owners must use in preparing their benchmarking submissions. The format of the report may be modified over time but content will remain consistent with the scope of this Notice.

Requirements for Underlying Utility Data

Use of whole building data, including owner-paid utilities, plus all tenant paid utilities (even if aggregated), is highly preferable when completing utility benchmarking analysis, as it will give the most accurate snapshot of a building's performance. However, to calculate the referenced metrics in Portfolio Manager, some owners may need to or choose to use a combination of whole owner-paid utility data and a sample of tenant-paid utility data as an alternative to using all of the above. Please be reminded that metrics calculated with less than whole building data are not accepted by EPA for the purposes of ENERGY STAR certification. If choosing to use sampled tenant-paid utility data, owners must meet or exceed the minimum sampling standards associated with existing Office of Multifamily Housing Programs' utility data reporting requirements (see table of related PRA collections below). Accepting the sampling already in use by anticipated respondents will significantly minimize the additional administrative burden benchmarking requirements impose on those respondents.

When completed in conjunction with a HUD utility allowance baseline analysis, the benchmarking analysis should generally include (or exceed) the number of units sampled for the utility allowance (see Notice H 2015–14 [16]). In other instances, the Department will accept analysis using sampled tenant data that meets or exceeds the lighter sampling protocol adopted by the Better Buildings Challenge.[17] HUD may establish a different standard for submittals associated with Capital Needs Assessments (CNA) or FHA green building financing programs. In all cases, owners are encouraged to collect as much utility data as possible and to sample from a variety of housing unit sizes and types within each development in order to improve the accuracy and usefulness of the resultant metrics. Owners must certify that the submitted Portfolio Manager data meets or exceeds the required minimum sample.

HUD will consider requests for additional time to submit benchmarking data from owners who experience unexpected delays in obtaining sufficient sample data from utility providers or encounter unforeseeable technical difficulties.

Other PRA Collections That Impact This Submission

The Department has identified eight discrete tasks associated with the process for obtaining and submitting Portfolio Manager scores, which are listed in the matrix below. Based on a review of other Paperwork Reduction Act submissions, the Department believes that the PRA requirements for seven of those eight tasks are addressed in other submissions, also identified in the matrix below. Burden hours calculated for the proposed Information Collection reflect only the time associated with generating a report in Portfolio Manager and submission to HUD. While the Department recognizes that respondents may spend significant time on preparatory activities in order to submit the data requested under this collection, the burden hours for those tasks are already accounted for under other approved collections.

[14] Under HUD's Section 8 Project-Based Rental Assistance (PBRA) program, owners must submit an analysis of the project's utility allowances in connection with annual rent adjustments and ". . . provide to HUD on an annual basis, such financial information as required by HUD . . .". See HUD regulations at 24 CFR 880.610, (applied to parts 881 and 883 by cross-reference), 24 CFR 884.220, 24 CFR 886.126, 24 CFR 891.645, and 24 CFR part 5 Subpart H.

[15] Under HUD's regulations at 24 CFR 200.78, insured properties "shall provide cost effective energy conservation in accordance with requirements established by" HUD.

[16] *https://portal.hud.gov/hudportal/documents/huddoc?id=15-04hsgn.pdf.*

[17] See Appendix C of the BBC Data Tracking Manual. *www.hudexchange.info/programs/utility-benchmarking.*

RELEVANT PRA INFORMATION COLLECTIONS

	Energy Star collection (OMB–2060–0347)	eCNA collection (OMB–2502–0505)	TRACS collection (utility allowance component) (OMB–2502–0204)	Multifamily project applications green building program component (OMB–2502–0029)	HUD's multi-family housing utility allowance submission (OMB 2502–0352)	Benchmarking (new collection)
Tasks Leading to Fulfillment of Requirement						
Tenants submit utility data to owners		X	X		X	
Tenants provide release for owner to request data from utility		X	X		X	
Utilities compile and share data with owners	X	(*)	(*)		(*)	
Owners compile/prepare tenant-paid utility data	X	(*)	(*)		(*)	
Owners compile/prepare owner-paid utility data	X	(*)		X		
Owners enter data into Portfolio Manager	X	(*)	(*)	(*)		
Direct Requirement Being Proposed						
Owners generate Portfolio Manager Report and submit to HUD						X

* In conjunction with FHA financing and Utility Allowance processes, a portion of owners are currently compiling utility consumption data and utilizing Portfolio Manager.

Effective Date

The utility benchmarking requirement described in this notice will apply when executing any covered transaction beginning 90 days after OMB approval of the PRA request, and not sooner than April 15, 2017. The first scheduled submission date for a majority of assisted-housing respondents is estimated to occur in 2019. HUD will alert owners of the effective date for reporting requirements and provide procedural instructions for submitting data through an Office of Housing Notice, issued after OMB issues a Notice of Action approving this PRA collection.

III. Information Collection Burden and Solicitation of Comment

A. Overview of Information Collection

Title of Information Collection: Multifamily Housing Energy Benchmarking.

OMB Approval Number: New proposed collection.

Type of Request: New proposed collection.

Form Number: N/A.

Description of the need for the information and proposed use: Please see Section II of this notice.

Respondents: Multifamily owners, managing agents and tenants.

Estimated Number of Respondents: 17,049.

Average Hours per Response: .50.

Total Estimated Burden Hours: 8,524.5.

Burden hours take into account other existing information collections covering the assembly of utility information by impacted properties and the use of ENERGY STAR Portfolio Manager, these include: HUD's Multifamily Housing Utility Allowance submission (OMB 2502–0352), HUD's Tenant Eligibility and Rent Procedures (OMB 2502–0204), CNAe requirements (OMB 2502–0505), HUD's Multifamily Project Applications Green Building Program component (OMB–2502–0029)and ENERGY STAR Certification (OMB–2060–0347) by the Environmental Protection Agency.

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.

Dated: September 28, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing—Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–23979 Filed 10–3–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5916–N–17]

60-Day Notice of Proposed Information Collection: Energy Benchmarking of Public Housing

AGENCY: Office the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 5, 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: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email

at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION:

I. Background

The President's Climate Action Plan

The President's Climate Action Plan calls on Federal agencies to increase investments in energy productivity, eliminate energy waste, ramp up efficiency standards, and deploy the tools and technology needed to build a new energy economy. The residential building sector is responsible for approximately 21 percent of the nation's greenhouse gas emissions. Utility costs (energy and water) account for approximately 22 percent of public housing operating budgets and in similar proportion across the assisted housing sector. HUD spends an estimated $6.4 billion annually to cover the costs of utilities in its public and assisted housing programs.[1]

HUD is committed to creating energy-efficient, water-efficient, and healthy housing as part of a broader effort to foster the development of inclusive, sustainable, and resilient communities. Investments in energy and water-efficiency pay dividends by improving occupant comfort, reducing tenant turnover, stabilizing operating costs, alleviating taxpayer burden, preserving affordable housing, ensuring disaster resilience, and mitigating climate change.

The Harvard Graduate School of Design in 2003 [2] and the Government Accountability Office in 2008 [3] strongly recommended that HUD require the practice of utility benchmarking across its housing portfolios in order to better manage energy and water consumption. Benchmarking is a valuable tool that compares a building's utility consumption pattern against similar buildings and helps owners measure and manage energy and water consumption across building portfolios. With utility benchmarking, HUD will better be able to analyze energy and water use patterns to identify and address underperforming buildings in order to reduce energy and water consumption while stabilizing and reducing utility costs.

Benchmarking buildings is considered an industry-standard best practice and although some obstacles remain, the process is rapidly becoming quicker, easier, and more automated. A growing number of municipal and state governments across the country are instituting benchmarking requirements to better track and analyze building performance. Most benchmarking requirements utilize the Environmental Protection Agency's (EPA) ENERGY STAR Portfolio Manager, which automatically calculates energy performance metrics including a benchmarking score for public housing properties. ENERGY STAR benchmarking scores range from 0–100, and properties that achieve a score of at least 75 points may be eligible for ENERGY STAR certification. It is anticipated that EPA's ENERGY STAR program will release a similar benchmark score for water consumption in approximately one year.

Benchmarking Requirements

At this time, HUD is proposing limited requirements for utility benchmarking in order to balance the need to manage the public housing portfolio against the burden on Public Housing Agencies (PHAs) to adopt a new process. Many local benchmarking laws require benchmarking on an annual basis, however HUD is currently proposing benchmarking every three years. Benchmarking laws typically require property owners to utilize whole-building data, however HUD intends to accept sampled tenant-paid utility data where whole building data is not readily available. The three-year requirement will allow building owners to begin utility benchmarking while the market continues to build support, integration, and automation into this practice.

HUD will aggregate the collected data and analyze the ranges in order to better understand the overall PHA portfolio. Overtime, HUD will use the benchmarking scores as well as other data and metrics from Portfolio Manager to measure whether energy and water efficiency is increasing, decreasing, or staying the same throughout the public housing portfolio. This information may help guide the development of new policy initiatives, financial incentives, and technical assistance for PHAs.

The Process and Benefits of Utility Benchmarking

Utility benchmarking helps building owners better understand their buildings' energy and water performance. Analyzing buildings across a portfolio enables building owners to identify underperforming buildings in order to prioritize capital improvements and plan future budget needs. Based on an analysis of more than 35,000 buildings covered by newly established local energy benchmarking laws, EPA found an average energy use reduction of seven percent between 2008 and 2011 after benchmarking.[4] In addition to PHA benefits, the sharing of utility benchmarking data will enable HUD to evaluate utility expenditures and offer better technical assistance.

In order to benchmark a building, two types of data must be collected and entered into Portfolio Manager. The first type of data is some basic information on the physical characteristics of a property. This includes items such as building location, square footage, heating system fuel, quantity of buildings for multiple building properties, etc. This information only needs to be entered once unless the property undergoes major construction and/or a renovation. The second type of data needed is at least 12 months of recent utility data. Once all of the required data are entered, Portfolio Manager automatically analyzes the information and calculates a variety of useful metrics including energy use intensity (EUI), water use intensity (WUI), and ENERGY STAR benchmarking scores.

In order to assist in the benchmarking process, a growing number of utility companies offer automatic utility data transfers into Portfolio Manager. When this feature is available, HUD highly encourages PHAs to utilize it, as it has the potential to significantly reduce the time burden and likelihood of data entry errors. When automatic digital data transfer is not possible, PHAs should consult their utility provider's Web site to see if they offer downloads of historical data.

In order to fully analyze a building, Portfolio Manager needs utility

[1] See *https://portal.hud.gov/hudportal/documents/huddoc?id=afrfy13_egyeff.pdf.*

[2] See *http://portal.hud.gov/hudportal/documents/huddoc?id=DOC_9238.pdf.*

[3] See *http://www.gao.gov/products/GAO-09-46.*

[4] See *http://www.energystar.gov/sites/default/files/buildings/tools/DataTrends_Savings_20121002.pdf.*

consumption for the whole building. HUD expects PHAs to submit whole building data where available. Metrics calculated with less than whole building data are not accepted by EPA for the purposes of Energy Star certification.

When a property's utilities are 100% PHA paid, PHAs should be able to collect and enter all of the required utility data. In properties where tenants pay some or all of the utility bills, PHAs should work with their local utility providers, as many utility providers offer digital data transfers containing whole building data including both owner-paid and tenant-paid accounts. Each utility provider will have unique requirements for releasing the data in order to protect tenant privacy. HUD recommends that PHAs pursue this option where available as it provides more complete and accurate data while minimizing the time burden. When utility companies are not able to provide data for tenant paid accounts, PHAs should collect a sample of tenant-paid utility data.

II. Proposed Information Collection

Through this notice, HUD proposes that PHAs operating 250 or more public housing units under an Annual Contributions Contract (ACC) use the ENERGY STAR Portfolio Manager program to benchmark all properties no less than every three years and report the automatically generated metrics to HUD beginning no later than 2018. PHAs are encouraged to voluntarily submit benchmarking data to HUD on an annual basis. Although not required, PHAs operating less than 250 ACC units are encouraged to benchmark and submit the requested metrics. In the future, HUD may expand this collection to PHAs that operate fewer than 250 ACC units and are already required by State and/or local law to benchmark their buildings using whole-building data or for other programs run by the Office of Public and Indian Housing where appropriate. In addition, ACC units in buildings that have or will convert to 100% Project Based Vouchers (PBV) through the Rental Assistance Demonstration (RAD) will also be required to benchmark. At this point, the Energy Star Score for Water is still under development. HUD will not require this data point until at least 120-days after this feature is completed and HUD has notified PHAs as such. The next three-year submission after the notification shall include both energy and water data.

HUD has identified the following tasks associated with the process for obtaining and submitting Portfolio Manager scores.

Year 1

1. Enter building data into ENERGY STAR Portfolio Manager.
2. Connect PHA account with the HUD account and share appropriate property information.
3. Compile and enter owner-paid utility data, where applicable.
4. Compile and enter tenant paid utility data, where applicable.
5. Report automatically generated metrics calculated by Portfolio Manager.

Subsequent Years

In subsequent years, PHAs will have less work to complete. The data required in step 1 will only need to be updated if the property underwent a major renovation including but not limited to an addition, demolition, or major change to the mechanical system (*i.e.:* Change in heating fuel, change to the domestic hot water system, etc.). Steps 3, 4, and 5 will need to be updated at the time of the data submission.

The required metrics will be considered valid for three years. For example, an ENERGY STAR Score based on the 2016 reporting period would be accepted by HUD for the 2016, 2017, and 2018 reporting years.

HUD is seeking feedback on the required submission parts and will finalize the schedule with the issuance of an Office of Public and Indian Housing Notice.

Required Format

PHAs will be required to enter data into ENERGY STAR Portfolio Manager and submit to HUD the automatically generated metrics. HUD anticipates collecting the required data and metrics via a web-based portal, database, or other simplified digital format. In addition to submitting metrics, PHAs may be asked to link their account with the HUD account and share property information to enable further analysis. Once PHAs connect their accounts with the HUD account and share property information, there is no additional time burden on PHAs as the relevant data automatically flows between the accounts.

Sampling Protocol

In order for Portfolio Manager to analyze a building, PHAs will need to gather and enter utility data for the whole building. This includes both PHA-paid and tenant-paid accounts. PHAs should work with their local utility companies to determine if they are able to provide the PHA with digital transfers of tenant paid accounts. Utility companies that offer this service generally have procedures in place to protect tenant privacy. If PHAs are not able to obtain complete tenant paid account data from the local utility company, or similar entity, PHAs shall collect a sample of tenant-paid utility data. If using a sample of tenant-paid accounts, PHAs must meet or exceed the minimum standards of the sampling protocol outlined below. As a reminder, metrics calculated with less than whole building data are not accepted by EPA for the purposes of ENERGY STAR certification.

PHAs have the choice of selecting one of two sampling protocols from existing programs—(a) a robust sampling protocol, appropriate for use in financial estimates; and (b) a lighter sampling protocol, appropriate for general use, which is outlined for use in the Better Buildings Challenge (BBC). PHAs are encouraged to collect as much utility data as possible and to sample from a variety of housing unit sizes and types in order to ensure the accuracy and usefulness of the resulting metrics.

In accordance with the BBC Multifamily Sampling Protocol, the minimum number of housing units for which tenant-paid utility data must be collected and included in the referenced metrics is based on the size of the property:

Housing units in development	Minimum sample size
1–4	1
5–9	2
10–19	3
21–29	4
30–49	5
50–74	6
75–99	7
100–149	8
150–200	9
201+	10

At some point HUD may establish a different sampling standard for submittals for the purpose of assisting PHAs in establishment of utility allowances. If HUD decides to pursue that path, HUD will provide sufficient advance notice before changing the sampling standard. HUD will consider requests for additional time to submit benchmarking data from PHAs who experience unexpected delays in obtaining sufficient sample data from utility providers or otherwise encounter unforeseeable technical difficulties.

Effective Date

The utility benchmarking requirement described in this notice will apply no later than 2018. This will allow HUD

and PHAs time to implement the protocol. HUD will alert owners of the effective date through an Office of Public and Indian Housing Notice, issued after OMB issues a Notice of Action approving this PRA collection.

III. Information Collection Burden and Solicitation of Comment

A. Overview of Information Collection

Title of Information Collection: Public Housing Energy Benchmarking.

OMB Approval Number: New proposed collection.

Type of Request: New proposed collection.

Form Number: N/A.

Description of the Need for the Information and Proposed Use: Please see Section II of this notice.

Respondents: Public Housing Agencies and tenants of public housing.

Estimated Number of Respondents: 3,089.

Estimated Number of Responses (Buildings/Developments): 7,715.

Average Hours per Response: 8.5.

Total Estimated Burden Hours: 65,578 hours.

HUD estimates that the burden requirements associated with these activities is approximately 8.5 hours per development for the first year and 15 minutes in subsequent years. The burden hours take into account another existing information collection covering the use of ENERGY STAR Portfolio Manager, ENERGY STAR Certification (OMB–2060–0347) by the Environmental Protection Agency. That collection allows for 5.25 hours per year per development for the input of utility consumption data into Portfolio Manager.

The Department expects to participate in roundtable discussions with stakeholders on Energy Benchmarking during the comment period, which will provide additional opportunities for receiving feedback on the proposed requirements.

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 written comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Dated: September 28, 2016.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2016–23978 Filed 10–3–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[17X LLUT030000 L17110000.PH0000 241A]

Notice of Grand Staircase-Escalante National Monument Advisory Committee Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the Department of the Interior, Bureau of Land Management (BLM), Grand Staircase-Escalante National Monument Advisory Committee (GSENMAC) will meet as indicated below.

DATES: The GSENM MAC will meet Thursday, November 3 (10 a.m.–6 p.m.) and November 4, 2016, (8 a.m.–1 p.m.) in Kanab, Utah.

ADDRESSES: The Committee will meet at the Bureau of Land Management Administrative Headquarters, located at 669 S. Highway 89A, Kanab, Utah.

FOR FURTHER INFORMATION CONTACT: Larry Crutchfield, Public Affairs Officer, Grand Staircase-Escalante National Monument, Bureau of Land Management, 669 South Highway 89A, Kanab, Utah, 84741; phone (435) 644–1209.

SUPPLEMENTARY INFORMATION: The 15-member GSENMAC was appointed by the Secretary of Interior on January 23, 2016, pursuant to the Monument Management Plan, the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA). As specified the Committee charter, the GSENMAC may be requested to: (1) Gather and analyze information, conduct studies and field examinations, seek public input or ascertain facts to develop recommendations concerning the use and management of the Monument; (2) review programmatic documents including the annual Monument Manager's Reports, and Monument Science Plans to provide recommendations on the achievement of the Management Plan objectives; (3) Compile monitoring data and assess and advise the DFO of the extent to which the Plan objectives are being met; (4) Make recommendations on Monument protocols and applicable planning projects to achieve the overall objectives are being met; (5) Review appropriate research proposals and make recommendations on project necessity and validity; (6) Make recommendations regarding allocation of research funds through review of research and project proposals as well as needs identified through the evaluation process; (7) Consult and make recommendations on issues such as protocols for specific projects, *e.g.,* vegetation restoration methods or standards for excavation and curation of artifacts and objects; and/or (8) Prepare an annual report summarizing the Committee's activities and accomplishments of the past year, and make recommendations for future needs and activities.

Topics to be discussed by the GSENMAC during this meeting include the ongoing Livestock Grazing Management Plan Amendment and Associated Environmental Impact Statement (LGMPA/AEIS), GSENM division reports, future meeting dates and other matters as may reasonably come before the GSENMAC.

The entire meeting is open to the public. Members of the public are welcome to address the Committee at 5 p.m., local time, on November 3, 2016; and at 12 p.m., local time, on November 4, 2016. Depending on the number of persons wishing to speak, a time limit could be established. Interested persons may make oral statements to the GSENMAC during this time or written statements may be submitted for the GSENMAC's consideration. Written statements can be sent to: Grand Staircase-Escalante National Monument, Attn.: Larry Crutchfield, 669 South Highway 89A, Kanab, Utah, 84741. Information to be distributed to the GSENMAC is requested 10 days prior to the start of the GSENMAC meeting.

All meetings are open to the public; however, transportation, lodging, and

meals are the responsibility of the participating public.

Jenna Whitlock,

Acting State Director.

[FR Doc. 2016–23937 Filed 10–3–16; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–956]

Certain Recombinant Factor VIII Products; Notice of Commission Determination To Grant a Joint Motion To Terminate the Investigation on the Basis of a Settlement Agreement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to grant a joint motion to terminate the above-captioned investigation based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, (202) 205–2000. General information concerning the Commission may also be obtained at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docketing system (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal at (202) 205–1810.

SUPPLEMENTARY INFORMATION: On May 22, 2015, the Commission instituted this investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, based on a complaint filed by Baxter Healthcare Corporation and Baxter Healthcare SA, both of Deerfield, Illinois. 80 *FR* 29745 (May 22, 2015). Baxalta Inc., Baxalta US Inc., and Baxalta GmbH were added as complainants after the filing of the complaint. 80 *FR* 62569 (Oct. 16, 2015). (The complainants are collectively referred to as ''Baxter.'') The Commission sought to determine whether there is a violation of Section 337(a)(1)(B) in the importation into the United States, the sale for importation into the United States, or the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of any of claims 19–21, 36, 37, and 39 of U.S. Patent No. 6,100,061 (''the '061 patent''); claims 20 and 21 of U.S. Patent No. 6,936,441 (''the '441 patent''); and claims 1, 5, 8, 10, 14, and 18 of U.S. Patent No. 8,084,252 (''the '252 patent''). 80 *FR* at 29746. The Commission directed the ALJ to make findings of fact and provide a recommended determination with respect to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), and (g)(1). *Id.* The notice of investigation named as respondents Novo Nordisk A/S of Bagsvaerd, Denmark and Novo Nordisk Inc., of Plainsboro, NJ (collectively, ''Novo Nordisk''). *Id.* The Office of Unfair Import Investigations (''OUII'') is also a party to this investigation. *Id.*

On December 8, 2015, Baxter moved for partial termination of this investigation based on the withdrawal of claims 21, 36, 37, and 39 of the '061 patent; claims 1 and 10 of the '252 patent; and claims 20 and 21 of the '441 patent. That motion was granted, leaving only claims 19 and 20 of the '061 and claims 5, 8, 14, and 18 of the '252 patent at issue. Order No. 23 (Dec. 10, 2016), *unreviewed,* Notice of Commission Determination Not to Review an Initial Determination Granting a Motion for Partial Termination of the Investigation with Respect to Certain Claims (Jan. 5, 2016).

On February 26, 2016, the ALJ issued an initial determination (''the Summary ID'') (Order No. 30), which concluded that Novo Nordisk infringed the '061 patent. Novo Nordisk filed a petition requesting that the Commission review the Summary ID and related claim construction orders. The Commission determined to defer its decision on whether to review those orders until the date on which the Commission determines whether to review the ALJ's final ID (''the Final ID''). Notice of Comm'n Determination to Extend the Date for Determining Whether to Review a Non-Final Initial Determination Granting Complainants' Motion for Summary Determination that the Accused Products Infringe U.S. Patent No. 6,100,061 (Mar. 29, 2016).

On May 27, 2016, the ALJ issued the Final ID, which found no violation of Section 337 as to either remaining asserted patent. On June 3, 2016, the ALJ issued the Recommended Determination on Remedy, Bonding, and the Public Interest, which contingently recommends both a limited exclusion order and a cease and desist order. The parties each petitioned for review of the Final ID. The Commission determined to review (1) the Summary ID's conclusion that the '061 patent is infringed (and the underlying claim constructions); (2) the Final ID's conclusion that the asserted claims of the '061 patent are anticipated and obvious; and (3) the Final ID's conclusion that the economic prong of the domestic industry is not met as to both remaining patents. 81 *FR* 51463, 51464 (Aug. 4, 2016). The Commission requested briefing on one issue under review and on remedy, the public interest, and bonding. *Id.* at 51464–65.

On September 12, 2016, the private parties filed a Joint Motion to Terminate the Investigation Based on a Settlement Agreement (''the Motion'') and a confidential and a public version of the settlement agreement. On September 14, 2016, OUII filed a response supporting the Motion.

The Commission has determined that the Motion complies with the requirements of section 210.21(b)(1) of the Commission's Rules of Practice and Procedure (19 CFR 210.21(b)(1)), and that there are no extraordinary circumstances that would prevent the requested termination. The Commission also finds that granting the Motion would not be contrary to the public interest pursuant to section 210.50(b)(2) of the Commission's Rules of Practice and Procedure (19 CFR 210.50(b)(2)). Accordingly, the Commission hereby grants the Motion. This investigation is terminated.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 28, 2016.

Katherine M. Hiner,

Acting Supervisory Attorney.

[FR Doc. 2016–23864 Filed 10–3–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–944 (Enforcement Proceeding)]

Certain Network Devices, Related Software and Components Thereof (I) Notice of Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has instituted a formal enforcement proceeding relating to June 23, 2016, cease and desist order issued in the above-referenced investigation.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the original investigation on January 27, 2015, based on a complaint filed by Cisco Systems, Inc. (''Cisco''). 80 *FR* 4314 (Jan. 27, 2015). Pertinent to this investigation, the complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation into the United States, and the sale within the United States after importation of certain network devices, related software, and components thereof by reason of infringement of any of claims 1–2, 8–11, and 17–19 of U.S. Patent No. 7,162,537 (''the '537 patent''). *Id.* The notice of institution of the investigation named Arista Networks, Inc. (''Arista'') as a respondent and the Office of Unfair Import Investigations (''OUII'') as a party. *Id.*

On June 23, 2016, the Commission found that a Section 337 violation occurred as to the '537 patent and therefore issued a cease and desist order (''CDO'') against Arista and a limited exclusion order (''LEO''). 81 *FR* 42375–76 (June 29, 2016). The CDO prohibited Arista from importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting United States agents or distributors for certain network devices, related software, and components thereof that infringe the asserted claims of the '537 patent. *Id.* at 42376.

On August 26, 2016, Cisco filed a complaint requesting that the Commission institute a formal enforcement proceeding under Commission Rule 210.75(b) to investigate alleged violations of the CDO by Arista. Having examined the enforcement complaint and the supporting documents, the Commission has determined to institute a formal enforcement proceeding to determine whether Arista is in violation of the June 23, 2016 CDO issued in the original investigation and to determine what, if any, enforcement measures are appropriate. Arista is named as a respondent and OUII is named as a party.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.75 of the Commission's Rules of Practice and Procedure (19 CFR 210.75).

By order of the Commission.

Issued: September 28, 2016,

Katherine M. Hiner,

Acting Supervisory Attorney.

[FR Doc. 2016–23863 Filed 10–3–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Fisher Clinical Services, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before November 3, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before November 3, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers importers, and exporters of, controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 17, 2016, Fisher Clinical Services, Inc., 700 A–C Nestle Way, Breinigsville, Pennsylvania 18031–1522 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methylphenidate (1724)	II
Levorphanol (9220)	II
Noroxymorphone (9668)	II
Tapentadol (9780)	II

The company plans to import the listed controlled substances for analytical research, testing, and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

The company plans to import an intermediate form of tapentadol (9780)

to bulk manufacture tapentadol for distribution to its customers.

Louis J. Milione,

Assistant Administrator, Diversion Control Division.

[FR Doc. 2016–23887 Filed 10–3–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On September 28, 2016, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Columbia in the lawsuit entitled *United States* v. *Anthony Spanos, Inc., et al.,* Civil Action No. 1:14-cv-01625–RJL.

The United States filed this lawsuit under the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''). The United States' complaint names Anthony Spanos, Inc., George A. Spanos, in his capacity as the trustee of the George A. Spanos Living Trust, and Gus Dinos as defendants. The United States' complaint seeks recovery of costs incurred and to be incurred by the Environmental Protection Agency in connection with the removal of hazardous substances at the Georgia Avenue PCE Site, located in Northwest Washington, DC. The consent decree resolves the United States' claims against George A. Spanos and does not resolve the United States' claims against Anthony Spanos, Inc. and Gus Dinos. George A. Spanos agrees to pay $125,000 of the United States' response costs and to perform the operation and maintenance of sub-slab depressurization systems at the Site. In return, the United States agrees not to sue George A. Spanos under sections 106 and 107 of CERCLA.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Anthony Spanos, Inc., et al.,* D.J. Ref. No. 90–11–3–10721. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–23926 Filed 10–3–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0021]

Cranes and Derricks in Construction; Extension of the Office of Management and Budget's (OMB) Approval Information Collection (Paperwork) Requirements

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

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the collections of information contained in the Cranes and Derricks in Construction Standard (29 CFR part 1926, subpart CC).

DATES: Comments must be submitted (postmarked, sent, or received) by December 5, 2016.

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

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2013–0021, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA–2013–0021) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Todd Owen or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the

Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Cranes and Derricks standard's information collection requirements impose a duty on employers to produce and maintain records that implement controls and take other measures to protect workers from hazards related to cranes and derricks used in construction. Accordingly, construction businesses with workers who operate or work in the vicinity of cranes and derricks must have, as applicable, the following documents on file and available at the job site: Equipment ratings, employee training records, written authorizations from qualified individuals, and program qualification audits. During an inspection, OSHA will have access to the records to determine compliance under conditions specified by the standard. An employer's failure to generate and disclose the information required in this standard will affect significantly the Agency's effort to control and reduce injuries and fatalities related to the use of cranes and derricks in construction.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting an adjustment decrease of 36 burden hours (from 386,066 to 386,030 burden hours). The decrease in burden hours is due to errors in calculations. There is also an adjustment increase in operation and maintenance costs of $103,775 from $2,183,970 to 2,287,745. The increase is mainly due to an increase in hourly wage rates.

OSHA will summarize the comments submitted in response to this notice, and will include this summary in its request to OMB to extend the approval of the information collection requirements contained in the Cranes and Derricks Standard.

Type of Review: Extension of a currently approved collection.

Title: Cranes and Derricks in Construction (29 CFR part 1926, subpart CC).

OMB Control Number: 1218–0261.

Affected Public: Business or other for-profits.

Number of Respondents: 209,851.

Total Responses: 2,737,482.

Frequency of Responses: On occasion.

Average Time per Response: Varies from 30 seconds (communicate employee's location to operator) to 1.5 hours (develop and document written assembly and disassembly procedures).

Estimated Total Burden Hours: 386,030 hours.

Estimated Cost (Operation and Maintenance): $2,287,745.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other materials must clearly identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2013–0021. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publically available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available from the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on September 29, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–23985 Filed 10–3–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0017]

Occupational Exposure to Noise Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

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

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend the Office of Management and

Budget's (OMB) approval of the collections of information contained in the Occupational Exposure to Noise Standard (29 CFR 1910.95).

DATES: Comments must be submitted (postmarked, sent, or received) by December 5, 2016.

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

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2010–0017, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA–2010–0017) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing collection of information requirements in accord with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The collections of information specified in the Noise Standard protect workers from suffering material hearing impairment. The collections of information contained in the Noise Standard include conducting noise monitoring; notifying workers when they are exposed at or above an 8-hour time-weighted average of 85 decibels; providing workers with initial and annual audiograms; notifying workers of a loss in hearing based on comparing audiograms; maintaining records of workplace noise exposure and workers' audiograms; and allowing workers access to materials and records required by the Standard.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed collection of information requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the collection of information requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting an adjustment increase of 115,855 burden hours (from 2,068,736 to 2,184,591 burden hours). The increase is a result of a 5.6% estimated increase in the number of workers and manufacturing establishments overall, according to U.S. Census Bureau statistics. The Agency is also requesting an adjustment increase in operation and maintenance costs from $26,296,876 to $31,242,929 (a total increase of $4,946,053), which reflects increased audiometric testing costs.

Type of Review: Extension of a currently approved collection.

Title: Occupational Exposure to Noise Standard (29 CFR 1910.95).

OMB Control Number: 1218–0048.

Affected Public: Business or other for-profits.

Number of Respondents: 221,603.

Total Responses: 15,356,111.

Frequency of Responses: Annually; On occasion.

Average Time per Response: Various.

Estimated Total Burden Hours: 2,184,591.

Estimated Cost (Operation and Maintenance): $31,242,929.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for this ICR (Docket No. OSHA–2010–0017). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of

comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627). Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as their social security number and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on September 29, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–23984 Filed 10–3–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–072)]

NASA Advisory Council; Science Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Science Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Wednesday, October 26, 2016, 1:00 p.m. to 5:45 p.m.; and Thursday, October 27, 2016, 1:00 p.m. to 5:45 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–888–790–1716 or toll number 1–212–287–1654, passcode 5882231, for both days. The WebEx link is *https://nasa.webex.com/;* the meeting number is 992 986 313 and the password is SC@Oct2016 (case sensitive), for both days.

The agenda for the meeting includes the following topics:

—Science Mission Directorate Division Updates
—Science Committee Subcommittee Reports
—Education Update

It is imperative that this meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–23872 Filed 10–3–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

[NARA–2016–054]

National Industrial Security Program Policy Advisory Committee (NISPPAC)

AGENCY: Information Security Oversight Office, National Archives and Records Administration (NARA).

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulation 41 CFR 101–6, NARA announces the following committee meeting.

DATES: The meeting will be on November 10, 2016, from 10:00 a.m. to 12:00 p.m. EDT.

ADDRESSES: National Archives and Records Administration; 700 Pennsylvania Avenue NW., Archivist's Reception Room, Room 105, Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Robert Tringali, Program Analyst, by mail at ISOO, National Archives Building; 700 Pennsylvania Avenue NW., Washington, DC 20408, by telephone at (202) 357–5335, or by email at *robert.tringali@nara.gov.* Contact ISOO at *ISOO@nara.gov* and the NISPPAC at *NISPPAC@nara.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to discuss National Industrial Security Program policy matters. The meeting will be open to the public. However, due to space limitations and access procedures, you must submit the name and telephone number of individuals planning to attend to the Information Security Oversight Office (ISOO) no later than Friday, November 4, 2016. ISOO will provide additional instructions for accessing the meeting's location.

Patrice Little Murray,

Committee Management Officer.

[FR Doc. 2016–23958 Filed 10–3–16; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2016–053]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of proposed extension request.

SUMMARY: We are proposing to use NA Form 16016, Limited Facility Report, to review the facility, environment, and staffing capabilities of non-NARA organizations that wish to borrow a National Archives Traveling Exhibit. We invite you to comment on this proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: We must receive written comments on or before December 5, 2016.

ADDRESSES: Send comments to Paperwork Reduction Act Comments (ID), Room 4400; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, fax

them to 301–713–7409, or email them to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301–837–1694, or by email at *tamee.fechhelm@nara.gov,* with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses. We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. In this notice, NARA solicits comments concerning the following information collection:

Title: Limited Facility Report.

OMB Number: 3095–00XX.

Agency Form Number: NA Form 16016.

Type of Review: Regular,

Affected Public: Not-for-profit institutions.

Estimated Number of Respondents: 75.

Estimated Time per Response: 60 minutes.

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 75 hours.

Abstract: NARA administers the National Archives Traveling Exhibits Services (NATES) in accordance with 44 U.S.C. 2108–9 to present exhibitions of its holdings and to enter into agreements under 44 U.S.C. 2305 to support such exhibitions.

NARA has developed NA Form 16016, Limited Facility Report, to serve as an application and to identify a venue's facility and environmental conditions. We provide a copy of the form, requirements for exhibition security, and regulations to the applicant. NARA needs the information contained on this form to determine whether the proposed facility meets the criteria under NARA Directive 1612, Exhibition Loans and Traveling Exhibitions.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2016–23935 Filed 10–3–16; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Permit Modification Request.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. This is the required notice of a requested permit modification.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 3, 2016. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2015–010) to Lockheed Martin Corporation (Lockheed Martin) on October 31, 2014 . Under the issued permit, Lockheed Martin, as the contractor proving operational support for the United States Antarctic Program (USAP), is responsible for waste management activities for the USAP. On August 16, 2016, the contract for USAP operational support transferred from Lockheed Martin to Leidos Innovations Group (Leidos), 7400 South Tucson Way, Centennial, CO 80112. This permit modification proposes to transfer the waste management permit (ACA 2015–010) from Lockheed Martin to Leidos, at their request, such that Leidos would become the new permit holder. All activities regulated under the permit and all other permit conditions remain the same.

DATES: October 1, 2016 to September 30, 2019.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2016–23900 Filed 10–3–16; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

Agenda

TIME AND DATE: 9:30 a.m., Tuesday, October 18, 2016.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTERS TO BE CONSIDERED:

8741A Aircraft Accident Report—Crash During Nonprecision Instrument Approach to Landing, British Aerospace HS 125–700A, N237WR, Akron, Ohio, November 10, 2015 (CEN16MA036)

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at *Rochelle.Hall@ntsb.gov* by Wednesday, October 11, 2016.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov.*

Schedule updates, including weather-related cancellations, are also available at *www.ntsb.gov.*

FOR MORE INFORMATION CONTACT: Candi Bing at (202) 314–6403 or by email at *bingc@ntsb.gov.*

FOR MEDIA INFORMATION CONTACT: Terry Williams at (202) 314–6100 or by email at *terry.williams@ntsb.gov.*

Dated: Thursday, September 29, 2016.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2016–24090 Filed 9–30–16; 4:15 pm]

BILLING CODE 7533–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

SES Performance Review Board

AGENCY: National Transportation Safety Board.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the National Transportation Safety Board, Performance Review Board (PRB).

FOR FURTHER INFORMATION CONTACT: Emily T. Carroll, Chief, Human Resources Division, Office of Administration, National Transportation Safety Board, 490 L'Enfant Plaza SW., Washington, DC 20594–0001, (202) 314–6233.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of Title 5, United States Code requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards. The board reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor and considers recommendations to the appointing authority regarding the performance of the senior executive.

The following have been designated as members of the Performance Review Board of the National Transportation Safety Board:

The Honorable T. Bella Dinh-Zarr, Vice Chairman, National Transportation Safety Board; PRB Chair.

The Honorable Robert L. Sumwalt, III; Member, National Transportation Safety Board.

Sharon W. Bryson, Director, Office of Safety Recommendations and Communications, National Transportation Safety Board.

Florence A.P. Carr, Director, Bureau of Trade Analysis, Federal Maritime Commission.

John A. Cavolowsky, Director, Airspace Operations and Safety Program, National Aeronautics and Space Administration.

Jerold Gidner, Senior Policy Advisor, Office of Natural Resources Revenue and Tribal Liaison Officer; Office of Policy, Management, and Budget; Department of the Interior (Alternate).

Candi R. Bing,

Federal Register Liaison.

[FR Doc. 2016–23867 Filed 10–3–16; 8:45 am]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Metallurgy & Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Metallurgy & Reactor Fuels will hold a meeting on October 21, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Friday, October 21, 2016—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review DG–1327, Reactivity-Initiated Accidents, which is a proposed new guide. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: *Christopher.Brown@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015, (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: September 28, 2016.

John Lai,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–23949 Filed 10–3–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Fukushima; Notice of Meeting

The ACRS Subcommittee on Fukushima will hold a meeting on October 19, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland 20852.

The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Wednesday, October 19, 2016—1:00 p.m. Until 5:00 p.m.

The Subcommittee will review Fukushima Recommendation evaluations for natural hazards other than seismic and flooding, periodic reconfirmation of natural hazards, and real time radiation monitoring. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Kathy Weaver (Telephone: 301–415–6236 or Email: *Kathy.Weaver@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown (Telephone: 240–888–9835) to be escorted to the meeting room.

Dated: September 27, 2016.

John Lai,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–23952 Filed 10–3–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Fukushima; Notice of Meeting

The ACRS Subcommittee on Fukushima will hold a meeting on October 19, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland 20852.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, October 19, 2016—8:30 p.m. Until 12:00 p.m.

The Subcommittee will discuss guidance on mitigating strategies assessment for new seismic information and the status of the mitigation of beyond-design-basis events rulemaking. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mike Snodderly (Telephone: 301–415–2241 or Email: *Mike.Snodderly@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown (Telephone: 240–888–9835) to be escorted to the meeting room.

Dated: September 27, 2016.

John Lai,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–23953 Filed 10–3–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–387, 50–388, and 72–28; NRC–2016–0187]

Susquehanna Nuclear, LLC; Susquehanna Steam Electric Station, Units 1 and 2; Consideration of Indirect License Transfer

AGENCY: Nuclear Regulatory Commission.

ACTION: Application for indirect license transfer; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of an application filed by Susquehanna Nuclear, LLC (Susquehanna Nuclear), on June 29, 2016. The application seeks NRC approval of the indirect transfer of Susquehanna Nuclear's interests in Renewed Facility Operating License Nos. NPF–14 and NPF–22 for Susquehanna Steam Electric Station, Units 1 and 2 (SSES), respectively, as well as the general license for the SSES Independent Spent Fuel Storage Installation (ISFSI), from the current parent holder, Talen Energy Corporation (Talen), to Riverstone Holdings, LLC (Riverstone). Because the application contains sensitive unclassified non-safeguards information (SUNSI) an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: Comments must be filed by November 3, 2016. A request for a hearing must be filed by October 24, 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 October 14, 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–2016–0187. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; e-mail: *Carol.Gallagher@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Hearingdocket@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

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: Tanya E. Hood, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1387; email: *Tanya.Hood@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0187 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–2016–0187.
- *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.* A publicly-available version of the application is available in ADAMS under Package Accession No. ML16181A414.
- *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–2016–0187 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The NRC is considering the issuance of an order under 10 CFR 50.80 approving the indirect transfer of control of Susquehanna Nuclear's interests in Renewed Facility Operating License Nos. NPF–14 and NPF–22 for SSES, as well as the general license for the ISFSI from Talen to Riverstone. Riverstone's portfolio companies currently hold 35 percent in the aggregate of the outstanding common stock of Talen.

According to the application for approval filed by Susquehanna Nuclear, acting on behalf of itself and Riverstone, the indirect transfer of control results from a transaction in which Talen, Susquehanna Nuclear's ultimate parent, will become wholly owned by the portfolio companies of Riverstone. As a result, all of the common stock of Talen will become privately held by affiliates of Riverstone, and Susquehanna Nuclear will become indirectly controlled by Riverstone as described in the application. Riverstone would acquire ownership of Susquehanna Nuclear's 90 percent interest in SSES. Susquehanna Nuclear will continue to operate the facility and hold the licenses.

No physical changes to SSES or operational changes are being proposed in the application.

The NRC's regulations at 10 CFR 50.80 state that no license for a production or utilization facility, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the indirect transfer of a license if the Commission determines that the proposed transaction, described above, will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the **ADDRESSES** section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and a petition to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons 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 petition is filed within 20 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 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 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 petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the 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 petitioner's interest. The petition must also set forth the specific contentions which the 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 petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion to support its position on the issue. 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 proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A 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 consistent with the NRC's regulations, policies, and procedures.

Petitions for leave to intervene must be filed no later than 20 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 20-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).

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 October 24, 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 set forth in this section, except that under 10 CFR 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

V. 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 (hereinafter ''petition''), 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, as amended at 77 FR 46562, August 3, 2012). 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 petition (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 available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/adjudicatory-sub.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 Electronic Filing Help Desk will not be able to offer assistance in using unlisted software.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a petition. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.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 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 Electronic Filing 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 Electronic Filing Help Desk is available between 9 a.m. and 7 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 stating why there is good cause for not filing electronically and 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 petition 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.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

For further details, see the application dated June 29, 2016.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

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 requestor 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 requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement

[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.

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 20 days after the requestor is granted access to that information.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff either 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 requestor 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) an officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requestor 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 proposed 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 28th day of September, 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.
20	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 requestor/petitioner reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor 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 requestor/petitioner 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 + 23	Deadline for submission of contentions whose development depends upon access to SUNSI.
A + 48	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 55	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 55	Decision on contention admission.

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[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0194]

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; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of four amendment requests. The amendment requests are for Palo Verde Nuclear Generating Station, Units 1, 2, and 3; Columbia Generating Station; Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2; and Virgil C. Summer Nuclear Station, Unit No. 1. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration. Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI) an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: Comments must be filed by November 3, 2016. A request for a hearing must be filed by December 5, 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 October 14, 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–2016–0194. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shirley J. Rohrer, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5411, email: *Shirley.rohrer@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0194, facility name, unit number(s), plant docket number, application date, and subject 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–2016–0194.
- *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 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–2016–0194, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be

considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if 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. If the Commission takes 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**. If the Commission makes 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 persons (petitioner) whose interest may be affected by this action may file a request for a hearing and a petition to intervene (petition) with respect to issuance of the amendment to the subject facility operating license or combined license. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons 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 petition 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 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 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 petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the 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 petitioner's interest. The petition must also set forth the specific contentions which the 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 petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A 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 the NRC's 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 December 5, 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 set forth in this section, except that under 10 CFR 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. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

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 (hereinafter ''petition''), 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, as amended at 77 FR 46562, August 3, 2012). 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 petition (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 available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/adjudicatory-sub.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 Electronic Filing Help Desk will not be able to offer assistance in using unlisted software.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a petition. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.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 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 Electronic Filing 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 Electronic Filing Help Desk is available between 9 a.m. and 7 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 stating why there is good cause for not filing electronically and 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 petition 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.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

Arizona Public Service Company, *et al.* (APS), Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2, and 3, Maricopa County, Arizona

Date of amendment request: July 1, 2016. A publicly-available version is in ADAMS under Accession No. ML16188A336.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendments would revise the Technical

Specifications (TSs) for PVNGS, Units 1, 2, and 3, to support the implementation of next generation fuel (NGF). In addition to the license amendment request (LAR), APS is requesting an exemption from certain requirements of 10 CFR 50.46, ''Acceptance Criteria for Emergency Core Cooling Systems [(ECCS)] for Light-Water Nuclear Power Reactors,'' and 10 CFR 50, Appendix K, ''ECCS Evaluation Models,'' to allow the use of Optimized ZIRLO™ as a fuel rod cladding material.

The proposed change will allow for the implementation of NGF including the use of Optimized ZIRLO™ fuel rod cladding material. The NGF assemblies contain advanced features to enhance fuel reliability, thermal performance, and fuel cycle economics.

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 change to TS Section 4.2.1 adds Optimized ZIRLO™ fuel rod cladding material as an acceptable material consistent with the permanent exemption request presented in Section 7 of [the] LAR.

The NRC approved topical report CENPD–404–P–A, Addendum 1–A and Addendum 2–A addresses Optimized ZIRLO™ and demonstrates that Optimized ZIRLO™ has essentially the same properties as currently licensed ZIRLO®. The fuel cladding itself is not an accident initiator and does not affect accident probability. Use of Optimized ZIRLO™ fuel cladding has been shown to meet all 10 CFR 50.46 design criteria and, therefore, will not increase the consequences of an accident.

Therefore, the proposed change to TS Section 4.2.1 does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to TS Section 5.6.5 have no impact on any plant configuration or system performance. Changes to the calculated core operating limits may only be made using NRC approved methodologies, must be consistent with all applicable safety analysis limits, and are controlled by the 10 CFR 50.59 process. The proposed changes to TS Section 5.6.5 will add the NRC approved topical reports, as described, to the list of referenced core operating analytical methods. APS has demonstrated that the limitations and conditions contained in the NRC Safety Evaluation for these topical reports, and their various supplements and revisions will be met as described in Attachment 5 to [the enclosure to APS's letter dated July 1, 2016].

Therefore, the proposed change to TS Section 5.6.5 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 to TS Section 4.2.1 adds Optimized ZIRLO™ fuel rod cladding material as an acceptable material consistent with the permanent exemption request presented in Section 7 of [the] LAR.

Use of Optimized ZIRLO™ clad fuel will not result in changes in the operation or configuration of the facility. Topical report CENPD–404–P–A demonstrated that the material properties of Optimized ZIRLO™ are similar to those of standard ZIRLO®.

Therefore, Optimized ZIRLO™ fuel rod cladding will perform similarly to those fabricated from standard ZIRLO® thus precluding the possibility of the fuel becoming an accident initiator and causing a new or different type of accident.

Therefore, the proposed change to TS Section 4.2.1 does not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes to TS Section 5.6.5 have no impact on any plant configuration or system performance. Changes to the calculated core operating limits may only be made using NRC approved methodologies, must be consistent with all applicable safety analysis limits, and are controlled by the 10 CFR 50.59 process. The proposed changes to TS Section 5.6.5 will add the NRC-approved topical reports, as described, to the list of referenced core operating analytical methods. APS has demonstrated that the limitations and conditions contained in the NRC Safety Evaluation for these topical reports, and their various supplements and revisions as identified in Attachment 5 to [the enclosure to APS's letter dated July 1, 2016], will be met as described in Section 3.2.

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 amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change to TS Section 4.2.1 adds Optimized ZIRLO™ fuel rod cladding material as an acceptable material consistent with the permanent exemption request presented in Section 7 of [the] LAR.

The proposed change will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating, transient, and accident scenarios, including both loss of coolant accident (LOCA) and non-LOCA scenarios. For LOCA scenarios, where the slight difference in Optimized ZIRLO™ material properties relative to standard ZIRLO® could have some impact on the overall accident scenario, plant-specific LOCA analyses using Optimized ZIRLO™ properties were performed. These LOCA analyses demonstrate that the acceptance criteria of 10 CFR 50.46 are satisfied when Optimized ZIRLO™ fuel rod cladding is implemented.

Therefore, the proposed change to TS Section 4.2.1 does not involve a significant reduction in a margin of safety.

The proposed changes to TS Section 5.6.5 have no impact on any plant configuration or system performance. The proposed changes to TS Section 5.6.5 will add the NRC-approved topical reports, as described, to the list of referenced core operating analytical methods. The proposed changes do not amend the cycle specific parameter limits located in the PVNGS unit specific [core operating limits report (COLR)] from the values presently required by the TS. The individual specifications continue to require operation of the plant within the bounds of the limits specified in PVNGS unit specific COLR.

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: Michael G. Green, Senior Regulatory Counsel, Pinnacle West Capital Corporation, P.O. Box 52034, Mail Station 8695, Phoenix, Arizona 85072–2034.

NRC Branch Chief: Robert J. Pascarelli.

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

Date of amendment request: June 28, 2016, as supplemented by letter dated August 18, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16183A365 and ML16231A511.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendment would revise the operating license and technical specifications to implement an increase in rated thermal power from the current licensed thermal power of 3486 megawatts thermal (MWt) to a measurement uncertainty recapture thermal power of 3544 MWt.

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 increase the Columbia Generating Station rated thermal power [(RTP)] from 3486 MWt to 3544 MWt. The reviews and evaluations performed to support the proposed uprated power conditions included all structures, systems and components that would be affected by the proposed changes. The reviews and evaluations determined that these structures, systems, and components are capable of performing their design function at the proposed uprated RTP of 3544 MWt. All accident mitigation systems will function as designed, and all performance requirements for these systems have been evaluated and were found acceptable.

Thus, the proposed changes do not create any new accident initiators or increase the probability of an accident previously evaluated.

The primary loop components (*e.g.*, reactor vessel, reactor internals, control rod drive housings, piping and supports, and recirculation pumps) remain within their applicable structural limits and will continue to perform their intended design functions.

Thus, there is no increase in the probability of a structural failure of these components.

The nuclear steam supply systems will continue to perform their intended design functions during normal and accident conditions. The balance of plant systems and components continue to meet their applicable structural limits and will continue to perform their intended design functions.

Thus, there is no increase in the probability of a failure of these components. The safety relief valves and containment isolation valves meet design sizing requirements at the uprated power level. Because the integrity of the plant will not be affected by operation at the uprated condition, Energy Northwest has concluded that all structures, systems, and components required to mitigate a transient remain capable of fulfilling their intended functions.

The current safety analyses remain applicable, since they were performed at power levels that bound operation at a core power of 3544 MWt. The results demonstrate that acceptance criteria of the applicable analyses continue to be met at the uprated conditions. As such, all applicable accident analyses continue to comply with the relevant event acceptance criteria. The analyses performed to assess the effects of mass and energy releases remain valid. The source terms used to assess radiological consequences have been reviewed and determined to bound operation at the uprated condition.

Power level is an input assumption to equipment design and accident analyses, but it is not a transient or accident initiator. Accident initiators are not affected by power uprate, and plant safety barrier challenges are not created by the proposed changes. 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.

No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed changes. The proposed changes do not adversely affect any current system interfaces or create any new interfaces that could result in an accident or malfunction of a different kind than previously evaluated. All structures, systems and components previously required for the mitigation of a transient remain capable of fulfilling their intended design functions. The proposed changes have no adverse effects on any safety-related system or component and do not challenge the performance or integrity of any safety-related system.

Plant operation at a RTP of 3544 MWt does not create any new accident initiators or precursors. Credible malfunctions are bounded by the current accident analysis of record or recent evaluations demonstrate that applicable criteria are still met with the proposed changes. Therefore, the proposed changes do 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 margins of safety associated with the power uprate are those pertaining to core thermal power. Operation at the uprated power condition does not involve a significant reduction in a margin of safety. Analyses of the primary fission product barriers have concluded that relevant design criteria remain satisfied, both from the standpoint of the integrity of the primary fission product barrier, and from the standpoint of compliance with the required acceptance criteria. As appropriate, all evaluations have been performed using methods that have either been reviewed or approved by the Nuclear Regulatory Commission, or that are in compliance with regulatory review guidance and standards.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William A. Horin, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Robert J. Pascarelli.

PSEG Nuclear LLC, Docket Nos. 50–354, 50–272, and 50–311, Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: June 30, 2016. A publicly-available version is in ADAMS under Accession No. ML16190A248.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendments would revise the Cyber Security Plan (CSP) Milestone 8 implementation schedule for Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2. Specifically, this change would extend the PSEG Nuclear LLC (PSEG) CSP Milestone 8 full implementation date as set forth in the PSEG CSP implementation schedule and revise the Facility Operating Licenses.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No

The proposed change to the CSP Implementation Schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No

The implementation of the PSEG CSP does not introduce new equipment that could create a new or different kind of accident, and no new equipment failure modes are created. No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of this proposed amendment.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change to the CSP Implementation Schedule is administrative in nature. In addition, the

milestone date delay for full implementation of the CSP has no substantive impact because other measures have been taken which provide adequate protection during this period of time. Because there is no change to established safety margins as a result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, PSEG Nuclear LLC—N21, P.O. Box 236, Hancocks Bridge, New Jersey 08038.

NRC Branch Chief: Douglas A. Broaddus.

South Carolina Electric and Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of amendment request: June 30, 2016, as supplement by letter dated August 4, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16188A105 and ML16221A034, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendment would revise the implementation date for Milestone No. 8 of the Cyber Security Plan.

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 revises the Cyber Security Plan Implementation Schedule. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change is a change to the completion date of Implementation Milestone 8, that in itself does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and have no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed 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 revises the Cyber Security Plan Implementation Schedule. This proposed change to modify the completion date of Implementation Milestone 8 does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems and components relied upon to mitigate the consequences of postulated accidents. This change also does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change revises the Cyber Security Plan Implementation Schedule. Because there is no change to these established safety margins as result of this change, the proposed change does not involve a significant reduction in a margin of safety. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn M. Sutton, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Avenue NW., Washington, DC 20004.

NRC Branch Chief: Michael T. Markley.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Arizona Public Service Company, et al. (APS), Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2, and 3, Maricopa County, Arizona

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

PSEG Nuclear LLC, Docket Nos. 50–354, 50–272, and 50–311, Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

South Carolina Electric and Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield 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]

[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 request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is provided access to that information. However, if more than 25 days remain between the date the petitioner is provided access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) an 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 proposed 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 September, 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).

the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012) 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.

Day	Event/activity
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2016–23210 Filed 10–3–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Radiation Protection and Nuclear Materials; Notice of Meeting

The ACRS Subcommittee on Radiation Protection and Nuclear Materials will hold a meeting on October 18, 2016, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, October 18, 2016—1:00 p.m. Until 5:00 p.m.

The Subcommittee will discuss the proposed final rule 10 CFR part 61, ''Low-Level Radioactive Waste Disposal'' and associated guidance. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–415–5375 or Email: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North Building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: September 28, 2016.

John Lai,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–23954 Filed 10–3–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–207 and CP2016–296, MC2016–208 and CP2016–297, MC2016–209 and CP2016–298, MC2016–210 and CP2016–299]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 5, 2016 (Comment due date applies to all Docket Nos. listed above).

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents

II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2016–207 and CP2016–296; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 36 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* October 5, 2016.

2. *Docket No(s).:* MC2016–208 and CP2016–297; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express Contract 42 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* October 5, 2016.

3. *Docket No(s).:* MC2016–209 and CP2016–298; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 32 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* October 5, 2016.

4. *Docket No(s).:* MC2016–210 and CP2016–299; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 33 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* October 5, 2016.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2016–23912 Filed 10–3–16; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Sunshine Act: Notice of Public Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on October 19, 2016, 10:00 a.m. at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois 60611. The agenda for this meeting follows:

Portion open to the public:

(1) Executive Committee Reports

The person to contact for more information is Martha P. Rico, Secretary to the Board, Phone No. 312–751–4920.

Dated: September 29, 2016.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2016–24029 Filed 9–30–16; 11:15 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78966; File No. SR–NYSE–2016–45]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, Amending the Co-Location Services Offered by the Exchange To Add Certain Access and Connectivity Fees

September 28, 2016.

On July 29, 2016, the New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (1) to provide additional information regarding access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to third party systems; and connectivity to DTCC provided to Users using data center local area networks; and (2) to establish fees relating to a User's access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to DTCC; and other services. The Exchange filed Amendment No. 1, which supersedes and replaces the proposed rule change in its entirety, on August 16, 2016.[3] The proposed rule change was published for comment in the **Federal Register** on August 17, 2016 without Amendment No. 1.[4] Amendment No. 1 was published for comment in the **Federal**

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 more closely aligns the proposed rule change with companion proposals filed by the Exchange's affiliates NYSE Arca and NYSE MKT. *See* Securities Exchange Act Release No. 34–78628 (August 22, 2016), 81 FR 59004 (August 26, 2016) (SR–NYSEArca–2016–89); Securities Exchange Act Release No. 34–78629 (August 22, 2016), 81 FR 58992 (August 26, 2016) (SR–NYSEMKT–2016–63). Amendment No. 1 is also available at *https://www.sec.gov/comments/sr-nyse-2016-45/nyse201645-1.pdf.*

[4] *See* Securities Exchange Act Release No. 34–78556 (August 11, 2016), 81 FR 54877 (''Notice'').

Register on September 26, 2016.[5] The Commission received one comment in response to the proposed rule change, as modified by Amendment No. 1.[6]

Section 19(b)(2) of the Act[7] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 1. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[8] designates November 15, 2016, as the date by which the Commission should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NYSE–2016–45), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23906 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

[5] *See* Securities Exchange Act Release No. 34–78887 (September 20, 2016), 81 FR 66095.

[6] *See* letter to Brent J. Fields, Secretary, Commission, from John Ramsay, Chief Market Policy Officer, Investors Exchange LLC (IEX), dated September 9, 2016.

In response to this Comment Letter, the NYSE submitted a response.

[7] 15 U.S.C. 78s(b)(2).

[8] *Id.*

[9] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78960; File No. SR–NSX–2016–12]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 11.26 To Implement the Regulation NMS Plan To Implement a Tick Size Pilot Program

September 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on 22 September, 2016, National Stock Exchange, Inc. (''NSX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change, as described in Items I, and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii)[4] thereunder, which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend NSX Rule 11.26 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program (the ''Plan''). The proposed rule change is substantially similar to proposed rule changes recently approved or published by the Commission for the Financial Industry Regulatory Authority, Inc. (''FINRA'') to amend FINRA Rule 6191, which also sets forth amendments to the requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan.[5] The Exchange has designated this proposal as a ''non-controversial'' proposed rule change and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.[6]

The text of the proposed rule change is available at the Exchange's Web site at *www.nsx.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] *See* Securities Exchange Act Release No. 78800 (September 9, 2016), 81 FR 63565 (September 15, 2016) (SR–FINRA–2016–35).

[6] 17 CFR 240.19b–4(f)(6)(iii).

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and statutory basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE Group, Inc., on behalf of BZX, Chicago Stock Exchange, Inc., Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., FINRA, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the Nasdaq Stock Market LLC, New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC, and NYSE Arca, Inc. (collectively ''Participants''), filed with the Commission, pursuant to Section 11A of the Act[7] and Rule 608 of Regulation NMS thereunder,[8] the Plan to Implement a Tick Size Pilot Program (''Pilot'').[9] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[10] The Plan[11] was published for comment in the **Federal Register** on November 7, 2014 and was thereafter approved by the Commission, as modified, on May 6, 2015.[12] On November 6, 2015, the Commission granted the Participants an exemption from implementing the Plan until October 3, 2016.[13] On March 3, 2016, the Commission noticed an

[7] 15 U.S.C. 78k–1.

[8] 17 CFR 242.608.

[9] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[10] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[11] Unless otherwise specified, capitalized terms used in this rule filing are based on the defined terms of the Plan.

[12] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (File No. 4–657) (''Approval Order'').

[13] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4-657) (Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program).

amendment to the Plan adding NSX as a Participant.[14]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stocks of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan. As is described more fully below, the proposed rules would require ETP Holders [15] to comply with the applicable data collection requirements of the Plan.[16]

The Pilot will include stocks of companies with $3 billion or less in market capitalization, an average daily trading volume of one million shares or less, and a volume weighted average price of at least $2.00 for every trading day. The Pilot will consist of a control group of approximately 1,400 Pilot Securities and three test groups with 400 Pilot Securities in each (selected by a stratified random sampling process).[17] During the pilot, Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group (''Test Group One'') will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[18] Pilot Securities in the second test group (''Test Group Two'') will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[19] Pilot Securities in the third test group (''Test Group Three'') will be subject to the same quoting and trading increments as Test Group Two and also will be subject to the ''Trade-at'' requirement to prevent price matching by a market participant that is not displaying at a Trading Center's ''Best Protected Bid'' or ''Best Protected Offer,'' unless an enumerated exception applies.[20] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS [21] will apply to the Trade-at requirement.

In approving the Plan, the Commission noted that the Trading Center data reporting requirements would facilitate an analysis of the effects of the Pilot on liquidity (*e.g.,* transaction costs by order size), execution quality (*e.g.,* speed of order executions), market maker activity, competition between trading venues (*e.g.,* routing frequency of market orders), transparency (*e.g.,* choice between displayed and hidden orders), and market dynamics (*e.g.,* rates and speed of order cancellations).[22] The Commission noted that Market Maker profitability data would assist the Commission in evaluating the effect, if any, of a widened tick increment on market marker profits and any corresponding changes in the liquidity of small-capitalization securities.[23]

Compliance With the Data Collection Requirements of the Plan

The Plan contains requirements for collecting and transmitting data to the Commission and to the public.[24] Specifically, Appendix B.I of the Plan (Market Quality Statistics) requires Trading Centers [25] to submit variety of market quality statistics, including information about an order's original size, whether the order was displayable or not, the cumulative number of orders, the cumulative number of shares of orders, and the cumulative number of shares executed within specific time increments, *e.g.,* from 30 seconds to less than 60 seconds after the time of order receipt. This information shall be categorized by security, order type, original order size, hidden status, and coverage under Rule 605.[26] Appendix B.I of the Plan also contains additional requirements for market orders and marketable limit orders, including the share-weighted average effective spread for executions of orders; the cumulative number of shares of orders executed with price improvement; and, for shares executed with price improvement, the share-weighted average amount per share that prices were improved.

Appendix B.II of the Plan (Market and Marketable Limit Order Data) requires Trading Centers to submit information relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, the National Best Bid and National Best Offer (''NBBO'') quoted price, the NBBO quoted depth, the average execution price-share-weighted average, and the average execution time-share-weighted average.

The Plan requires Appendix B.I and B.II data to be submitted by Participants that operate a Trading Center, and by members of the Participants that operate Trading Centers. The Plan provides that each Participant that is the Designated Examining Authority (''DEA'') for a member of the Participant that operates a Trading Center shall collect such data in a pipe delimited format, beginning six months prior to the Pilot Period and ending six months after the end of the Pilot Period. The Plan also requires the Participant, operating as DEA, to transmit this information to the SEC within 30 calendar days following month end.

Pursuant to the aforementioned requirements, the Exchange submitted and the Commission noticed a rule filing to adopt Exchange Rule 11.26(b), Compliance with Data Collection Requirements.[27] The Exchange now proposes to amend Rule 11.26(b) to modify certain data collection and reporting requirements.[28] First,

[14] *See* Securities Exchange Act Release No. 77277 (March 3, 2016), 81 FR 12162 (March 8, 2016).

[15] An ''ETP Holder'' is a registrant of NSX to which NSX has issued an ETP. An ''ETP'' is defined as ''. . . an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's trading facilities. . . .'' *See* Exchange Rule 1.5.E(1).

[16] Interpretations and Policies .11 to Rule 11.26 to [sic] provide that the Rule shall be in effect during a pilot period to coincide with the pilot period for the Plan (including any extensions to the pilot period for the Plan).

[17] *See* Section V of the Plan for identification of Pilot Securities, including criteria for selection and grouping.

[18] *See* Section VI(B) of the Plan.

[19] *See* Section VI(C) of the Plan.

[20] *See* Section VI(D) of the Plan.

[21] 17 CFR 242.611.

[22] *See* Approval Order, 80 FR at 27543.

[23] *Id.*

[24] The Exchange is also required by the Plan to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with applicable quoting and trading requirements specified in the Plan. In that regard, the Exchange adopted Rule 11.26(c), Compliance With Quoting and Trading Restrictions, describing the responsibilities of the Exchange and of ETP Holders in complying with the quoting and trading provisions of the Plan. *See* Securities Exchange Act Release No. 78391 (July 21, 2016), 81 FR 49348 (July 27, 2016) (SR–NSX–2016–05).

[25] The Plan incorporates the definition of a ''Trading Center'' from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a ''Trading Center'' as ''a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent.'' *See* 17 CFR 242.600(b).

[26] 17 CFR 242.605.

[27] *See* Securities Exchange Act Release No. 77483 (March 31, 2016), 81 FR 20040 (April 6, 2016) (SR–NSX–2016–01).

[28] FINRA, on behalf of the Participants submitted a letter to Commission requesting an exemption from certain provisions of the Plan related to data collection. *See* letter dated August 30, 2016 from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA to Robert W. Errett, Deputy Secretary, Commission. The Commission, pursuant to its authority under Rule 608(e) of Regulation NMS, granted each Participant a limited exemption from the requirement to comply with certain provisions of the Plan as specified in the letter and noted herein, as long as each Participant submits proposed rule amendments to reflect the changes. *See,* letter dated August 30, 2016 from

Continued

Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. The Exchange and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.,* without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. The Exchange, therefore, proposes to modify Interpretations and Policies .04 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. The Exchange and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. The Exchange therefore proposes to amend Interpretations and Policies .06 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and the Exchange and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). The Exchange and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are ''resting.'' The Exchange, therefore, proposes to amend Interpretations and Policies .06 to make this change.

In the fourth change, the Exchange proposes to renumber Interpretations and Policies .09 to .10 and add new Interpretations and Policies .09 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. The Exchange and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. The Exchange is therefore proposing this change as part of Interpretations and Policies .09. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. The Exchange and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and the Exchange is therefore proposing this change as part of Interpretations and Policies.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the-quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the National Best Bid or National Best Offer (NBBO) at the time of or immediately before the trade for both share and trade participation calculations. The Exchange and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. The Exchange therefore proposes to make this change as part of Interpretations and Policies .09.

Finally, the Exchange proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Interpretations and Policies .10, which is being renumbered to .11, provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Exchange and the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. Accordingly, the Exchange is revising Interpretations and Policies .10 (which will be re-numbered .11) to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[29] The Exchange will also renumber Interpretations and Policies .11 to .12.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [30] in general, and furthers the objectives of Section 6(b)(5) of the Act [31] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant of the

David S. Shillman, Associate Director, Division of Trading and Markets, Commission to Marcia E. Asquith, FINRA.

[29] NYSE, NYSE MKT, and Nasdaq published an automated list of securities eligible for the Pilot on the evening of September 2, 2016. At that time, all securities were designated for the Control Group. All securities will continue to be reflected as Control Group securities for the entire month of September 2016. On September 6, 2016, NYSE, NYSE MKT, and Nasdaq published a manual list identifying the final Test Group assignment for each eligible security.

[30] 15 U.S.C. 78f(b).

[31] 15 U.S.C. 78f(b)(5).

Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan and applies specific obligations to ETP Holders in furtherance of compliance with the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will not affect the data collection and reporting requirements for members that operate Trading Centers; the proposed changes will only affect how the Exchange and Participants that operate Trading Centers collect and report data. The Exchange notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and Exchange Rule 11.26. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, the Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From ETP Holders, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30 day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30 day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[36]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [37] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSX–2016–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NSX–2016–12. This file number should be included in the subject line if email is used. To help the Commission process and review comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. eastern time. Copies of such filings will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. Interested persons should submit only information that they wish to make available publicly.

All submissions should refer to file number SR–NSX–2016–12 and should be submitted on or before October 25, 2016.

For the Commission by the Division of Trading and Markets, pursuant to the delegated authority.[38]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23929 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[37] 15 U.S.C. 78s(b)(2)(B).

[38] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Infinex Ventures, Inc.; Order of Suspension of Trading

September 30, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Infinex Ventures, Inc. (CIK No. 0001076310) (''Infinex'') because of questions regarding the accuracy of statements in Infinex reports posted on the OTC Link operated by OTC Markets Group, Inc. and in company press releases. This includes concerns that, between May 5 and September 17, 2014, Infinex appears to have made false and misleading statements concerning its operations and financial condition, its acquisition of Marijuana Funding, Inc., and its rights to financing to develop a marijuana business. Since that time, Infinex does not appear to have made any information publicly available about itself. Infinex is a Nevada corporation whose corporate status is listed as revoked by the Nevada Secretary of State. Its principal place of business is in Denver, Colorado. Infinex's stock is quoted on OTC Link, under the ticker symbol INFX.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading of the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT on September 30, 2016 through 11:59 p.m. EDT on October 13, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–24061 Filed 9–30–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78967; File No. SR–NYSEArca–2016–89]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change Amending the Co-Location Services Offered by the Exchange To Add Certain Access and Connectivity Fees

September 28, 2016.

On August 16, 2016, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (1) to provide additional information regarding access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to third party systems; and connectivity to DTCC provided to Users using data center local area networks; and (2) to establish fees relating to a User's access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to DTCC; and other services. The proposed rule change was published for comment in the **Federal Register** on August 26, 2016.[3] The Commission received no comments in response to the proposed rule change.[4]

Section 19(b)(2) of the Act [5] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates November 24, 2016, as the date by which the Commission should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NYSEArca–2016–89).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23907 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–78628 (August 22, 2016), 81 FR 59004 (''Notice'').

[4] The Commission notes that it did receive one comment letter on a related filing, NYSE–2016–45, which is equally relevant to this filing.

In response to the comment letter, the NYSE submitted a response.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(57).

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, October 6, 2016 at 3 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 Stein, 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;

Resolution of litigation claims; 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 Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: September 29, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–24091 Filed 9–30–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78959; File No. SR–NYSEMKT–2016–71]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 8313 Relating to the Exchange's Ability To Publicly Release Disciplinary Complaints, Decisions and Other Information Modeled on the Text of FINRA Rule 8313; Amending Rules and Adopting a New Rule 9291 Relating to the Imposition of Temporary or Permanent Cease and Desist Orders To Correspond to Recent Amendments by FINRA; and Making Certain Technical and Conforming Changes to Rule 9310

September 28, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on September 19, 2016, NYSE MKT LLC (''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes amendments to Rule 8313 relating to the Exchange's ability to publicly release disciplinary complaints, decisions and other information modeled on the text of Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 8313; (2) amendments to Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 and a new Rule 9291 relating to the imposition of temporary or permanent cease and desist orders to correspond to recent amendments by FINRA to its Rule 9100, 9200, 9550, and 9800 Series; and (3) certain technical and conforming changes to Rule 9310..[sic] The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes:

(1) Amendments to Rule 8313 (Release of Disciplinary Decisions) relating to the Exchange's ability to publicly release disciplinary complaints, decisions and other information, modeled on the text of FINRA Rule 8313; [4]

(2) amendments to Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 and a new Rule 9291 relating to temporary or permanent cease and desist orders to correspond to recent amendments by FINRA to its Rule 9100, 9200, 9550, and 9800 Series; and

(3) certain technical and conforming changes to Rule 9310.[5]

Background

In 2016, NYSE MKT adopted disciplinary rules that are, with certain exceptions, substantially the same as the Rule 8000 Series and Rule 9000 Series of its affiliate the New York Stock Exchange LLC (the ''NYSE'') and FINRA, and which set forth rules for conducting investigations and enforcement actions.[6] The NYSE MKT disciplinary rules were implemented on April 15, 2016.[7]

In adopting the NYSE and FINRA disciplinary rules, NYSE MKT retained its longstanding practice of publishing all final disciplinary decisions, other than minor rule violations, on its Web site and accordingly adopted the NYSE's version of Rule 8313.[8] The NYSE had declined to adopt the text of FINRA Rule 8313, which provides that disciplinary complaints and decisions that meet certain criteria will be either published or made available upon request.[9] At the time, the Exchange was not directly performing enforcement-related regulatory functions, having entered into a Regulatory Services Agreement with FINRA in 2010 to perform those functions, among others, on the Exchange's behalf.[10]

In adopting the NYSE and FINRA disciplinary rules, the Exchange adopted NYSE's and FINRA's rules and procedures for imposing temporary or permanent cease and desist orders. In particular, the Exchange adopted NYSE and FINRA Rule 8310 as NYSE MKT Rule 8310, which, among other things, allows the Exchange to impose a temporary or permanent cease and desist order.[11] NYSE MKT Rule 9290, based on NYSE and FINRA Rule 9290, provides for expedited disciplinary proceedings.[12] Rule 9556, based on NYSE and FINRA Rule 9556, provides procedures and consequences for a failure to comply with temporary and permanent cease and desist orders. The

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] References to rules are to NYSE MKT rules unless otherwise indicated.

[5] In addition, the Exchange proposes the following technical and conforming changes to the harmonized rules: (1) Including the terms ''member,'' ''member organization,'' ''ATP Holder,'' ''covered person,'' and ''person'' as defined in the NYSE MKT rules where appropriate in the following Rules to reflect the Exchange's equities and options membership: 8313, 9120, 9269, 9291, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, and 9840; (2) substituting the term ''Exchange'' for ''FINRA''; (3) changing certain cross-references to FINRA rules to cross-references to Exchange rules; (4) substituting a reference to the Exchange's Chief Regulatory Officer for a reference to a senior officer at FINRA; and (5) changing certain references to Adjudicators to make them consistent with references to Adjudicators throughout the Rule 9000 Series.

[6] *See* Securities Exchange Act Release Nos. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30) (''2016 Notice'').

[7] *See* NYSE MKT Information Memorandum 16–02 (March 14, 2016).

[8] 2016 Notice, 81 FR at 11321.

[9] *See* Securities Exchange Act Release Nos. 69045 (March 5, 2013), 78 FR 15394, 15395 (March 11, 2013) (SR–NYSE–2013–02).

[10] *See* Securities Exchange Act Release No. 62354 (June 22, 2010), 75 FR 36730, 36731 (June 28, 2010) (SR–NYSEAmex–2010–57), as corrected by 75 FR 38860 (July 6, 2010) (SR–NYSEAmex–2010–57) (C1–2010–15649).

[11] 2016 Notice, 81 FR at 11321.

[12] *Id.* at 11328. Under Rule 9290, for any disciplinary proceeding, the subject matter of which also is subject to a temporary cease and desist proceeding initiated pursuant to Rule 9810 or a temporary cease and desist order, hearings are required to be held and decisions rendered at the earliest possible time. *See id.*

Exchange also adopted the NYSE and FINRA Rule 9800 Series, which sets forth the procedures for issuing temporary cease and desist orders, as the NYSE MKT Rule 9800 Series.[13]

In 2015, FINRA adopted a series of amendments to its substantive and procedural rules governing temporary and permanent cease and desist orders.[14] In particular, FINRA amended its Rule Series 9800 to, among other things, revise the evidentiary standard for finding a violation to ''a showing of likelihood of success on the merits.'' [15] FINRA also amended its Rules 9120, 9268, 9269, 9270, 9291,[16] 9551, 9552,[17] 9554, 9555, 9556, 9557, 9558, 9559, 9810,[18] 9830, 9840, 9850 and 9860 to adopt a new expedited proceeding for failure to comply with a temporary cease and desist order or a permanent cease and desist order; harmonized the provisions governing how documents are served in temporary cease and desist proceedings and related expedited proceedings; clarified the process for issuing permanent cease and desist orders; eased FINRA's administrative burden in temporary cease and desist proceedings; and made conforming changes throughout its Code of Procedure.[19]

On January 1, 2016, the Exchange reintegrated certain regulatory functions previously performed on its behalf by FINRA.[20] Among other things, the Exchange now directly performs enforcement-related regulatory functions, including investigating potential violations of Exchange rules, and bringing enforcement actions and conducting disciplinary proceedings arising out of such investigations.

Proposed Rule Change

Amendments to Rule 8313 Governing Release of Disciplinary Complaints, Decisions and Other Information Based on FINRA Rule 8313

Rule 8313 currently provides that the Exchange shall publish a copy of final disciplinary actions under the Rule 9000 Series, other than minor rule violations, on its Web site. The Exchange proposes to restructure Rule 8313 and add four subsections and text modeled on FINRA Rule 8313, as described below. The scope of proposed Rule 8313 would be limited to publication of materials relating to the disciplinary process set forth in the Rule 8000 and 9000 Series. In that regard, the Exchange has determined not to adopt the FINRA rule in all respects at this time.

General Standards

The Exchange proposes to add a new subsection (a) to Rule 8313 entitled ''General Standards'' and text that would set forth general standards for the release to the public of disciplinary complaints, decisions or information.

Proposed Rule 8313(a)(1) would retain, as modified, the current text of Rule 8313. The word ''publish'' would be replaced with ''release to the public'' to conform to the FINRA rule. The phrase ''final disciplinary action'' would be deleted as unnecessary in light of the more detailed provisions throughout the proposed Rule. The proposed Rule would provide that the Exchange shall release to the public a copy of and, at the Exchange's discretion, information with respect to, any disciplinary complaint or disciplinary decision issued by the Exchange, as defined in proposed Rule 8313(e) under the Rule 9000 Series, other than minor rule violations, on its Web site. Proposed Rule 8313(a)(1) would also provide that, in response to a request, the Exchange shall also release to the requesting party a copy of any identified disciplinary complaint or disciplinary decision issued by the Exchange, as defined in proposed Rule 8313(e). These proposed amendments are modeled on FINRA Rule 8313(a)(1) and would be substantially similar to the FINRA rule.

Proposed Rule 8313(a)(2) provides that the Exchange shall release to the public a copy of, and at the Exchange's discretion information with respect to, any statutory disqualification decision, notification, or notice issued by the Exchange pursuant to the Rule 9520 Series that will be filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') and any temporary cease and desist order or decision issued by the Exchange pursuant to the Rule 9800 Series. Proposed Rule 8313(a)(2) is modeled on FINRA Rule 8313(a)(2) but would substitute the term ''Exchange'' for ''FINRA.''

Proposed Rule 8313(a)(3) provides that the Exchange shall release to the public information with respect to any suspension, cancellation, expulsion, or bar that constitutes final Exchange action imposed pursuant to Rules 9552, 9554,[21] 9555, 9556, and 9558, as well as information with respect to any suspension imposed pursuant to Rule 9557. Proposed subsection (a)(3) would also provide that the Exchange shall release to the public a copy of, and information with respect to, any decision issued pursuant to Rule 9559 that constitutes final Exchange action. Further, the proposed subsection would provide that the Exchange shall release to the public information with respect to the summary suspension or expulsion of a member organization or the summary revocation of the registration of a covered person for a failure to pay fines, other monetary sanctions, or costs pursuant to Rule 8320. Proposed Rule 8313(a)(3) is modeled on FINRA Rule 8313(a)(3) but would (1) exclude failure to pay Exchange fees from its scope; [22] (2) substitute the term ''Exchange'' for ''FINRA''; and (3) use the terms ''member organization'' and ''covered person'' rather than ''member'' and ''person associated with a member,'' which have different meanings under FINRA and Exchange rules.[23]

[13] *Id.* at 11332.

[14] *See* Securities Exchange Act Release Nos. 75333 (June 30, 2015), 80 FR 38783 (July 7, 2015) (SR–FINRA–2015–019) (''2015 FINRA Notice''), 75629 (August 6, 2015), 80 FR 48379 (August 12, 2015) (SR–FINRA–2015–019) (''2015 FINRA Filing'').

[15] *Id.* at 48379.

[16] FINRA also amended its Rules 9348 (Powers of the National Adjudicatory Council on Review) and 9351 (Discretionary Review by FINRA Board). The Exchange did not adopt either rule and instead, like the NYSE, retained the substance of its appeals process.

[17] FINRA also amended Rule 9553, which concerns failure to pay fees, dues, assessments or other charges. The Exchange, following the NYSE, did not adopt FINRA Rule 9553 in 2016. *See* 2016 Notice, 81 FR at 11330.

[18] FINRA also amended Rule 9820 (Appointment of Hearing Officers and Hearing Panel) to expand the pool of persons eligible to serve on hearing panels in order to ease certain administrative burdens on FINRA's Office of Hearing Officers. See 2015 FINRA Filing, 80 FR at 48380. The Exchange is not adopting these changes.

[19] *Id.* at 48379. The Exchange's affiliate NYSE recently (1) amended the text of its Rule 8313; (2) amended its Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 and adopted a new Rule 9291 relating to temporary or permanent cease and desist orders to correspond to the recent FINRA amendments to its Rule 9100, 9200, 9550, and 9800 Series; and (3) made certain technical and conforming amendments to its Rule 9310. *See* Securities Exchange Act Release No. 78664 (August 24, 2016), 81 FR 59678 (August 30, 2016) (SR–NYSE–2016–40).

[20] *See* 2016 Notice, 81 FR at 11312, n. 11.

[21] FINRA's version of Rule 8313 also includes a reference to FINRA Rule 9553, which relates to failure to pay FINRA dues, fees and other charges. In 2016, the Exchange adopted the text of FINRA Rule 8320, which addresses the non-payment of fines and monetary sanctions, but did not adopt FINRA Rule 9553. *See* 2016 Notice, 81 FR at 11321 and note 16 [sic], *supra.* Instead, the Exchange adopted Rule 41, which relates to failure to pay Exchange fees and other amounts due to the Exchange. *See* 2016 Notice, 81 FR at 11317. Inasmuch as the scope of the proposed rule change would be limited to publication of materials relating to the disciplinary process under the Rule 8000 and 9000 Series, the Exchange proposes to include Rule 8320 but not Rule 41 within the scope of proposed Rule 8313(a)(3).

[22] *See* note 21, *supra.*

[23] Under FINRA Rules, a ''member'' means an individual, partnership, corporation or other legal

Proposed Rule 8313(a)(4) provides that the Exchange may release to the public a copy of, and information with respect to, any decision or notice issued pursuant to the Rule 9600 Series, and any other decision appealable to the SEC under Exchange Act Section 19(d). Proposed Rule 8313(a)(4) is modeled on FINRA Rule 8313(a)(5). FINRA Rule 8313(a)(5) also contains cross references to FINRA Rule 6490 and the FINRA Rule 9700 Series. FINRA Rule 6490 (Processing of Company-Related Actions) applies to issuers of non-exchange listed equity and debt securities quoted on the OTC marketplace. FINRA's Rule 9700 Series provides redress for persons aggrieved by the operations of any automated quotation, execution, or communication system owned or operated by FINRA. FINRA Rule 6490 has no analogue in the Exchange's Rules. The Exchange does not propose to include either Rule 18—Equities, which addresses compensation in connection with an Exchange system failure, or Rule 905NY, which addresses Exchange liability for use of its options trading platform, within the scope of Rule 8313. As noted above, the Exchange has determined to limit the scope of Rule 8313 to publication of materials relating to the disciplinary process under the Rule 8000 and 9000 Series.[24] The Exchange would also substitute the term ''Exchange'' for ''FINRA.'' [25]

Release Specifications

The Exchange proposes to add a new subsection (b) to Rule 8313 entitled ''Release Specifications'' modeled on FINRA Rules 8313(b)(1) and (2).

Proposed Rule 8313(b)(1) provides that copies of, and information with respect to, any disciplinary complaint released to the public pursuant to paragraph (a) of the proposed Rule shall indicate that a disciplinary complaint represents the initiation of a formal proceeding by the Exchange in which findings as to the allegations in the complaint have not been made and does not represent a decision as to any of the allegations contained in the complaint. The proposed Rule would be the same as FINRA Rule 8313(b)(1) except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

Proposed Rule 8313(b)(2) provides that copies of, and information with respect to, any disciplinary decision or other decision, order, notification, or notice released to the public pursuant to paragraph (a) of the proposed Rule prior to the expiration of the time period provided for an appeal or call for review as permitted under Exchange rules or the Exchange Act, or while such an appeal or call for review is pending, shall indicate that the findings and sanctions imposed therein are subject to review and modification by the Exchange or the SEC. The proposed Rule would be the same as FINRA Rule 8313(b)(2) except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

Discretion To Redact Certain Information or Waive Publication

The Exchange has determined that, subject to limited exceptions, disciplinary information should be released to the public in unredacted form. The Exchange proposes to add a new subsection (c) to Rule 8313 entitled ''Discretion to Redact Certain Information or Waive Publication,'' modeled on FINRA Rule 8313(c)(1) and (2).

With respect to the limited exceptions, proposed Rule 8313(c)(1) would provide that the Exchange reserves the right to redact, on a case-by-case basis, information that contains confidential customer information, including customer identities, or information that raises significant identity theft, personal safety, or privacy concerns that are not outweighed by investor protection concerns. The proposed Rule would be the same as FINRA Rule 8313(c)(1) except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

Similarly, proposed Rule 8313(c)(2) provides that, notwithstanding paragraph (a) of the proposed rule, the Exchange may determine, in its discretion, to waive the requirement to release a copy of, or information with respect to, any disciplinary complaint, disciplinary decision or other decision, order, notification, or notice under those extraordinary circumstances where the release of such information would violate fundamental notions of fairness or work an injustice. The proposed Rule would be the same as FINRA Rule 8313(c)(1) [sic] except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

Notice of Appeals of Exchange Decisions

The Exchange proposes to add a new subsection (d) to Rule 8313 entitled ''Notice of Appeals of Exchange Decisions to the SEC'' modeled on FINRA Rule 8313(d). Proposed Rule 8313(d) provides that the Exchange must provide notice to the public when a disciplinary decision of the Exchange is appealed to the SEC and that the notice shall state whether the effectiveness of the decision has been stayed pending the outcome of proceedings before the Commission. The proposed Rule would be the same as FINRA Rule 8313(d)(1) except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

Definitions

Finally, the Exchange proposes to add a new subsection (e) to Rule 8313 entitled ''Definitions.'' Proposed Rule 8313(e) would set forth definitions of the terms ''disciplinary complaint'' and ''disciplinary decision'' as used in the Rule, modeled on the definitions contained in FINRA Rule 8313(e).

First, Rule 8313(e)(1) would define the term ''disciplinary complaint'' to mean any complaint issued pursuant to the Rule 9200 Series. The proposed text is identical to FINRA Rule 8313(e)(1).

Second, Rule 8313(e)(2) would define the term ''disciplinary decision'' to mean any decision issued pursuant to the Rule 9000 Series, including,

entity admitted to membership in FINRA under Articles III and IV of the FINRA By-Laws. *See* FINRA Rule 0160(b)(10). Article III, Sec. 1(a) of the FINRA By-Laws generally limits membership to registered brokers, dealers, municipal securities brokers or dealers, or government securities brokers or dealers. NYSE MKT's equivalent term is ''member organization.'' *See* Rule 2(b)(i)—Equities (defining ''member organization'' as a registered broker or dealer (unless exempt pursuant to the Act) that is a member of FINRA or another registered securities exchange). Under Rule 2(a)—Equities, the term ''member'' means a natural person associated with a member organization who has been approved by the Exchange and designated by such member organization to effect transactions on the floor of the Exchange or any facility thereof. A ''member'' is not a registered broker-dealer and does not have employees; only member organizations have employees. An ''ATP Holder,'' on the other hand, may be a natural person or an organization, and can thus be a member or member organization. *See* Rule 900.2NY(5). Further, a natural person who is an ATP Holder may have registered or non-registered employees. *See id.* For purposes of the proposed amendments to its disciplinary rules, the Exchange proposes to continue using the phrase ''covered person'' to indicate employees of a member organization or ATP Holder. *See* 2016 Notice, 81 FR at 11318. The Exchange also proposes to use the term ''ATP Holder'' where appropriate in the proposed rules.

[24] For the same reasons, the Exchange also does not propose to adopt FINRA Rule 8313(a)(6), which provides that that FINRA may release to the public a copy of, and information with respect to, any complaint, decision, order, notification or notice issued under FINRA rules, where the release of such information is deemed by FINRA's CEO (or such other senior officer as the CEO may designate) to be in the public interest, in such format as he or she finds appropriate.

[25] The Exchange is not proposing to adopt rule text similar to FINRA Rule 8313(a)(4), which provides that FINRA may release to the public a copy of, and information with respect to, any decision or notice issued pursuant to NASD Rules 1015 and 1016 governing appeals from adverse membership and continuing membership decisions. As noted above, the Exchange has determined to limit the scope of Rule 8313 to publication of materials relating to the disciplinary process under the Rule 8000 and 9000 Series.

decisions issued by a Hearing Officer, Hearing Panel, Extended Hearing Panel, or the Board of Directors, and orders accepting offers of settlement, and Letters of Acceptance, Waiver and Consent. Under proposed subsection (e)(2), the term would not include decisions issued pursuant to the Rule 9550 Series, Rule 9600 Series, or Rule 9800 Series, or decisions, notifications, or notices issued pursuant to the Rule 9520 Series, which are addressed by paragraphs (a)(2), (a)(3) and (a)(4) of the proposed Rule. Finally, Rule 8313(e)(2) provides that minor rule violation plan letters issued pursuant to Rules 9216 and 9217 are not subject to the proposed Rule. The proposed Rule would be the same as FINRA Rule 8313(e)(2) except that the proposed Rule would substitute the term ''Exchange'' for ''FINRA.''

* * * * *

The Exchange believes that greater access to information regarding disciplinary actions provides valuable guidance and information to member organizations, associated persons, other regulators, and investors.[26] Further, releasing detailed disciplinary information to the public can serve to deter and prevent future misconduct and improve overall business standards in the securities industry as well as allowing investors to consider firms' and representatives' disciplinary histories when considering whether to engage in business with them.[27] Publishing more detailed information than the Exchange currently does would also allow member organizations to utilize that information to educate associated persons as to compliance matters, highlight potential violations and related sanctions, as well as inform the firms' compliance procedures involving similar business lines, products, or industry practices. Finally, the Exchange believes that any member organization or individual facing allegations of rule violations would also have access to more information to gain greater insight on related facts and sanctions.[28]

Harmonization With FINRA Rules Relating to Temporary or Permanent Cease and Desist Orders

The Exchange also proposes to harmonize its disciplinary rules and procedures relating to the imposition of temporary and permanent cease and desist orders with approved FINRA amendments. To effectuate these changes, the Exchange proposes the following amendments to Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, and 9830, 9840, 9850, and 9860. The Exchange also proposes to adopt a new Rule 9291 based on FINRA's recently adopted Rule 9291.

- The Exchange proposes to amend the Rule 9120 definitions applicable to the Rule 9000 Series as follows:
  - The Exchange proposes to amend the definition of ''Hearing Panel'' in Rule 9120(s) to encompass a Hearing Panel constituted under the Rule 9800 Series to conduct a temporary cease and desist proceeding.
  - The Exchange proposes to amend the definition of ''Interested Staff'' in Rule 9120(t)(A) to encompass any staff that issues a petition under the Rule 9000 Series.[29]
  - The Exchange proposes to amend the definition of ''Panelist'' in Rule 9120(v) to encompass the use of the term in the Rule 9550 Series and the Rule 9800 Series.
  - Finally, the Exchange proposes to amend the definition of ''Respondent'' in Rule 9120(y) to provide that in a proceeding governed by the Rule 9800 Series, the term ''Respondent'' means a member organization or covered person that has been served with a notice initiating a cease and desist proceeding.
- Rule 9268 sets forth the timing and the contents of a decision of the Hearing Panel or Extended Hearing Panel and the procedures for a dissenting opinion, service of the decision, and any requests for review. The Exchange proposes to amend Rule 9268(b), which sets forth the contents of a panel decision, by adding a new subsection (7), providing that when the sanctions include a permanent cease and desist order, the decision should include a statement that is consistent with the requirements of Rule 9291(a) concerning the content, scope, and form of a permanent cease and desist order. The proposed change is identical to that recently adopted by FINRA to its version of Rule 9268.
- Rule 9269 governs the process for the issuance and review of default decisions when a Respondent fails to timely answer a complaint or fails to appear at a pre-hearing conference or hearing where due notice has been provided. The Exchange proposes to amend Rule 9269(a), governing issuance of default decisions, to add a new subsection (4) that provides that the Office of Hearing Officers shall provide a copy of the default decision to each member organization or ATP Holder with which a Respondent is associated. The proposed change is identical to recently adopted FINRA Rule 9269(a)(4), except for conforming references to member organizations.
- Rule 9270 provides a settlement procedure for a Respondent who has been notified that a proceeding has been instituted against him or her. The Exchange proposes two amendments to this Rule. First, the Exchange would amend Rule 9270(c), which details the content and signature requirements for offers of settlement, to add a new subsection (7) providing that, if applicable, the offer should describe in detail a proposed permanent cease and desist order to be imposed that is consistent with the requirements of proposed Rule 9291(a) concerning the content, scope, and form of a permanent cease and desist order. This proposed amendment is substantially the same as recently adopted FINRA Rule 9270(c)(6).[30]

Second, the Exchange proposes to add the phrase ''including, if applicable, a permanent cease and desist order'' to Rule 9270(f)(1), governing uncontested offers of settlement, and a sentence to Rule 9270(f)(3) providing that Enforcement shall provide a copy of an issued order of acceptance to each member organization or ATP Holder with which a Respondent is associated. The proposed amendments are identical to FINRA Rules 9270(e)(1) and 9270(e)(3), respectively, except for conforming references to the Exchange's Enforcement group, member organizations and ATP Holders.

- The Exchange proposes to amend the notice and service requirements for expedited proceedings under the Rule 9550 Series, by providing for service upon counsel and service by email. Specifically, the Exchange proposes to make amendments to subsection (b) of the following Rules, consistent with recent changes to the counterpart FINRA rules, regarding service on

[26] *See* Securities Exchange Act Release Nos. 69178 (March 19, 2013), 78 FR 17975, 17976 (March 25, 2013) (SR–FINRA–2013–018) and 69825 (June 21, 2013), 78 FR 38771, 38775 (June 27, 2013) (SR–FINRA–2013–018).

[27] *See* Release No. 69178, 78 FR at 17976.

[28] *See id.*

[29] The Exchange adopted the NYSE's streamlined definition of ''Interested Staff'' in Rule 9120(t) and, as a result, the NYSE MKT and FINRA definitions of ''Interested Staff'' are organized differently. *See* 2016 Notice, 81 FR at 11322. However, both definitions encompass supervisory personnel up to the most senior level, including the CRO, when staff reporting to such supervisory personnel directly participated in a matter. *See* Securities Exchange Act Release No. 76436 (November 13, 2015), 80 FR 72460, 72462 (November 19, 2015) (June 27, 2013) (SR–NYSE–2015–35). The proposed change to Rule 9120(t)(A) would bring any staff that issues a petition under the Rule 9000 Series within the ambit of the definition, and thus remain consistent with the FINRA definition, as amended, in the 2015 FINRA Filing.

[30] The Exchange also proposes a non-substantive amendment at the end of Rule 9270(c)(5) to delete the word ''and'', and non-substantive amendments at the end of Rule 9270(c)(6) to delete a period, add a semicolon, and add the word ''and.''

counsel or other representative and the requirements for service by email:

○ The Exchange proposes to add a clause to the first sentence of subsection (b) of Rule 9551 (Failure to Comply with Public Communication Standards), which governs expedited proceedings relating to a member or member organization's departure from the public communication standards of Rule 2210, providing that Regulatory Staff shall alternatively serve counsel representing the member or member organization, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member or member organization with the required notice under the Rule and that the notice can also be provided by email.

The Exchange proposes to delete the sentence, ''When counsel for the member or member organization or other person authorized to represent others under Rule 9141 agrees to accept service of such notice, then Regulatory Staff may serve notice on counsel or other person authorized to represent others under Rule 9141 as specified in Rule 9134,'' and add a sentence to the end of subsection (b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with subsections (a)(1) and (3) and (b)(1) and (2) of Rule 9134.

The Exchange would also add text providing that the papers served on counsel for a member or member organization, or other person authorized to represent others under Rule 9141, by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with Rule 9134(a)(1) and (3). Finally, the Exchange would add a sentence specifying that service is complete upon sending the notice by email, mailing the notice by U.S. Postal Service first class mail, first class certified mail, first class registered mail, or Express Mail, sending the notice through a courier service, or delivering it in person, except that, where duplicate service is required, service is complete when the duplicate service is complete;

○ Rule 9552 (Failure to Provide Information or Keep Information Current), which sets forth procedures for expedited proceedings relating to a member organization or covered person's failure to provide information or keep information current, would be amended to add a clause to the first sentence of subsection (b) providing that Regulatory Staff shall alternatively serve counsel representing the member organization or covered person, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member organization or covered person with the required notice under the Rule and that the notice can also be provided by email.

The Exchange proposes to delete the sentence, ''When counsel for the member organization or covered person, or other person authorized to represent others under Rule 9141 agrees to accept service of such notice, then Regulatory Staff may serve notice on counsel or other person authorized to represent others under Rule 9141 as specified in Rule 9134,'' and add a sentence to the end of Rule 9552(b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134.

Further, the proposed rule text would provide that papers served on a person by email shall be sent to the person's last known email address and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) of Rule 9134. The proposed amendment would specify that papers served on counsel for a member organization or covered person, or other person authorized to represent others under Rule 9141, by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with Rule 9134(a)(1) and (3). Finally, the proposed amendment would provide that service is complete upon sending the notice by email, mailing the notice by U.S. Postal Service first class mail, first class certified mail, first class registered mail, or Express Mail, sending the notice through a courier service, or delivering it in person, except that, where duplicate service is required, service is complete when the duplicate service is complete;

○ The Exchange proposes to add a clause to the first sentence of subsection (b) of Rule 9554 (Failure to Comply with an Arbitration Award or Related Settlement or an Order of Restitution or Settlement Providing for Restitution), which governs expedited proceedings relating to noncompliance with an arbitration award, settlement agreement, or restitution order, providing that Regulatory Staff shall alternatively serve counsel representing the member organization or covered person, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member organization or covered person with the required notice under the Rule and that the notice can also be provided by email.

The Exchange would also delete the sentence, ''When counsel for the member organization or covered person, or other person authorized to represent others under Rule 9141 agrees to accept service of such notice, then Regulatory Staff may serve notice on counsel or other person authorized to represent others under Rule 9141 as specified in Rule 9134,'' and add a sentence to the end of Rule 9554(b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134.

Further, the proposed amendment would specify that papers served on a person by email shall be sent to the person's last known email address and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) of Rule 9134.

The proposed amendment would also specify that papers served on counsel for a member organization or covered person, or other person authorized to represent others under Rule 9141, by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) of Rule 9134.

Finally, the proposed amendment would provide that service is complete upon sending the notice by email, mailing the notice by U.S. Postal Service first class mail, first class certified mail, first class registered mail, or Express Mail, sending the notice through a courier service, or delivering it in person, except that, where duplicate service is required, service is complete when the duplicate service is complete;

○ The Exchange proposes to add a clause to the first sentence of subsection (b) of Rule 9555 (Failure to Meet the Eligibility or Qualification Standards or

Prerequisites for Access to Services), which governs expedited proceedings in connection with the failure to meet the eligibility or qualification standards or prerequisites for access to services offered by the Exchange, providing that Exchange staff shall alternatively serve counsel representing the member organization or covered person, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member organization or covered person with the required notice under the Rule and that the notice can also be provided by email.

The Exchange would also delete the sentence, ''When counsel for the member organization or covered person, or other person authorized to represent others under Rule 9141 agrees to accept service of such notice, then Exchange staff may serve notice on counsel or other person authorized to represent others under Rule 9141 as specified in Rule 9134,'' and add a sentence to the end of Rule 9554(b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134.

Further, the proposed amendment would specify that papers served on a person by email shall be sent to the person's last known email address and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) of Rule 9134. The proposed amendment would also specify that the papers served on counsel for a member organization or covered person, or other person authorized to represent others under Rule 9141, by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with Rule 9134(a)(1) and (3).

Finally, the proposed amendment would provide that service is complete upon sending the notice by email, mailing the notice by U.S. Postal Service first class mail, first class certified mail, first class registered mail, or Express Mail, sending the notice through a courier service, or delivering it in person, except that, where duplicate service is required, service is complete when the duplicate service is complete;

○ The Exchange proposes to amend subsection (b) of Rule 9556 (Failure to Comply with Temporary and Permanent Cease and Desist Orders), which governs expedited proceedings relating to noncompliance with a temporary or permanent cease and desist order, to add the word ''email'' to the list of service methods in the first sentence. The proposed Rule would therefore permit Regulatory Staff to serve the member organization or covered person subject to a notice issued under the Rule (or upon counsel representing the member organization or covered person, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept) by email in addition to overnight courier or personal delivery.

The Exchange would also add a sentence to subsection (b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134. Further, the proposed amendment would specify that papers served on a person by email shall be sent to the person's last known email address and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) of Rule 9134. The proposed amendment would also specify that the papers served on counsel for a member organization or covered person, or other person authorized to represent others under Rule 9141 by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with Rule 9134(a)(1) and (3).

Finally, the Exchange proposes to amend the last sentence of subsection (b) to provide that service is complete upon ''sending'' rather than ''mailing,'' which word would be deleted; adding the phrase ''email or'' to the list of service methods; and adding an exception clause providing that ''except that, where duplicate service is required, service is complete upon sending the duplicate service'';

○ Rule 9557 (Procedures for Regulating Activities Under Rules 470, 471, 4110—Equities, 4120—Equities and 4130—Equities Regarding a Member or Member Organization Experiencing Financial or Operational Difficulties), which allows the Exchange to issue a notice directing a member organization to comply with the provisions of Rule 470 (Capital Requirements for Members and Member Organizations), 471 (Business Expansion Restrictions and Business Reduction Requirements), 4110—Equities (Capital Compliance), 4120—Equities (Regulatory Notification and Business Curtailment) or 4130—Equities (Regulation of Activities of Section 15C Member Organizations Experiencing Financial and/or Operational Difficulties) or restrict its business activities, either by limiting or ceasing to conduct those activities consistent with Rule 470, 471, 4110—Equities, 4120—Equities or 4130—Equities, would be amended to add a clause to the first sentence of subsection (b) providing Exchange staff shall alternatively serve counsel representing the member or member organization, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member or member organization and that the notice can also be provided by email. The Exchange would also amend the second sentence of subsection (b) referencing the rules to which papers served by overnight courier or personal delivery must conform by adding a reference to Rule 9134(b)(1) before the existing reference to paragraph (b)(2) of Rule 9134.

The Exchange would also add a sentence to subsection (b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134. Further, the proposed amendment would specify that papers served on counsel for a member or member organization or other person authorized to represent others under Rule 9141 by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) of Rule 9134.

Finally, the last sentence of subsection (b) would be amended to reflect that service is complete upon ''sending'' rather than ''mailing,'' which word would be deleted; adding the phrase ''email or'' to the list of service methods; and adding an exception clause providing that ''except that, where duplicate service is required, service is complete upon sending the duplicate service''; and

○ Subsection (b) of Rule 9558 (Summary Proceedings for Actions Authorized by Section 6(d)(3) of the Exchange Act), which allows the

Exchange's Chief Regulatory Officer to provide written authorization to Exchange staff to issue a written notice for a summary proceeding for an action authorized by Section 6(d)(3) of the Act, would be amended to add a clause to the first sentence providing Exchange staff shall alternatively serve counsel representing the member organization or covered person, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the member organization or covered person and adding ''email'' to the list of service methods.

The Exchange would also add a sentence to subsection (b) providing that papers served on a member or member organization by email shall be sent to the email address on file with the Exchange and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) and (2) of Rule 9134.

Papers served on a person by email shall be sent to the person's last known email address and shall also be served by either overnight courier or personal delivery in conformity with paragraphs (a)(1) and (3) and (b)(1) of Rule 9134. Further, the proposed amendment would specify that papers served on counsel for a member organization or covered person, or other person authorized to represent others under Rule 9141 by email shall be sent to the email address that counsel or other person authorized to represent others under Rule 9141 provides and shall also be served by either overnight courier or personal delivery in conformity with Rule 9134(a)(1) and (3).

Finally, the last sentence of subsection (b) would be amended to reflect that service is complete ''sending'' rather than ''mailing,'' which word would be deleted; adding the phrase ''email or'' to the list of service methods; and adding an exception clause providing that ''except that, where duplicate service is required, service is complete upon sending the duplicate service.''

• With the exception of conforming changes to reflect the Exchange's membership, omission of service by facsimile,[31] and omission of a reference to ''the email address listed in the FINRA Contact System submitted to FINRA pursuant to Article 4, Section III of the FINRA By-Laws,'' [32] the text of the proposed amendments to NYSE MKT Rules 9551, 9552, 9554, 9555, 9556, 9557, and 9558 is substantially similar to that of FINRA Rules 9551, 9552, 9554, 9555, 9556, 9557, and 9558.

• The Exchange proposes amending Rule 9556(g) to add the phrase, ''imposed after the process described in paragraphs (a) through (f) of'' (and delete the word ''under'') before the phrase, ''this Rule,'' to conform to the recent changes to FINRA Rule 9556(g). The Exchange believes that the proposed change adds greater specificity to the Rule.

• The Exchange also proposes adding a new subsection (h) to Rule 9556 titled ''Subsequent Proceedings,'' permitting Regulatory Staff (with prior written authorization from the CRO) to file a petition seeking a hearing if the subject of a temporary or permanent cease and desist order fails to comply with that order and has previously been served with a notice under Rule 9556(a) for a failure to comply with any provision of the same temporary or permanent cease and desist order.

○ Under the proposed Rule, the petition shall be served in accordance with Rule 9556(b) and filed with the Office of Hearing Officers.[33] The proposed Rule would also require the petition to explicitly identify the provision of the permanent or temporary cease and desist order that is alleged to have been violated; contain a statement of facts specifying the alleged violation; describe with particularity the sanctions that Regulatory Staff seeks to have imposed; and note that a hearing under Rule 9559 is requested. Regulatory Staff may seek the imposition of any fitting sanction.[34]

○ Proposed Rule 9556(h)(3) provides that, in contrast to other Rule 9556 proceedings, a Respondent's compliance with the temporary or permanent cease and desist order is not a ground for dismissing the Rule 9556(h) proceeding. Thus, a Respondent's compliance with a temporary or permanent cease and desist order after a Rule 9556(h) proceeding has been initiated would not prevent an adjudicator from reviewing the matter and imposing a fitting sanction for the Respondent's violation.

○ Finally, Proposed Rule 9556(h)(4) provides that Regulatory Staff can withdraw the petition without prejudice and can refile a petition based on allegations concerning the same facts and circumstances that are set forth in the withdrawn petition. As with the FINRA rule on which it is based, the proposed provision provides the Exchange with the flexibility to withdraw the petition where, for instance, the Respondent evidences a good faith intent to comply with the temporary or permanent cease and desist order without the need to adjudicate the petition, while preserving the Exchange's right to refile the petition if the Respondent fails to do so.[35] Proposed Rule 9556(h) is substantially similar to FINRA Rule 9556(h).

• Rule 9559 (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series) sets forth uniform hearing procedures for all expedited proceedings under the Rule 9550 Series. The Exchange proposes to amend Rule 9559 to reflect the new expedited proceedings set forth in proposed Rule 9556(h). The proposed changes are substantially similar to those recently adopted by FINRA for its Rule 9559. Specifically:

○ Rule 9559(a) would be amended to add the phrase ''or who is served with a petition instituting an expedited proceeding under Rule 9556(h).''

○ Rule 9559(c), which governs stays, would be amended to add a new subparagraph (1)(B) specifying that stays under subsection (c) would not apply to a petition instituting an expedited proceeding under Rule 9556(h).

○ Rule 9559(d), governing the appointment and authority of hearing officers and hearing panels, would similarly be amended to add references to proceedings under Rule 9556(h).

○ Rule 9559(f), governing time of hearing, would be amended to add a new subsection (2) providing that a hearing shall be held within ten days after a Respondent is served a petition seeking an expedited proceeding issued under Rule 9556(h), adding a reference to Rule 9556(h) to current subsection (2), and renumbering the remaining subsections.

○ Rule 9559(g), governing notice of hearing, would be amended to add a new subsection (2) providing that a Hearing Officer shall issue a notice stating the date, time, and place of the hearing at least six days prior to the

[31] *See* 2015 FINRA Filing, 80 FR at 48380 (''FINRA proposed to explicitly allow service by facsimile and on counsel, as well as by email, across all temporary cease and desist and expedited proceedings'').

[32] *See id.* The proposed rule change permitting email service in Rules 9551, 9552, 9554, 9555, 9556, 9557, and 9558 is the same as that contained in the corresponding FINRA rules, except the proposed rules provide that papers served on a member organization by email shall be sent to ''the email address on file with the Exchange'' instead of ''the email address listed in the FINRA Contact System submitted to FINRA pursuant to Article 4, Section III of the FINRA By-Laws.'' The Exchange's membership department collects and maintains email contact information for member organizations.

[33] Proposed Rule 9556(h)(1).

[34] *Id.* at (2).

[35] *See* 2015 FINRA Notice, 80 FR at 38785.

hearing in the case of an action brought pursuant to Rule 9556(h), adding a reference to Rule 9556(h) to current subsection (2), and renumbering the remaining subsections.

○ Rule 9559(h) governing transmission of documents would be amended as follows to reflect the new expedited proceeding the Exchange proposes under Rule 9556(h) for enforcing violations of a temporary or permanent cease and desist orders [sic]. The changes closely parallel FINRA's amendments to its version of Rule 9559(h) to bring Rule 9556(h) proceedings within the scope of the rule and distinguish them from actions brought under Rule 9556 and already reflected in the rule.

The first sentence of subsection (h)(1) would be amended to add the clause ''not less than six days before the hearing in an action brought under Rule 9556(h)'' after ''Not less than two business days before the hearing in an action brought under Rule 9557,'' to specifically bring proposed proceedings under Rule 9556(h) within the scope of the Rule. The clause ''not less than seven days before the hearing in an action brought under Rules 9556 and 9558'' that would follow the proposed addition would be amended to carve out Rule 9556(h) proceedings by adding the words ''except Rule 9556(h)'' after ''Rules 9556'' and before ''and 9558.'' Subsection (h)(1) would be further amended to reflect that ''the respondent who has received a petition pursuant to Rule 9556(h)'' would also be provided with all documents that were considered in issuing the notice, and that these documents could be provided by email or personal delivery in addition to overnight courier. The Exchange also proposes to add the sentence ''Documents served by email shall also be served by either overnight courier or personal delivery'' before the last sentence in Rule 9559(h)(1).

The last sentence of subsection (h)(1) would be amended to delete the word ''such'' and add the word ''the'' before ''criteria,'' and to add the clause ''in this paragraph'' after the word ''criteria.''

Rule 9559(h)(2) would be amended to provide that exhibit and witness lists shall be served by email or personal delivery in addition to overnight courier. Finally, the Exchange proposes to add a sentence to the end of subsection (h)(2) providing that ''Documents served by email shall also be served by either overnight courier or personal delivery.''

○ Rule 9559(m), governing failure to appear at a pre-hearing conference or hearing or to comply with a Hearing Officer order requiring production of information, would be amended to add a new subsection (2) providing that a Hearing Officer may issue a default decision against a Respondent who is the subject of a petition [36] filed pursuant to Rule 9556(h), and may deem the allegations against that Respondent admitted. The contents of a default decision shall conform to the content requirements of Rule 9559(p). A Respondent may, for good cause shown, file a motion to set aside a default. Upon a showing of good cause, the Hearing Officer that entered the original order shall decide the motion. If the Hearing Officer is not available, the Chief Hearing Officer shall appoint another Hearing Officer to decide the motion. If a default decision is not called for review pursuant to Rule 9559(q), the default decision shall become the final Exchange action.

○ Finally, Rule 9559(n) governing sanctions, costs and remands would be amended to add references to Rule 9556(h) proceedings. Rule 9559(n) would also be amended to add a new subsection (2) providing that, in an action brought under Rule 9556(h), the Hearing Officer may impose any fitting sanction. The remaining subsections of the Rule would be renumbered. These proposed changes are identical to those recently adopted in FINRA Rule 9559.

• Rule 9810 (Initiation of Proceeding) sets forth procedures for initiating temporary cease and desist proceedings. The Exchange proposes various amendments to the Rule to harmonize it with FINRA Rule 9810, as follows:

○ Rule 9810(a) governing service and filing of a notice would be amended to add text providing that a proceeding can alternatively be initiated by service upon counsel representing the Respondent, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the Respondent. Rule 9810(a) would also be amended to specifically provide for service by email, and text would be added to the Rule providing that if service is made by email, Enforcement shall send an additional copy of the notice by personal service or overnight commercial courier and that service is complete upon sending the notice by email or overnight courier or delivering it in person, except that, where duplicate service is required, service is complete when the duplicate service is complete. Finally, the Rule would be amended to provide that the notice shall be effective when service is complete.

○ Rule 9810(b) sets forth the requirements for the contents of the notice, and would be amended to add a new subsection (2) providing that the notice also be accompanied by a memorandum of points and authorities setting forth the legal theories upon which Enforcement relies. Current subsection (2) would be renumbered. The Exchange also proposes to clarify the required contents of the notice by specifying that the notice shall state whether Enforcement is requesting the Respondent to be required to take action, refrain from taking action ''or both.''

○ The Exchange proposes to add a new subsection (c) to Rule 9810 entitled ''Authority to Approve Settlements,'' providing that if the Parties agree to the terms of the proposed temporary cease and desist order, the Hearing Officer shall have the authority to approve and issue the order.

○ Current subsection (c) of Rule 9810 governing filing of the underlying complaint would become subsection (d). The Exchange also proposes to add a sentence providing that service of the complaint can be made in accordance with the service provisions in paragraph (a).

• Rule 9830 (Hearing) sets forth hearing procedures for temporary cease and desist proceedings. The Exchange proposes the following changes to harmonize the Rule with FINRA's recent amendments:

○ Rule 9830(a) would be amended to specify that either the Chief Hearing Officer or Deputy Chief Hearing Officer can extend the date of hearing for good cause shown and eliminate the need for consent of the parties.

○ Rule 9830(b) would be amended to add text specifying that the Office of Hearing Officers can also serve notice of a hearing upon counsel representing the Respondent, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the Respondent, and to specify that service can be by email. The Rule would also be amended to add text specifying that if service is made by email, the Office of Hearing Officers shall send an additional copy of the notice by personal service or overnight commercial courier. Service is complete upon sending the notice by email or overnight courier or delivering it in

[36] The first paragraph of Rule 9559(m) would also be amended to add ''or petition'' after the word ''notice'' to reflect proposed expedited proceedings under Rule 9556(h). In the penultimate sentence of the first paragraph, the comma after ''In such cases'' would be deleted, and a colon would be added in its place. The remainder of the sentence, together with the last sentence of the current rule, would be renumbered as new subsection (1).

person, except that, where duplicate service is required, service is complete when the duplicate service is complete.

○ Rule 9830(e) would be amended to add text specifying that, prior to the hearing, the Hearing Officer may order a Party to furnish to all other Parties and the Hearing Panel such information as deemed appropriate, including any or all of the pre-hearing submissions described in Rule 9242(a). The Rule would also provide that documentary evidence submitted by the Parties would not become part of the record, unless the Hearing Officer or Hearing Panel orders some or all of the evidence included pursuant to Rule 9830(g). The Exchange would also change the phrase, ''its consideration'' to ''the Hearing Panel's consideration,'' to add greater specificity.

• Rule 9840 (Issuance of Temporary Cease and Desist Order by Hearing Panel) sets forth the basis, including the evidentiary standard, for issuance of a temporary cease and desist order. The Exchange proposes the following changes to harmonize the Rule with FINRA's recent amendments:

○ Rule 9840(a) would be amended to specify that either the Chief Hearing Officer or Deputy Chief Hearing Officer can extend the ten day period for issuance of a decision stating whether a cease and desist order shall be imposed for good cause shown and eliminate the need for consent of the parties. Rule 9840(a)(1) would be amended to revise the evidentiary standard in temporary cease and desist proceedings to ''a showing of likelihood of success on the merits.'' This was one of the main changes recently effectuated by FINRA.[37] Rule 9840(a)(2) would be amended to add ''alleged'' before the term ''violative conduct'' in keeping with the recent FINRA amendment.

○ Rule 9840(b)(1) and (3) would be amended to apply to any successor of a Respondent, where the Respondent is a member organization. This proposed change is similar to the proposed change with respect to Rule 9291, discussed above [sic]. Subsection (3) would also be amended to remove the words ''is to'' and ''or'' and add the words ''or both'' to the end of the clause.

○ Rule 9840(c) would be amended to provide that, alternatively, a temporary cease and desist order would remain effective and enforceable until a settlement offer is accepted pursuant to Rule 9270.

○ Rule 9840(d) would be amended to specify that the Hearing Panel's decision and any temporary cease and desist order should be served by the Office of Hearing Officers on Enforcement and the Respondent or upon counsel representing the Respondent, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the Respondent. The Rule would also be amended to specify that service can be by email and that if service is made by email, the Office of Hearing Officers shall send an additional copy of the decision and any temporary cease and desist order by personal service or overnight commercial courier. Under the proposed Rule, service is complete upon sending the notice by email or overnight courier or delivering it in person, except that, where duplicate service is required, service is complete when duplicate service is complete. The Office of Hearing Officers provides a copy of the temporary cease and desist order to each member organization or ATP Holder with which a Respondent is associated.

○ Finally, the Exchange proposes to add a new subsection (e) headed ''Delivery Requirement'' that provides that where a Respondent is a member organization or ATP Holder, Respondent shall deliver a copy of a temporary cease and desist order, within one business day of receiving it, to its covered persons.

• Rule 9850 (Review by Hearing Panel) sets forth the process for a Party to petition the Hearing Panel to modify, set aside, limit or suspend a temporary cease and desist order. The Exchange proposes the following changes to harmonize the Rule with FINRA's recent amendments:

○ The first sentence of Rule 9850 would be amended to add a clause specifying that the Office of Hearing Officers can also serve a temporary cease and desist order upon counsel representing the Respondent, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the Respondent.

○ Rule 9850 would be amended to add a sentence providing that the Hearing Panel that presided over the temporary cease and desist order proceeding shall retain jurisdiction to modify, set aside, limit, or suspend the temporary cease and desist order, unless at the time the application is filed a Hearing Panel has already been appointed in the underlying disciplinary proceeding commenced under Rule 9211 in which case the Hearing Panel appointed in the disciplinary proceeding has jurisdiction.

○ Rule 9850 would also be amended to specify that either the Chief Hearing Officer or Deputy Chief Hearing Officer can extend the time for the Hearing Panel to respond to a request under the Rule for good cause shown and eliminate the need for consent of the parties.

○ Rule 9850 would be amended to add text specifying that the Hearing Panel's response can also be served upon counsel representing the Respondent, or other person authorized to represent others under Rule 9141, when counsel or other person authorized to represent others under Rule 9141 agrees to accept service for the Respondent, and that email is a permitted method of service. A sentence would also be added before the last sentence in the Rule providing that if service is made by email, the Office of Hearing Officers shall send an additional copy of the temporary cease and desist order by personal service or overnight commercial courier.

• Rule 9860 (Violation of Temporary Cease and Desist Orders) provides that a Respondent who violates a temporary cease and desist order may have its association or membership suspended or canceled under Rule 9556. The Exchange proposes to amend the Rule to add that a Respondent may also be subject to any fitting sanction under Rule 9556.

• Finally, the Exchange proposes to adopt the text of FINRA Rule 9291 governing the content, scope, form and delivery requirements of permanent cease and desist orders. Under proposed Rule 9291(a), when a decision issued under Rule 9268 or Rule 9269 or an order of acceptance issued under Rule 9270 imposes a permanent cease and desist order, the decision shall: Order a Respondent (and any successor of a Respondent, where the Respondent is a member organization) to cease and desist permanently from violating a specific rule or statutory provision; set forth the violation; and describe in reasonable detail the act or acts the Respondent (and any successor of a Respondent, where the Respondent is a member organization) shall take or refrain from taking.

[37] *See* 2015 FINRA Notice, 80 FR at 38784. The current evidentiary standard for imposing a temporary cease and desist order, set forth in Rule 9840(a)(1), is ''a preponderance of the evidence that the alleged violation specified in the notice has occurred.'' As explained in the 2015 FINRA Notice, the ''preponderance of the evidence'' standard sets too high an evidentiary threshold for this critical investor-protection tool. Indeed, it is the identical standard for proving a violation in the concurrent underlying disciplinary proceeding. This poses administrative challenges that create a strong disincentive to seek a temporary cease and desist order. *See id.*

The proposed Rule would also require Respondents that are member organizations or ATP Holders to deliver a copy of a permanent cease and desist order, within one business day of receiving it, to its covered persons.[38] With the exception of conforming changes to reflect the Exchange's membership, the text of the proposed Rule is the same as FINRA Rule 9291. The Exchange currently does not have a similar rule.

Technical and Conforming Changes

The Exchange proposes technical and conforming changes to Rule 9310.

Rule 9310(b), which governs reviews by the Exchange Board of Directors, would be amended to specify that the determinations or penalties imposed subject to Board review would include the terms of any permanent cease and desist order.

2. Statutory Basis

Amendments to Rule 8313

The Exchange believes that the proposed changes to Rule 8313 are consistent with Section 6(b) of the Act,[39] in general, and Section 6(b)(1)[40] in particular, in that they enable NYSE MKT to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of NYSE MKT. In particular, the Exchange believes that the proposed changes to Rule 8313 regarding release of disciplinary complaints, decisions and other information are consistent with Section 6(b) of the Act because they would establish general standards for the release of disciplinary information to the public to provide greater access to information regarding the Exchange's disciplinary actions.

For the same reasons, the Exchange believes that the proposed changes to Rule 8313 further the objectives of Section 6(b)(5) of the Act[41] because the changes are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. In particular, the proposed amendments to Rule 8313 further the objectives of Section 6(b)(5) of the Act by providing greater clarity, consistency, and transparency regarding the release of disciplinary complaints, decisions and other information to the public. By adopting the proposed amendments to Rule 8313 modeled on FINRA's rule, the Exchange would establish standards for the release of disciplinary information to the public in line with those in effect at FINRA that provide greater access to information regarding the Exchange's disciplinary actions and describe the scope of information subject to proposed Rule 8313. The Exchange believes that this proposed rule change promotes greater transparency to the Exchange's disciplinary process, and that the proposed rule change provides greater access to information regarding its disciplinary actions, and also provides valuable guidance and information to member organizations, associated persons, other regulators, and the investing public.[42]

Harmonization With FINRA Rules

The Exchange believes that the proposed changes to Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 and adopting a new Rule 9291 regarding the imposition of temporary or permanent cease and desist orders are consistent with Section 6(b) of the Act,[43] in general, and Section 6(b)(1)[44] in particular, in that they enable NYSE MKT to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the NYSE MKT's rules. In particular, the Exchange believes that the proposed changes are consistent with Section 6(b) of the Act because the changes would enhance the Exchange's ability to utilize its temporary cease and desist authority, thereby making it a more viable investor-protection tool and allowing the Exchange to take appropriate action against member organizations and their associated persons engaged in serious misconduct.

For the same reasons, the Exchange believes that the proposed changes to the Exchange's rules further the objectives of Section 6(b)(5) of the Act[45] because the changes are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

In addition, revising the evidentiary standard for obtaining temporary cease and desist orders by harmonizing the Exchange's rules with those of FINRA would better serve the investor protection purposes of the Exchange's temporary cease and desist authority and allow the Exchange to initiate and resolve temporary cease and desist proceedings more expeditiously. Further, these proposed changes, including the revised evidentiary standard, would also improve the Exchange's ability to enforce compliance with applicable laws and rules by its member organizations and persons associated with member organizations, and the Exchange's ability to prevent fraudulent and manipulative acts and practices.

The Exchange also believes that the proposed rule change supports the objectives of Section 6(b)(5) of the Act by providing greater harmonization between Exchange and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance for common members. As previously noted, the text of Rules 9120, 9268, 9269, 9270, 9291, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 relating to the imposition of temporary or permanent cease and desist orders is substantially the same as FINRA's rule text. To the extent the Exchange has proposed changes that differ from the FINRA version of the Exchange rules, such changes are generally technical in nature and do not change the substance of the rules.

In addition, the Exchange believes that the proposed changes to Rules 9120, 9268, 9269, 9270, 9551, 9552, 9554, 9555, 9556, 9557, 9558, 9559, 9810, 9830, 9840, 9850, and 9860 and adopting a new Rule 9291 further the objectives of Section 6(b)(7) of the Act[46] in that they provide fair procedures for, among other things, the disciplining of members and persons associated with members[47] because the rules governing temporary cease and desist orders and expedited proceedings require notice and an opportunity to be heard before a neutral tribunal, in addition to the

[38] *See* proposed Rule 9291(b).

[39] 15 U.S.C. 78f(b).

[40] 15 U.S.C. 78f(b)(1).

[41] 15 U.S.C. 78f(b)(5).

[42] *See* Release No. 69178, 78 FR at 17981.

[43] 15 U.S.C. 78f(b).

[44] 15 U.S.C. 78f(b)(1).

[45] 15 U.S.C. 78f(b)(5).

[46] 15 U.S.C. 78f(b)(7).

[47] Under the Exchange's equities rules, the equivalent to the term ''member'' in this context is ''member organization.'' *See* note 23, *supra*.

numerous other procedural safeguards described above and included in the rules. At the same time, the proposed rule change maintains all of the existing restraints on the Exchange's temporary cease and desist authority, including rule provisions that restrict who may authorize the initiation of a temporary cease and desist proceeding; narrowly define the violations that a temporary cease and desist order can address; and limit the issuance of temporary cease and desist orders to situations where the alleged violative conduct or continuation thereof is likely to result in significant dissipation or conversion of assets or other significant harm to investors.[48]

Finally, making conforming amendments to Rule 9310 in connection with the proposed harmonization of the Exchange's rules governing temporary cease and desist orders and expedited proceedings supports the objectives of Section 6(b)(5) of the Act. The conforming amendments will update and add specificity to the Exchange's rules, which will promote just and equitable principles of trade and help to protect investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues, but rather it is designed to (1) enhance the Exchange's rules governing the release of disciplinary complaints, decisions and other information to the public, thereby providing greater clarity and consistency and resulting in less burdensome and more efficient regulatory compliance and facilitating performance of regulatory functions, and (2) provide greater harmonization among Exchange and FINRA rules of similar purpose regarding the imposition of temporary cease and desist orders and expedited proceedings, thereby enhancing the quality of the Exchange's regulatory program, resulting in less burdensome and more efficient regulatory compliance and facilitating performance of regulatory functions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[49] and Rule 19b–4(f)(6) thereunder.[50] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[51] and Rule 19b–4(f)(6) thereunder.[52]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2016–71 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–71. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–71, and should be submitted on or before October 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23902 Filed 10–3–16; 8:45 am]

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[48] *See* Rule 9840(a)(2). Under Rule 9810(a), with the prior written authorization of the Exchange's CRO or such other senior officers as the CRO may designate, Enforcement may initiate a temporary cease and desist proceeding with respect to alleged violations of Section 10(b) of the Act, SEC Rules 10b–5 and 15g–1 through 15g–9, Rule 476(a)(6) or Rule 2010—Equities (if the alleged violation is unauthorized trading, or misuse or conversion of customer assets, or based on violations of Section 17(a) of the Securities Act); or Rule 476(a)(5) or Rule 2020—Equities. *See also* 2015 FINRA Notice, 80 FR at 38784.

[49] 15 U.S.C. 78s(b)(3)(A).

[50] 17 CFR 240.19b–4(f)(6).

[51] 15 U.S.C. 78s(b)(3)(A).

[52] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[53] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78965; File No. SR–FINRA–2016–032]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change Relating to FINRA Rule 2232 (Customer Confirmations) To Require Members To Disclose Additional Pricing Information on Retail Customer Confirmations Relating to Transactions in Fixed Income Securities

September 28, 2016.

On August 12, 2016, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rule 2232 to require its members to disclose additional pricing information on retail customer confirmations relating to transactions in fixed income securities. The proposed rule change was published for comment in the **Federal Register** on August 19, 2016.[3] The Commission has received nine comments on the proposal.[4]

Section 19(b)(2) of the Act [5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is October 3, 2016. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates November 17, 2016, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–FINRA–2016–032).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23905 Filed 10–3–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Sierra Resource Group, Inc.; Order of Suspension of Trading

September 29, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sierra Resource Group, Inc. (CIK No. 1076966) because it has not filed a periodic report since it filed its Form 10–Q for the period ending September 30, 2013, filed on November 19, 2013. Sierra Resource Group, Inc. is a Nevada corporation with its principal offices in Las Vegas, Nevada. The company's common stock (ticker ''SIRG'') is quoted on OTC Link (previously ''Pink Sheets'') operated by OTC Markets Group, Inc.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Sierra Resource Group, Inc. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of Sierra Resource Group, Inc. is suspended for the period from 9:30 a.m. EDT on September 29, 2016, through 11:59 p.m. EDT on October 12, 2016.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–23996 Filed 9–29–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Rainbow International, Corp., a/k/a Raintree Brands Incorporated; Order of Suspension of Trading

September 30, 2016.

It appears to the Securities and Exchange Commission (''Commission'') that there is a lack of current and accurate information concerning the securities of Rainbow International, Corp. (CIK No. 0001522538) (''Rainbow'') because Rainbow has confirmed for the Commission staff that the company is no longer operating. In addition, there is a lack of accurate information concerning the securities of Rainbow because in Form 8–Ks filed with the Commission on May 5, 2014, May 12, 2014, and Sept. 4, 2014 by Rainbow, the company appears to have made false and misleading statements concerning, among other things, a purported acquisition, company business relationships, its purported development of products, purported rental revenues, and a purported purchase of company shares by a company officer. The company appears not to have made any information publicly available about itself for approximately two years. Rainbow, also known as Raintree Brands Incorporated, is a Nevada corporation in default whose principal place of business is listed as Centennial, Colorado. Rainbow shares are quoted on OTC Link, operated by OTC Markets Group, Inc., under the ticker symbol ''RNBI.''

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Rainbow.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78573 (Aug. 15, 2016), 81 FR 55500.

[4] *See* Letter from Manisha Kimmel, Chief Regulatory Officer, Wealth Management, Thomson Reuters to Brent J. Fields, Secretary, Securities and Exchange Commission (Sept. 19, 2016); Letter from Mary Lou Von Kaenel, Managing Director, Financial Information Forum to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission (Sept. 9, 2016); Letter from Sean Davy, Managing Director, Capital Markets Division and Leslie M. Norwood, Managing Director and Associate General Counsel, Municipal Securities Division, SIFMA to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission (Sept. 9, 2016); Letter from Norman L. Ashkenas, Chief Compliance Officer, Fidelity Brokerage Services, LLC and Richard J. O'Brien, Chief Compliance Officer, National Financial Services, LLC to Brent J. Fields, Secretary, Securities and Exchange Commission (Sept. 9, 2016); Letter from Mike Nicholas, Chief Executive Officer, Bond Dealers of America to Brent J. Fields, Secretary, Securities and Exchange Commission (Sept. 9, 2016); Letter from Robert J. McCarthy, Director of Regulatory Policy, Wells Fargo Advisors, LLC to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission (Sept. 9, 2016); Letter from Scott A. Eichhorn, Practitioner in Residence and Supervising Attorney, Investor Rights Clinic, University of Miami, *et al.,* to Brent Fields, Secretary, Securities and Exchange Commission (Sept. 8, 2016); Letter from Manisha Kimmel, Chief Regulatory Officer, Wealth Management, Thomson Reuters to Brent J. Fields, Secretary, Securities and Exchange Commission (Sept. 8, 2016); and Letter from Hugh Berkson, President, PIABA to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission (Sept. 7, 2016).

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

Therefore, it is ordered, pursuant to Section 12(k) of the Exchange Act, that trading in the securities of Rainbow International, Corp. is suspended for the period from 9:30 a.m. EDT on September 30, 2016, through 11:59 p.m. EDT on October 13, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–24062 Filed 9–30–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78968; File No. SR–NYSEMKT–2016–63]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change Amending the Co-Location Services Offered by the Exchange To Add Certain Access and Connectivity Fees

September 28, 2016.

On August 16, 2016, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change (1) to provide additional information regarding access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to third party systems; and connectivity to DTCC provided to Users using data center local area networks; and (2) to establish fees relating to a User's access to various trading and execution services; connectivity to market data feeds and testing and certification feeds; connectivity to DTCC; and other services. The proposed rule change was published for comment in the **Federal Register** on August 26, 2016.[3] The Commission received no comments in response to the proposed rule change.[4]

Section 19(b)(2) of the Act [5] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates November 24, 2016, as the date by which the Commission should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NYSEMKT–2016–63).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23908 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78964; File No. SR–BatsBZX–2016–59]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Update BZX Rules 21.1, 21.7 and 21.9 To Align the Exchange's Rules and Functionality Applicable to the Exchange's Options Platform, BZX Options, With the Exchange's Affiliated Options Platform, EDGX Options, Which Is Operated by Bats EDGX Exchange, Inc.

September 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on September 19, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b-4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to update Rules 21.1, 21.7 and 21.9 to align the Exchange's rules and functionality applicable to the Exchange's options platform (''BZX Options'') with the Exchange's affiliated options platform (''EDGX Options''), which is operated by Bats EDGX Exchange, Inc. (''EDGX''). The Exchange has designated this proposal as a non-controversial filing and requests that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) under the Act.[5] If such waiver is granted by the Commission, the Exchange shall implement this rule proposal immediately.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make two changes to the Exchange's rules and functionality applicable to the BZX Options as described below. The changes are being proposed in order to allow the Exchange to conform certain

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–78629 (August 22, 2016), 81 FR 58992.

[4] The Commission notes that it did receive one comment letter on a related filing, NYSE–2016–45, which is equally relevant to this filing.

In response to the comment letter, the NYSE submitted a response.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] 17 CFR 240.19b–4(f)(6)(iii).

functionality between BZX Options and EDGX Options.

First, the Exchange proposes to eliminate ''WAIT'' orders, which are orders that that when entered into the System,[6] the order is held for one second without processing for potential display and/or execution. After one second, an order designated as ''WAIT'' is processed for potential display and/or execution in accordance with all order entry instructions as determined by the entering party. WAIT orders were originally adopted by the Exchange based on similar functionality available on other options exchanges and were intended to enhance compliance with the order exposure requirement set forth in Rule 22.12 (Order Exposure Requirements). Rule 22.12 prohibits Options Members[7] from executing as principal on BZX Options orders they represent as agent unless (i) agency orders are first exposed on BZX Options for at least one (1) second or (ii) the Options Member has been bidding or offering on BZX Options for at least one (1) second prior to receiving an agency order that is executable against such bid or offer (the ''Order Exposure Rule'').

Although the Order Exposure Rule still applies on BZX Options and the Exchange is not proposing any changes to such rule in connection with this proposal, Options Members have other means to comply with the Rule, including programming their own systems to comply, and very rarely use orders with a time-in-force of WAIT. Further, such orders are not offered by EDGX Options. Accordingly, the Exchange proposes to stop offering WAIT orders on BZX Options and to eliminate reference to such orders from Rule 21.1 (Definitions). In connection with this change, the Exchange proposes to remove reference to WAIT orders from the Exchange's rule regarding the opening procedures on the Exchange, Rule 21.7 (Market Opening Procedures).

Second, the Exchange proposes to modify the ''Aggressive'' Re-Route instruction contained in Exchange Rule 21.9 (Order Routing) to align the operation of such functionality with that offered by EDGX Options. Under the current Aggressive Re-Route instruction on BZX Options, set forth in Rule 21.9(a)(3)(A), to the extent the unfilled balance of a routable order has been posted to the BZX Options Book pursuant to paragraph (a)(2), should the order subsequently be *locked or crossed* by another accessible options exchange, the System shall route the order to the locking or crossing options exchange if the User[8] has selected the Aggressive Re-Route instruction. In contrast, on EDGX Options, the Aggressive Re-Route instruction routes an order posted to EDGX Options only if such order is subsequently *crossed* by another accessible options exchange. The Exchange proposes to modify the Aggressive Re-Route instruction to mirror the behavior offered on EDGX Options such that an order posted to BZX Options that has been flagged with the Aggressive Re-Route instruction will only be routed away to the extent such order is subsequently crossed by another accessible options exchange.

Although the Exchange intentionally offers certain features that differ from those offered by EDGX Options and will continue to do so, the Exchange believes that offering similar functionality on both EDGX Options and BZX Options to the extent practicable will reduce potential confusion for Users.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(5) of the Act[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Consistent rules and functionality between the Exchange and EDGX will reduce complexity and help avoid potential confusion by the Users of the Exchange that are also participants on EDGX. The Exchange again notes that WAIT orders are very rarely used by Users of BZX Options and that such orders are not offered by EDGX Options. Like WAIT orders, the Aggressive Re-Route instruction is very rarely used. The Exchange also notes that the proposed changes to the Aggressive Re-Route instruction are based on EDGX rules and will result in consistent functionality between BZX Options and EDGX Options.

Also, with respect to the current implementation of Aggressive and Super Aggressive functionality, the Exchange notes that this implementation is due to a change previously made to the functionality that was primarily made by the Exchange in order to keep functionality consistent on BZX Options with the Exchange's equity securities platform (''BZX Equities'').[11] Although as implemented on BZX Equities both Aggressive and Super Aggressive Re-Route functionality re-routes if an order is locked or crossed, there are other differences between the two features make the Super Aggressive option more aggressive. These differences, however, are not applicable to BZX Options and therefore Aggressive and Super Aggressive are redundant options. The proposed change will again make the Aggressive feature less aggressive than Super Aggressive, such that an order marked for Aggressive Re-Route will re-route an order only such order is crossed. A User who wishes to achieve the current Aggressive functionality to have the Exchange re-route an order if it is locked or crossed can instead select the Super Aggressive instruction.

The Exchange believes the proposed amendment will reduce complexity and increase the understanding of the Exchange's operations for all Users of the Exchange. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule changes do not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on EDGX Options already.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposal will further promote consistency between the Exchange and EDGX, thereby reducing complexity and avoiding potential confusion by Users of the Exchange that are also participants on EDGX. The Exchange does not believe that either of the proposed changes will have any direct impact on competition.

[6] Exchange Rule 16.1(a)(59) defines ''System'' as ''the automated trading system used by BZX Options for the trading of options contracts.''

[7] An Options Member is defined as ''a firm, or organization that is registered with the Exchange pursuant to Chapter XVII of these Rules for purposes of participating in options trading on BZX Options as an 'Options Order Entry Firm' or 'Options Market Maker.'" *See* Exchange Rule 16.1(a)(38).

[8] A User is defined as ''any Options Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access).'' *See* Exchange Rule 16.1(a)(63).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] See Securities Exchange Act Release No. 76623 (December 11, 2015), 80 FR 78800 (December 17, 2015) (SR–BATS–2015–112) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Rules 11.13(b)(4)(A) and 21.9(a)(3)(A), Amending Aggressive Re-Route Instruction).

Thus, the Exchange does not believe that the proposal creates any significant impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [14] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [15] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay would allow the Exchange to immediately provide functionality that is consistent with functionality provided by EDGX, thereby reducing complexity and avoiding potential confusion. The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BatsBZX–2016–59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR-BatsBZX–2016–59. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BatsBZX–2016–59, and should be submitted on or before October 25, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23904 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32293; 812–14538]

Virtus Alternative Solutions Trust, et al.; Notice of Application

September 28, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and Sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers. The order would also supersede prior orders.[1]

APPLICANTS: Virtus Alternative Solutions Trust, Virtus Equity Trust, Virtus Insight Trust, Virtus Opportunities Trust, Virtus Retirement Trust and Virtus Variable Insurance Trust (each, a ''Trust''), each registered under the Act as an open-end management investment company with multiple series (each, a ''Series'') and each a Delaware statutory trust, except Virtus Insight Trust, a Massachusetts business trust, and Virtus Alternative Investment Advisers, Inc., a Connecticut

[17] 17 CFR 200.30–3(a)(12).

[1] Virtus Alternative Solutions Trust et al., Investment Company Act Release Nos. 30986 (March 19, 2014) (notice) and 31014 (April 15, 2014) (order); Phoenix Equity Trust et al., Investment Company Act Release Nos. 28375 (September 3, 2008) (notice) and 28410 (September 29, 2008) (order).

corporation, Virtus Investment Advisers, Inc., a Massachusetts corporation, and Virtus Retirement Investment Advisers, LLC, a Delaware limited liability company, each registered as an investment adviser under the Investment Advisers Act of 1940 (each, an ''Advisor,'' and, collectively with the Trusts, the ''Applicants'').

FILING DATES: The application was filed August 21, 2015, and amended February 12, 2016, August 9, 2016, and September 9, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 24, 2016, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: c/o James E. Thomas, Esq., Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA 02199.

FOR FURTHER INFORMATION CONTACT: Kaitlin C. Bottock, Senior Counsel, at (202) 551–8658, or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. An Advisor will serve as the investment adviser to the Subadvised Series pursuant to an investment advisory agreement with the Trust (each, an ''Investment Management Agreement'').[2] The Advisor will provide the Subadvised Series with continuous and comprehensive investment management services subject to the supervision of, and policies established by, each Subadvised Series' board of trustees (the ''Board''). Each Investment Management Agreement permits the Advisor, subject to the approval of the Board, to delegate to one or more Sub-Advisors the responsibility to provide the day-to-day portfolio investment management of each Subadvised Series, subject to the supervision and direction of the Advisor.[3] The primary responsibility for managing the Subadvised Series will remain vested in the Advisor. The Advisor will hire, evaluate, allocate assets to and oversee the Sub-Advisors, including determining whether a Sub-Advisor should be terminated, at all times subject to the authority of the Board.

2. Applicants request an exemption to permit the Advisor, subject to Board approval, to hire a Non-Affiliated Sub-Advisor or a Wholly-Owned Sub-Advisor, pursuant to Sub-Advisory Agreements and materially amend Sub-Advisory Agreements with Non-Affiliated Sub-Advisors and Wholly-Owned Sub-Advisors without obtaining the shareholder approval required under section 15(a) of the Act and rule 18f–2 under the Act.[4] Applicants also seek an exemption from the Disclosure Requirements to permit a Subadvised Series to disclose (as both a dollar amount and a percentage of the Subadvised Series' net assets): (a) The aggregate fees paid to the Advisor and any Wholly-Owned Sub-Advisors; (b) the aggregate fees paid to Non-Affiliated Sub-Advisors; and (c) the fee paid to each Affiliated Sub-Advisor.

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Subadvised Series' shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of the Subadvised Series' shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the application, the Investment Management Agreements will remain subject to shareholder approval, while the role of the Sub-Advisors is substantially equivalent to that of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Subadvised Series. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Advisor's ability to negotiate fees paid to the Sub-Advisors that are more advantageous for the Subadvised Series.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–23911 Filed 10–3–16; 8:45 am]

BILLING CODE 8011–01–P

[2] Applicants request that the relief sought herein apply to the named Applicants, as well as to any future Series and any other existing or future registered open-end management investment company or series thereof that intends to rely on the requested order in the future and that (i) is advised by an Advisor, its successors, and any entity controlling, controlled by or under common control with an Advisor or its successors (included in the term ''Advisor''), (ii) uses the multi-manager structure described in this application, and (iii) complies with the terms and conditions of this application (each, a ''Subadvised Series''). For the purposes of the requested order, ''successor'' is limited to an entity resulting from a reorganization into another jurisdiction or a change in the type of business organization.

[3] A ''Sub-Advisor'' for a Series is (1) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the Advisor for that Series, or (2) a sister company of the Advisor for that Series that is an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the same company that, indirectly or directly, wholly owns the Advisor (each of (1) and (2) a ''Wholly-Owned Sub-Advisor''), or (3) an investment sub-adviser for that Series that is not an ''affiliated person'' (as such term is defined in Section 2(a)(3) of the Act) of the Series or the Advisor, except to the extent that an affiliation arises solely because the Sub-Advisor serves as a sub-adviser to one or more Series (each a ''Non-Affiliated Sub-Advisor'') .

[4] The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Advisor, who is an affiliated person, as defined in section 2(a)(3) of the Act, of the Subadvised Series or the Manager, other than by reason of serving as a sub-adviser to one or more of the Subadvised Series (''Affiliated Sub-Advisor'').

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 November 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 SBA's Premier Certified Lenders Program (PCLP) transfers considerable authority and autonomy to Premier Certified Development Companies (Premier CDCs). The PCLP forms (Forms 2233 and 2234) collect loan information to assist the agency in carrying-out its lender, portfolio and program oversight responsibilities. Form 2233 will collect loan loss reserve information to ensure Premier CDC compliance with statutory requirements. SBA will use Form 2234 to approve loan eligibility and track portfolio performance.

Solicitation of Public Comments

Title: PCLP Quarterly Loan Loss Reserve Report and PCLP Guarantee Request

Description of Respondents: Small Business Lending Companies

Form Number's: SBA Form 2233, 2234A, 2234B, 2234C

Total Estimated Annual Responses: 20

Total Estimated Annual Hour Burden: 30

Curtis B. Rich,

Management Analyst.

[FR Doc. 2016–23765 Filed 10–3–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of 30-day Reporting Requirements Submitted for OMB Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required 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.

DATES: Submit comments on or before November 3, 2016. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer,* 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.*

SUPPLEMENTARY INFORMATION:

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

Abstract: In accordance with Title 13 of the Code of Federal Regulations, Section 124.403, each 8(a) participant must annually review its business plan with the assigned Business Opportunity Specialist (BOS) and modify the plan, as appropriate, within 30 days after the close of each program year. The Participant must also submit a statement describing its current contract performance capabilities as part of its update business plan. SBA uses the information collected to assess the participant's financial condition and continued eligibility.

Title: 8(a) Annual Update.

Frequency: On Occasion.

SBA Form Number: 1450.

Description of Respondents: 8(a) Participants.

Responses: 7,814.

Annual Burden: 14,846.

Curtis Rich,

Management Analyst.

[FR Doc. 2016–23732 Filed 10–3–16; 8:45 am]

BILLING CODE 8025–01–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 November 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*

SUPPLEMENTARY INFORMATION:

Respondent are applicants for a Certified Development Company (CDC) loan (or 504 loan) and the CDC's certified by SBA to issue such loans. The information is necessary for the Small Business Administration (SBA) to determine whether applicants meet the Agency's criteria for eligibility, creditworthiness, and repayment ability, and also whether to approve CDC's request for debenture guarantees.

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.

Solicitation of Public Comments

Title: Application for Section 504 Loans.

Description of Respondents: Small Business Lending Companies.

Form Number's: SBA Forms 1244, 2450.

Estimated Annual Responses: 9,100.

Estimated Annual Hour Burden: 21,749.

Curtis B. Rich,

Management Analyst .

[FR Doc. 2016–23764 Filed 10–3–16; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fifteenth Meeting of the RTCA Tactical Operations Committee

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

ACTION: Fifteenth Meeting of the RTCA Tactical Operations Committee.

SUMMARY: The FAA is issuing this notice to advise the public of the Fifteenth Meeting of the RTCA Tactical Operations Committee.

DATES: The meeting will be held October 27, 2016, 10:00 a.m.–04:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Trin Mitra at *tmitra@rtca.org* or 202–330–0655, the RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for the Fifteenth Meeting of the RTCA Tactical Operations Committee. The agenda will include the following:

Thursday, October 27, 2016—10 a.m.–4 p.m.

1. Opening of Meeting/Introduction of TOC Members—Co-Chairs Dale Wright and Bryan Quigley
2. Official Statement of Designated Federal Official—Elizabeth Ray
3. Approval of June 23, 2016 Meeting Summary
4. FAA Update—Elizabeth Ray
5. Review Draft Recommendations from Graphical TFR Task Group
6. Update from PBN Route Structure Task Group
   a. High Altitude Group
   b. Overview briefing on Alaska needs
   c. Low Altitude Groups
7. Update on Previous TOC Recommendations
8. Discuss Potential Future TOC Tasks
9. Update on the NextGen Advisory Committee (NAC)
10. Update on the Drone Advisory Committee (DAC)
11. Plan for Future TOC Meetings
12. Other Business
13. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on September 28, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–23896 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–101]

Petition for Exemption; Summary of Petition Received; Airbus SAS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before October 24, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–7400 using any of the following methods:

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *deana.stedman@faa.gov,* phone (425) 227–2148.

This notice is published pursuant to 14 CFR 11.85.

Issued in Renton, Washington, on September 22, 2016.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–7400.

Petitioner: Airbus SAS.

Section(s) of 14 CFR Affected: § 25.813(e) and § 121.310(f)(5).

Description of Relief Sought: Airbus has requested an exemption from 14 CFR 25.813(e) and 121.310(f)(5) to permit the installation of 32 mini-suites in the Business Class of Model A350 airplanes.

[FR Doc. 2016–23960 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind Notice of Intent To Prepare Environmental Impact Statement, Route 82/85/11 Corridor, New London County, Connecticut

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: The FHWA is issuing this notice to advise the public that FHWA is rescinding its Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) for transportation improvements within the Connecticut Route 82/85/11 corridor in the towns of Salem, Montville, Waterford, and East Lyme, Connecticut.

FOR FURTHER INFORMATION CONTACT: Amy D. Jackson-Grove, Division Administrator, Federal Highway Administration, 628–2 Hebron Avenue, Suite 303, Glastonbury, CT 06033, Telephone: (860) 659–6703.

SUPPLEMENTARY INFORMATION: An NOI to prepare an EIS for the Route 82/85/11 corridor was published in the **Federal Register** in 1998 (**Federal Register** Vol. 63, No. 50; FR Doc. 98–6598). The Draft EIS was issued in February 1999, and the Final EIS was issued in July 2007. A Record of Decision was never signed due to environmental concerns and lack of financial resources to construct the project.

Numerous environmental studies have exposed the magnitude of potential environmental impacts to a variety of resources, such as wetlands, endangered species, Section 4(f), and cultural resources. Accordingly, FHWA is hereby rescinding the NOI.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: September 28, 2016.

Amy Jackson-Grove,

Division Administrator, Glastonbury, Connecticut.

[FR Doc. 2016–23934 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Transfer of Federally Assisted Facility

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of intent to transfer Federally assisted facility.

SUMMARY: Section 5334(h) of the Federal Transit Laws, as codified, 49 U.S.C. 5301, et. seq., permits the Administrator of the Federal Transit Administration (FTA) to authorize a recipient of FTA funds to transfer land or a facility to a public body for any public purpose with no further obligation to the Federal Government if, among other things, no Federal agency is interested in acquiring the asset for Federal use. Accordingly, FTA is issuing this Notice to advise Federal agencies that VIA Metropolitan Transit (VIA) intends to transfer the facility at 7535 Merton Mintor, Bexar County, San Antonio, Texas, to University Health System (a.k.a Bexar County Hospital District, hereinafter ''District''), a political subdivision of the State of Texas in San Antonio, Texas, serving Bexar County. The facility is attached and connected to a building and parking garage at the South Texas Medical Center. VIA used the facility from approximately 1998 to 2012 as a transfer facility. VIA discontinued use of the facility in December 2012 with the opening of its new medical center transfer facility at a different location.

The District intends to use the facility for various hospital departments, including the Information Technology Department, and a Pediatric Food Bank. The transfer will provide benefits to the hospital by providing space for hospital department personnel and operations. The transfer will provide a benefit to the community in the form of the Pediatric Food Bank, filling a need for children that will allow them to stay nourished and healthy, with the goal of avoiding unnecessary hospital stays. The District plans to use the facility for at least 20 years and is planning renovations to the facility and its systems.

DATES: Effective Date: Any Federal agency interested in acquiring the facility must notify the FTA Region VI office of its interest no later than November 3, 2016.

ADDRESSES: Interested parties should notify the Regional Office by writing to Robert C. Patrick, Regional Administrator, Federal Transit Administration, 819 Taylor Street, Room 8A36, Fort Worth, TX 76102

FOR FURTHER INFORMATION CONTACT: Eldridge Onco, Regional Counsel, (817) 978–0557.

SUPPLEMENTARY INFORMATION:

Background

49 U.S.C. 5334(h) provides guidance on the transfer of capital assets. Specifically, if a recipient of FTA assistance decides an asset acquired under this chapter at least in part with that assistance is no longer needed for the purpose for which it was acquired, the Secretary of Transportation may authorize the recipient to transfer the asset to a local governmental authority to be used for a public purpose with no further obligation to the Government. 49 U.S.C. 5334(h)(1).

Determinations

The Secretary may authorize a transfer for a public purpose other than mass transportation only if the Secretary decides:

(A) The asset will remain in public use for at least 5 years after the date the asset is transferred;

(B) There is no purpose eligible for assistance under this chapter for which the asset should be used;

(C) The overall benefit of allowing the transfer is greater than the interest of the Government in liquidation and return of the financial interest of the Government in the asset, after considering fair market value and other factors; and

(D) Through an appropriate screening or survey process, that there is no interest in acquiring the asset for Government use if the asset is a facility or land.

Federal Interest in Acquiring Land or Facility

This document implements the requirements of 49 U.S.C. 5334(h)(1)(D) of the Federal Transit Laws. Accordingly, FTA hereby provides notice of the availability of the facility further described below. Any Federal agency interested in acquiring the affected facility should promptly notify the FTA. If no Federal agency is interested in acquiring the existing facility, FTA will make certain that the other requirements specified in 49 U.S.C. 5334(h)(1)(A) through (C) are met before permitting the asset to be transferred.

Additional Description of Land or Facility

The subject improvement is located on property legally described as: NCB 12816 BLK 6 LOT NE IRR 781.56 FT OF 4. The subject property consists of an easement encumbered with an improvement (building) and does not include fee to the land. The improvement is approximately 1925 square feet consisting of a waiting area, two restrooms, ticket office and an elevator. The elevator goes up to the crosswalk of the University Health Center crosswalk. The facility is in fair to good condition. Public utilities are available: Water; sewer; telephone; and

cable. The improvements are attached to a parking garage owned by the District. The facility is no longer used by VIA because the agency constructed a new transfer center in the immediate vicinity. The easement to VIA restricts the use to public transportation purposes.

If no Federal agency is interested in acquiring the existing facility, FTA will make certain that the other requirements specified in 49 U.S.C. 5334(h)(1)(A) through (C) are met before permitting the asset to be transferred.

Robert C. Patrick,

Regional Administrator, Federal Transit Administration Region VI.

[FR Doc. 2016–23940 Filed 10–3–16; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of six individuals and six entities whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act).

DATES: The designations by the Acting Director of OFAC of the six individuals and six entities identified in this notice pursuant to section 805(b) of the Kingpin Act are effective on September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department of the Treasury, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's Web site at *http://www.treasury.gov/ofac.*

Background

The Kingpin Act, 21 U.S.C. 1901–1908, 8 U.S.C. 1182, became law on December 3, 1999. The Kingpin Act provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Kingpin Act provides that the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security, may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On September 29, 2016, the Acting Director of OFAC designated the following six individuals and six entities whose property and interests in property are blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. MUNOZ MEJIA, Jonathan (Latin: MUÑOZ MEJIA, Jonathan) (a.k.a. MUNOZ MEJIA, Jhonathan), Colombia; Mexico; DOB 07 Nov 1985; POB Manizales, Caldas, Colombia; nationality Colombia; Cedula No. 75107204 (Colombia); C.U.R.P. MUMJ851107HNEXJN01 (Mexico) (individual) [SDNTK] (Linked To: AVICAL S.A.; Linked To: INVERSIONES LA PLATA M & M S. EN C.A.; Linked To: ROMIK S.A.; Linked To: MUNSA INTERNATIONAL INVESMENTS S.A.). Directed by, or acting for or on behalf of, German MUNOZ HOYOS, AVICAL S.A., INVERSIONES LA PLATA M & M S. EN C.A. (a.k.a. A.K.A. INVERSIONES LA PLATA M Y M), and/or ROMIK S.A., and therefore meets the statutory criteria for designation as an SDNT pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

2. MUNOZ HOYOS, Carlos Ivan (Latin: MUÑOZ HOYOS, Ivan Carlos), Colombia; DOB 23 Dec 1957; POB Aranzazu, Caldas, Colombia; nationality Colombia; Cedula No. 10234256 (Colombia) (individual) [SDNTK] (Linked To: AVICAL S.A.). Directed by, or acting for or on behalf of, German MUNOZ HOYOS, Jonathan MUNOZ MEJIA (a.k.a. MUNOZ MEJIA, Jhonathan), and/or AVICAL S.A. and therefore meets the statutory criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

3. MUNOZ MEJIA, Eliana (Latin: MUÑOZ MEJIA, Eliana), Colombia; Mexico; DOB 12 Jun 1989; POB Manizales, Caldas, Colombia; nationality Colombia; Cedula No. 1053795962 (Colombia); C.U.R.P. MUME890612MNEXJL02 (Mexico); Identification Number 89061251694 (Colombia) (individual) [SDNTK] (Linked To: AVICAL S.A.; Linked To: INVERSIONES LA PLATA M & M S. EN C.A.). Directed by, or acting for or on behalf of, German MUNOZ HOYOS, AVICAL S.A., and/or INVERSIONES LA PLATA M & M S. EN C.A. (a.k.a. A.K.A. INVERSIONES LA PLATA M Y M), and therefore meets the statutory criteria for designation as an SDNT pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

4. MUNOZ MEJIA, Jhonny German (Latin: MUÑOZ MEJIA, Jhonny German), Colombia; Mexico; DOB 17 Dec 1986; POB Manizales, Caldas, Colombia; nationality Colombia; Cedula No. 1053768644 (Colombia); C.U.R.P. MUMJ861217HNEXJH05 (Mexico); Identification Number 86121753660 (Colombia) (individual) [SDNTK] (Linked To: AVICAL S.A.; Linked To: INVERSIONES LA PLATA M & M S. EN C.A.; Linked To: ROMIK S.A.). Directed by, or acting for or on behalf of, German MUNOZ HOYOS, AVICAL S.A., INVERSIONES LA PLATA M & M S. EN C.A. (a.k.a. A.K.A. INVERSIONES LA PLATA M Y M), and/or ROMIK S.A., and therefore meets the statutory criteria for designation as an SDNT pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

5. MUNOZ HOYOS, German (Latin: MUÑOZ HOYOS, German), Colombia; Mexico; DOB 26 Jan 1965; POB Manizales, Caldas, Colombia; nationality Colombia; citizen Colombia; alt. citizen Mexico; Cedula No. 10268158 (Colombia); Passport A0630659 (Colombia); alt. Passport G15527939 (Mexico); C.U.R.P. MUHG650126HNEXYR06 (Mexico) (individual) [SDNTK] (Linked To: AVICAL S.A.; Linked To: INVERSIONES LA PLATA M & M S. EN C.A.; Linked To: ROMIK S.A.; Linked To: GEMUHO HOLDING, INC; Linked To: UNIREFRICLIMA S.A.). Plays a

significant role in international narcotics trafficking and therefore meets the statutory criteria for designation pursuant to section 805(b)(4) of the Kingpin Act, 21 U.S.C. 1904(b)(4).

6. MURILLO SALAZAR, Claudia Julieta, Colombia; Mexico; DOB 29 Jul 1975; POB Manizales, Caldas, Colombia; nationality Colombia; Cedula No. 30335610 (Colombia); C.U.R.P. MUSC750729MNERU04 (Mexico) (individual) [SDNTK] (Linked To: AVICAL S.A.; Linked To: MUNSA INTERNATIONAL INVESMENTS S.A.). Directed by, or acting for or on behalf of, German MUNOZ HOYOS and/or AVICAL S.A., and therefore meets the statutory criteria for designation as an SDNT pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

Entities

1. AVICAL S.A., Transversal 72 No. 16–11, Glorieta de Milan, Manizales, Caldas, Colombia; Carrera 18 No. 30–65, Manizales, Caldas, Colombia; Calle 161 No. 91A–53, Bogota, Cundinamarca, Colombia; Medellin, Antioquia, Colombia; Dosquebradas, Risaralda, Colombia; NIT #810006566–9 (Colombia) [SDNTK]. Owned, controlled, or directed by, or acting for or on behalf of German MUNOZ HOYOS and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

2. GEMUHO HOLDING, INC, Costa de Este, P.H. Sevilla, Torre 1, apartamento 43B, Panama City, Panama; RUC #2388488–1–803204 (Panama) [SDNTK]. Controlled, or directed by, or acting for or on behalf of German MUNOZ HOYOS and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

3. INVERSIONES LA PLATA M & M S. EN C.A. (a.k.a. INVERSIONES LA PLATA M Y M), Carrera 18 No. 30–65, Manizales, Caldas, Colombia; Transversal 72 No. 16–11, Glorieta de Milan, Manizales, Caldas, Colombia; NIT #900324723–2 (Colombia) [SDNTK]. Owned, controlled, or directed by, or acting for or on behalf of German MUNOZ HOYOS, Jonathan MUNOZ MEJIA (a.k.a. MUNOZ MEJIA, Jhonathan), and/or AVICAL, S.A., and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

4. MUNSA INTERNATIONAL INVESMENTS S.A., Panama City, Panama; RUC #155608664–2–2015 (Panama) [SDNTK]. Controlled or directed by, or acting for or on behalf, of Claudia Julieta MURILLO SALAZAR.

5. ROMIK S.A., P.H. Plaza 2000, Piso 11, Urbanizacion Marbella, Panama City, Panama; RUC #1661921–1–677849 (Panama) [SDNTK]. Controlled or directed by, or acting for or on behalf of, MUNOZ HOYOS, Jonathan MUNOZ MEJIA, and/or Jhonny German MUNOZ MEJIA, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

6. UNIREFRICLIMA S.A., Panama City, Panama; RUC #155608664–2–2015 (Panama) [SDNTK]. Controlled, or directed by, or acting for or on behalf of German MUNOZ HOYOS and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

Dated: September 29, 2016.

Andrea Gacki

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–23942 Filed 10–3–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2004–15

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 2004–15, Waivers of Minimum Funding Standards.

DATES: Written comments should be received on or before December 5, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the revenue procedure should be directed to Martha R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Waivers of Minimum Funding Standards.

OMB Number: 1545–1873.

Revenue Procedure Number: Revenue Procedure 2004–15.

Abstract: Revenue Procedure 2004–15 describes the process for obtaining a waiver from the minimum funding standards set forth in section 412 of the Code.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations not-for-profit institutions, farms and state, local or tribal governments.

Estimated Number of Respondents: 110.

Estimated Annual Average Time per Respondent: 43 hours.

Estimated Total Annual Hours: 4,730 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 22, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–23944 Filed 10–3–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0619]

Proposed Information Collection (Inquiry Routing & Information System (IRIS)) Activity: Comment Request

AGENCY: Office of Information and Technology, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of Information and Technology (OIT), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to route IRIS inquiries generated on the department's Contact Us, Ask A Question Web site to appropriate locations throughout VA for response and to gather sufficient information to be able to respond timely without repeated requests from VA for more information.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before December 5, 2016.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy Tucker, Department of Veterans Affairs, Office of Information & Technology, VA Enterprise Applications, (005F4), 550 Foothill Blvd., Salt Lake City, Utah 84113 or email to *nancy.tucker@va.gov.* Please refer to ''OMB Control No. 2900–0619'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy Tucker at 801–580–7884.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OIT invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of IRIS functions, including whether the information will have practical utility; (2) the accuracy of OIT's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Inquiry Routing & Information System (IRIS).

OMB Control Number: 2900–0619.

Type of Review: Extension of a currently approved collection.

Abstract: The IRIS Ask A Question form on the VA Web site's Contact Us link is used by Web site visitors to submit inquiries to locations and business lines across VA to respond to any questions, complaints, suggestions or other issues.

Affected Public: Individuals and Households (Any individual who utilizes Contact Us via the department Web site).

Estimated Annual Burden: 66,000 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Daily.

Estimated Number of Respondent: 33,000 per month.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–23964 Filed 10–3–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C., App. 2, that the Executive Committee of the VA Voluntary Service (VAVS) National Advisory Committee (NAC) will meet October 20–21, 2016, at the Veterans Health Administration's Conference Center, 2011 Crystal Drive, Suite 150, Arlington, Virginia. On October 20, the meeting will begin at 8:30 a.m. and end at 4:30 p.m. On October 21, the meeting will begin at 8:30 a.m. and end at 12:00 noon. The meeting is open to the public.

The Committee, comprised of fifty-three major Veteran, civic, and service organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities and strategic partnerships within VA health care facilities, in the community, and on matters related to volunteerism and charitable giving. The Executive Committee consists of 20 representatives from the NAC member organizations.

On October 20, agenda topics will include: NAC goals and objectives; review of minutes from the May 4, 2016 Executive Committee meeting; VAVS update on the Voluntary Service program's activities; VHA Update, strategic partnership vetting; strategic partnership panel; Parke Board update; evaluations of the 2016 NAC annual meeting; review of membership criteria and process; and plans for 2017 NAC annual meeting (to include workshops and plenary sessions).

On October 21, agenda topics will include: subcommittee reports; review of standard operating procedures; review of Fiscal Year 2016 organization data; 2018 NAC annual meeting plans; and any new business.

No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review to Mrs. Sabrina C. Clark, Designated Federal Officer, Voluntary Service Office (10B2A), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, or email at *Sabrina.Clark@VA.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Mrs. Clark at (202) 461–7300.

Dated: September 28, 2016.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–23920 Filed 10–3–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 81 Tuesday,
No. 192 October 4, 2016

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1904, 1910, 1915, and 1926
Standards Improvement Project-Phase IV; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1904, 1910, 1915, and 1926

[Docket No. OSHA–2012–0007]

RIN 1218–AC67

Standards Improvement Project-Phase IV

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

ACTION: Proposed rule; request for comments.

SUMMARY: In response to the President's Executive Order 13563, ''Improving Regulations and Regulatory Review,'' the Occupational Safety and Health Administration (OSHA) is continuing its efforts to remove or revise outdated, duplicative, unnecessary, and inconsistent requirements in its safety and health standards. The current review, the fourth in this ongoing effort, is called Standards Improvement Project-Phase IV (SIP–IV). The goal of the proposed rulemaking is to reduce regulatory burden while maintaining or enhancing employees' safety and health. SIP–IV focuses primarily on OSHA's construction standards.

DATES: Submit comments and hearing requests by December 5, 2016. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments and additional material using any of the following methods:

Electronic. Submit comments and attachments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions online for making electronic submissions.

Facsimile. Commenters may fax submissions, including any attachments that are no longer than 10 pages in length to the OSHA Docket Office at (202) 693–1648; OSHA does not require hard copies of these documents. Commenters must submit lengthy attachments that supplement these documents (*e.g.,* studies, journal articles) to the OSHA Docket Office, Technical Data Center, Room N–2625, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210. These attachments must clearly identify the commenter's name, date, subject, and docket number (*i.e.,* OSHA–2012–0007) so the Agency can attach them to the appropriate comments.

Regular mail, express mail, hand (courier) delivery, or messenger service. Submit a copy of comments and any additional material (*e.g.,* studies, journal articles) to the OSHA Docket Office, Docket No. OSHA–2012–0007, Technical Data Center, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350 (TDY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, or messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

Instructions. All submissions received must include the Agency name and the docket number for this rulemaking (*i.e.,* OSHA–2012–0007). OSHA places all submissions, including any personal information provided, in the public docket without change; this information will be available online at *http://www.regulations.gov.* Therefore, the Agency cautions commenters about submitting information they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

OSHA requests comments on all issues related to this proposed rule, including whether these revisions will have any economic, paperwork, or other regulatory impacts on the regulated community.

Docket. To read or download submissions or other material in the docket (including material referenced in the preamble), go to *http://www.regulations.gov,* or contact the OSHA Docket Office at the address listed above. While the Agency lists all documents in the docket in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are accessible at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries. Contact Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information. Contact Blake Skogland, Office of Construction Standards and Guidance, OSHA Directorate of Construction, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3468, Washington, DC 20210; telephone: (202) 693–2020; fax: (202) 693–1689; email: *skogland.blake@dol.gov.*

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SUPPLEMENTARY INFORMATION:

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I. Executive Summary

OSHA is proposing 18 revisions to existing standards in its recordkeeping, general industry, maritime, and construction standards, with most of the revisions to its construction standards. The purpose of Standards Improvement Projects (SIPs) is to remove or revise outdated, duplicative, unnecessary, and inconsistent requirements in OSHA's safety and health standards, which will permit better compliance by employers and reduce costs and paperwork burdens where possible, without reducing employee protections. OSHA is conducting SIP–IV in response to the President's Executive Order 13563, ''Improving Regulations and Regulatory Review'' (76 FR 38210). OSHA would update three standards to align with current medical practice, including a reduction to the number of necessary employee x-rays, updates to requirements for pulmonary function testing, and updates to the table used for decompression of employees during underground construction. Additionally, the proposed revisions include an update to the consensus standard incorporated by reference for signs and devices used to protect workers near automobile traffic, a revision to the requirements for roll-over protective structures to comply with current consensus standards,

updates for storage of digital x-rays and the method of calling emergency services to allow for use of current technology, and a revision to lockout/tagout requirements in response to a court decision, among others. OSHA is also proposing to remove from its standards the requirements that employers include an employee's social security number (SSN) on exposure monitoring, medical surveillance, and other records in order to protect employee privacy and prevent identity fraud.

SIP rulemakings do not address new significant risks or estimate benefits and economic impacts of reducing such risks. Overall, SIP rulemakings are reasonably necessary under the OSH Act because they provide cost savings, or eliminate unnecessary requirements. The Agency does estimate cost savings and paperwork reductions for SIP rulemakings. The Agency has estimated that one revision (updating the method of identifying and calling emergency medical services) may increase construction employers costs by about $28,000 per year while two provisions (reduction in the number of necessary employee x-rays and elimination of posting requirements for residential construction employers) provide estimated costs savings of $3.2 million annually. The Agency has not estimated or quantified benefits to employees from reduced exposure to x-ray radiation or to employers for the reduced cost of storing digital x-rays rather than x-ray films, among others. The Agency has preliminarily concluded that the proposed revisions are economically feasible and do not have any significant economic impact on small businesses. The Preliminary Economic Analysis in this preamble provides an explanation of the economic effects of the proposed revisions.

II. Background

The purpose of the SIP–IV rulemaking is to remove or revise outdated, duplicative, unnecessary, and inconsistent requirements in OSHA's safety and health standards. The Agency believes that improving OSHA standards will increase employers' understanding of their obligations, which will lead to increased compliance, improve employee safety and health, and reduce compliance costs.

In 1995, in response to a Presidential memorandum to improve government regulation,[1] OSHA began a series of rulemakings designed to revise or remove standards that were confusing, outdated, duplicative, or inconsistent. OSHA published the first rulemaking, ''Standards Improvement Project, Phase I'' (SIP–I) on June 18, 1998 (63 FR 33450).[2] Two additional rounds of SIP rulemaking followed, with final SIP rules published in 2005 (SIP–II) (70 FR 1111) and 2011 (SIP–III) (76 FR 33590).[3]

As stated above, the President's Executive Order 13563 (E.O.), ''Improving Regulations and Regulatory Review,'' sets out the goals and criteria for regulatory review, and requires agencies to review existing standards and regulations to ensure that these standards and regulations continue to protect public health, welfare, and safety effectively, while promoting economic growth and job creation. The E.O. encourages agencies to use the best, least burdensome means to achieve regulatory objectives, to perform periodic reviews of existing standards to identify outmoded, ineffective, or burdensome standards, and to modify, streamline, or repeal such standards when appropriate.

The Agency believes that the SIP rulemaking process is an effective means to improve its standards and advised the Advisory Committee for Construction Safety and Health (ACCSH) at a public meeting held on December 16, 2011 that it intended to review its standards under the SIP criteria, with particular emphasis on construction standards. A transcription of these proceedings (ACCSH Transcript) is available at Docket No. OSHA–2011–0124–0026.

Recognizing the importance of public participation in the SIP process, the Agency published a Request for Information (RFI) on December 6, 2012 (77 FR 72781) asking the public to identify standards that were in need of revision or removal, and to explain how such action would reduce regulatory burden while maintaining or increasing the protection afforded to employees. The Agency received 26 comments in response to the RFI. As discussed below, several of the proposed amendments contained in this proposed rule were recommended in the public comments received in response to the RFI. Other proposed SIP amendments were identified by the Agency's own internal review and by ACCSH.

III. Summary and Explanation of the Proposed Rule

OSHA is proposing a number of actions amending its standards, including revisions to its general industry, maritime, and construction standards. A detailed discussion of each of the proposed revisions follows, including a discussion of comments the Agency received in response to the RFI. Some of the proposed revisions affect more than one industry (*i.e.,* general industry, construction). When proposed revisions to a general industry standard would affect additional industries, OSHA will discuss the revisions fully in the general industry section and then reference the provisions affected in the sections covering the other industries.

A. Proposed Revision in Occupational Injuries and Illnesses Recording and Reporting Standards (29 CFR Part 1904)

Subpart C—Recording Forms and Recording Criteria, Recording Criteria for Cases Involving Occupational Hearing Loss in 29 CFR 1904.10

The provisions of 29 CFR part 1904 provide for the recording and reporting of occupational injuries and illnesses. Section 1904.10 sets out the recordkeeping criteria for recording cases involving occupational hearing loss. Current § 1904.10(b)(6) provides that ''[i]f a physician or other licensed health care professional determines that a hearing loss is not work-related or has not been significantly aggravated by occupational noise exposure, [the employer is] not required to consider the case work-related or to record the case on the OSHA 300 log.'' Section 1904.5 provides the requirements for determining whether an injury or illness is work-related.

To clarify the relationship between §§ 1904.10(b)(6) and 1904.5, OSHA incorporated the following language

[1] Clinton, W.J. Memorandum for Heads of Departments and Agencies. Subject: Regulatory Reinvention Initiative. March 4, 1995.

[2] Revisions made by the SIP–I rulemaking included adjustments to the medical-surveillance and emergency-response provisions of the Coke Oven Emissions, Inorganic Arsenic, and Vinyl Chloride standards, and removal of unnecessary provisions from the Temporary Labor Camps standard and the textile industry standards.

[3] In the final SIP–II rulemaking published in 2005 (70 FR 1111), OSHA revised a number of provisions in its health and safety standards identified as needing improvement either by the Agency or by commenters during the SIP–I rulemaking. These included updating or removing notification requirements from several standards, updating requirements for first aid kits to reflect newer consensus standards, updating requirements for laboratories analyzing samples under the vinyl chloride standard, making worker exposure monitoring frequencies consistent under certain health standards, among other things. The final SIP–III rule, published in 2011 (76 FR 33590), updated consensus standards incorporated by reference in several OSHA rules, deleted provisions in a number of OSHA standards that required employers to prepare and maintain written training-certification records for personal protective equipment, revised several sanitation standards to permit hand drying by high-velocity dryers, and modified OSHA's sling standards to require that employers use only appropriately marked or tagged slings for lifting capacities.

into the recordkeeping compliance directive:

> Physician or other licensed health care professional (PLHCP) must follow the rules set out in 1904.5 to determine if the hearing loss is work-related. If an event or exposure in the work environment either caused or contributed to the hearing loss, or significantly aggravated a pre-existing hearing loss, the PLHCP must consider the case to be work-related. It is not necessary for work to be the sole cause, or the predominant cause, or even a substantial cause of the hearing loss; any contribution from work makes the case work-related. The employer is responsible for ensuring that the PLHCP applies the analysis in Section 1904.5 when evaluating work-related hearing loss, if the employer chooses to rely on the PLHCP's opinion in determining recordability.

(CPL 02–00–135, Chapter 5, Section IX, Question 10–4, 01/12/2012.)

In this rulemaking, OSHA is proposing to add a specific cross reference to § 1904.5 in paragraph § 1904.10(b)(6) to make the language in § 1904.10(b)(6) consistent with the above-quoted language from the compliance directive. The reference specifies that employers must comply with the provisions of § 1904.5 when making a determination of whether a worker's hearing loss is work-related. OSHA believes the proposed revision will assist employers in complying with the hearing-loss recording requirement.

B. Proposed Revisions in General Industry Standards, Shipyard Standards, and Construction Standards (29 CFR Parts 1910, 1915, and 1926)

1. Subpart J of 1910—General Environmental Controls, Control of Hazardous Energy (Lockout/Tagout) in 29 CFR 1910.147

The Control of Hazardous Energy (Lockout/Tagout) standard, 29 CFR 1910.147, establishes requirements for the control of hazardous energy, including electrical, pneumatic, mechanical, hydraulic, chemical or thermal energy, during the servicing and maintenance of machinery and equipment. Workers who service equipment without preventing the discharge of this energy can be electrocuted or suffer burns, amputations, lacerations, bone fractures, or crushing injuries, among others.

According to its terms, the lockout/tagout standard applies to servicing and maintenance operations ''in which the *unexpected* energization or startup of the machines or equipment, or the release of stored energy could cause injury to employees'' (§ 1910.147(a)(1)(i) (emphasis in original)). Because OSHA believes the term ''unexpected'' has been misinterpreted to exclude some operations where employees are subject to injury from startup or the release of stored energy, the Agency is proposing to remove the word from § 1910.147(a)(1) and several other places it appears in the standard (§§ 1910.147(a)(2)(iii)(A), (a)(3)(i), (b), (c)(1), (c)(4)(i), (f)(4), and in Appendix A). The lockout/tagout standard was designed to protect workers from being injured if a machine or other piece of equipment they are servicing releases stored energy, for example, by starting or moving during the servicing. The standard protects these employees by requiring that machines or equipment be de-energized and locked or tagged out *by the worker performing the servicing or maintenance* before the work is performed. The essence of the standard's protection is that a de-energized machine or piece of equipment *cannot* be restarted unless the worker servicing it personally removes the lockout or tagout device he or she has applied.

Thus, OSHA intended the phrase ''unexpected energization'' to mean any re-energization or startup that occurs before the servicing employee removes the lockout/tagout device from the energy isolation device or equivalent energy control mechanism.

In line with this intent, OSHA has historically interpreted the term ''unexpected energization'' to mean energization that is unintended or unplanned *by the servicing employee* (72 FR 72452, 72496, December 20, 2007; CPL 02–00–147). OSHA believes that preventing this type of unintended or unplanned energization during servicing is necessary to fully effectuate the standard's purpose of protecting workers through the control of hazardous energy. (*See* CPL 02–00–147, *The Control of Hazardous Energy—Enforcement Policy and Inspection Procedures at 3–1* (Feb. 11, 2008) (''Quite simply, the [lockout/tagout] standard is violated when an employee is, or may be, exposed to hazardous energy that has not been isolated, even if the employee knows that the energy has not been controlled and continues to constitute a hazard.''))

Several decisions of the Occupational Safety and Health Review Commission (OSHRC) support this interpretation. In *Burkes Mechanical, Inc.,* 21 BNA OSHC 2136, 2139 & n.4 (No. 04–0475, 2007), OSHRC rejected an argument that the lockout/tagout standard did not apply to employees who were servicing conveyor equipment that was operating. The fact that they knew the equipment was moving did not mean that the hazard fell outside the scope of the standard. Similarly, OSHRC found the standard applied in *Otis Elevator Co.,* 24 BNA OSHC 1081 (No. 09–1278, 2013), *aff'd,* 762 F.3d 116 (D.C. Cir. 2014), where an employee was trying to unjam the stuck gate assembly of an elevator car without proper energy control measures in place. The energization was unexpected because, although the worker knew the gate assembly would start to move when unjammed, he could not predict when it would become unjammed. The United States Court of Appeals for the District of Columbia Circuit affirmed OSHRC's decision for the same reason. *Otis Elevator Co.* v. *Secretary of Labor,* 762 F.3d 116, 122 (D.C. Cir. 2014).

On the other hand, OSHA's understanding of the standard has not always been accepted. In *Reich* v. *General Motors Corp., Delco Chassis Div. (GMC Delco),* 17 BNA OSHC 1217 (Nos. 91–2973, 91–3116, 91–3117, 1995); *aff'd* 89 F.3d 313 (6th Cir. 1996), both OSHRC and the United States Court of Appeals for the Sixth Circuit rejected OSHA's interpretation. Instead they held that the lockout/tagout standard did not apply where a startup procedure for a machine provided a warning to a worker servicing it that it was about to start. In that case, workers were servicing machines that used an eight-to-twelve-step startup procedure, including time delays, and audible or visual warnings. The court and OSHRC held that, because these features would warn the servicing employees that the machines were about to start, the startup would not be ''unexpected.'' According to the Sixth Circuit, ''the plain language of the lockout standard unambiguously renders the rule inapplicable where an employee is alerted or warned that the machine being serviced is about to activate.'' 89 F.3d at 315.

OSHA believes that the *GMC Delco* decisions fundamentally misconstrue the ''unexpected'' language of the lockout/tagout standard by allowing employers to use warning and delay systems as alternatives to following the requirements of the standard. Warning devices are not as protective as a lockout/tagout program, and the standard does not allow them to be used as an alternative to a lockout/tagout program. Indeed, the exclusive use of warning devices subverts the intent of the standard by removing control over the hazardous energy from individual authorized employees and instead placing the burden on those exposed employees to become cognizant of and to recognize the warnings, so that they can attempt to escape danger zones before they are injured. In adopting the standard, OSHA considered this approach to be impractical and dangerous. Instead, OSHA intended to

protect employees effectively from all forms of hazardous energy by isolating machines from their energy sources during servicing and/or maintenance and providing the workers who were servicing them with control over the energy isolation devices (see CPL 02–00–147 at 3–3 & ch. 4).

In addition, by holding that work on a device that gives warning before startup does not fall within the standard, the *GMC Delco* decisions, in essence, require a case-by-case assessment of various warning schemes to determine the applicability of the standard. To enforce the standard consistent with those decisions, OSHA has provided its compliance officers with 11 different factors to evaluate to determine whether particular warning devices are adequate and reliable enough to allow all employees to escape all types of hazardous energy in all circumstances that may occur (see CPL 02–00–147 at 3–5 to 3–6). This creates a degree of uncertainty about the applicability of the standard for the regulated community that OSHA did not intend.

As a result of the *GMC Delco* decisions, OSHA is proposing to remove the term ''unexpected'' from the lockout/tagout standard to revert to its original understanding of the standard. The proposal is intended to make clear that the lockout/tagout standard covers all equipment servicing activities in which there are energization, startup, or stored energy hazards.

This proposal is consistent with the court's recognition that the rulemaking process provides OSHA with the opportunity to change the application of the lockout/tagout standard. *GMC Delco,* 89 F.3d at 316. It will also make the standard consistent with OSHA's shipyard lockout/tagout standard, which is almost identical to the general industry standard except that it omits the word ''unexpected'' from the scope provision. 29 CFR 1915.89. The shipyard lockout/tagout proposal gave the same reasons for deleting the word as are provided here (72 FR 72452, 72496, December 20, 2007), and OSHA finalized the rule after failing to receive any comments addressing the issue. (76 FR 24576, 24704, May 2, 2011).

Removing the word ''unexpected'' will improve protection of workers under the standard, eliminate the confusion regarding applicability of the standard caused by the *GMC Delco* decisions, and make the lockout/tagout standard consistent with the lockout/tagout provisions in the General Working Conditions in Shipyard Employment standard.

2. Subpart Z of 1910, 1915, and 1926—Toxic and Hazardous Substances, Asbestos in 29 CFR 1910.1001, Inorganic Arsenic in 29 CFR 1910.1018, Cadmium in 29 CFR 1910.27, Coke Oven Emissions in 29 CFR 1910.29, Acrylonitrile in 29 CFR 1910.1045, Asbestos in 29 CFR 1915.1001, Asbestos in 29 CFR 1926.1101, Cadmium in 29 CFR 1926.1127

OSHA is proposing a series of revisions to requirements addressing employee chest X-rays in the Agency's health standards. In particular, OSHA is proposing to remove the requirement in several of its standards that employers provide periodic chest X-rays to screen for lung cancer; to allow employers to use digital films and other reasonably-sized standard films for X-rays; and to update terminology and references to ILO guidelines included in its asbestos standards.

Removing Periodic Chest X-Ray Requirements for Lung-Cancer Screening

OSHA requires medical surveillance in its health standards to detect early indications of adverse health effects in exposed workers before symptoms occur, so that appropriate interventional measures can be taken. Several OSHA standards currently require periodic chest X-rays (CXR), also referred to as posterior-anterior CXR, radiographs, or roentgenograms (a term no longer used). When the Agency published these standards, routine screening for lung cancer with CXR was appropriate clinical practice. However, since then, large studies with many years of follow-up have not shown a benefit to CXR screening, either on lung cancer incidence or mortality. Therefore, OSHA is proposing to remove the requirement for periodic CXR in the following standards: §§ 1910.1018, Inorganic Arsenic; 1910.1029, Coke Oven Emissions; and 1910.1045, Acrylonitrile. OSHA is not proposing to remove the requirement for a baseline CXR in these, or any other, standards. OSHA is also not proposing to remove the CXR requirements in standards where it is used for purposes other than periodic screening for lung cancer. For example, the proposal does not affect periodic CXRs required by OSHA's standards to detect or monitor the progression of pneumoconiosis.

Similarly, OSHA is proposing to amend Appendix H of the asbestos standard, § 1910.1001.[4] Appendix H provides non-mandatory guidelines for asbestos medical exposure, and OSHA proposes to include the text ''Plural plaques and thickening may be observed on chest X-rays.'' OSHA is retaining CXRs in the asbestos standard to continue screening for asbestosis, and the proposed text notes the changes related to asbestosis that can be seen on CXRs. The change thus explains the purpose of the CXR.

Section 6(b)(7) of the Occupational Safety and Health Act, 29 U.S.C. 655(b)(7), allows OSHA to modify medical examination requirements in existing standards when ''warranted by experience, information, or medical or technological developments.'' OSHA has used this authority on several occasions. For example, when contemporary evidence indicated that sputum cytology did not improve lung-cancer survival rates, OSHA removed the sputum-cytology-examination requirements from the Coke Oven and Inorganic Arsenic standards in the SIP–I rulemaking (63 FR 33450, 33458–59, June 18, 1998). In addition, OSHA also reduced CXR frequencies from semi-annual to annual for some workers exposed to inorganic arsenic and coke oven emissions in SIP–I. The Agency based this reduction on data available at the time indicating that semi-annual x-rays provided no additional protection, when compared to annual x-rays, in improving the detection of, and survival from, lung cancer for higher risk persons (63 FR 33459–60). This eliminated unnecessary radiation exposure for employees and reduced the burden on employers. OSHA retained the medical history and physical-examination requirements in these standards.

For the reasons discussed below, OSHA has made a preliminary determination that the current literature shows that there is no evidence of benefit, either in lung cancer incidence or mortality, from screening with CXR in the general population. The primary goal of population-based screening is to detect disease at an early stage when cure or control is possible, thereby decreasing the number of people who die from the disease (Black and Welch, 1997; U.S. Preventive Services Task Force (USPSTF), 2013; Mazzone, 2012).[5] Several large-scale, randomized controlled trials have been conducted over the years to determine whether

[4] OSHA is also proposing the same change for the parallel appendices in the Maritime and Construction Asbestos standards, 29 CFR 1915.1001 Appendix I and 1926.1101 Appendix I.

[5] Materials referenced are posted on *http://regulations.gov,* Docket No. OSHA–2012–0007, and are accessible at OSHA's Docket Office, U.S. Department of Labor, 200 Constitution Avenue NW., Room N2625, Washington, DC 20210; telephone (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) OSHA Docket Office hours of operation are 8:15 a.m. to 4:45 p.m., E.T.

screening with chest x-rays, with or without the addition of sputum cytology tests, was effective in reducing mortality from lung cancer. These studies are discussed below. The Mayo Lung Project compared participants in an ''intervention'' group, who were offered chest radiography and sputum cytology every four months, with those in a ''control'' group offered standard medical care. Participants were middle-aged and older men who were chronic heavy cigarette smokers and thus at high risk of developing lung cancer. After the initial prevalence screening, 9,211 male smokers aged 45 and older who completed the prevalence screening with negative results and who qualified for incidence rescreening were randomized to either of the two groups. The more screening-intensive intervention group was encouraged (and reminded) to undergo free chest x-rays and free sputum cytology tests every four months for six years. While the ''controls'' were offered standard medical care, they also were advised to undergo annual chest x-rays and sputum cytology tests, resulting in significant contamination of the control group by CXR performed off protocol. Follow-up ranged from one to five years, and averaged three years.

At the end of the follow-up (July 1, 1983), the Mayo Clinic study observed no difference in lung cancer mortality between the intervention and control groups, but observed an excess of 46 cases in the intervention group, a possible indication of over-diagnosis in lung cancer screening. The excess number of cases also could have resulted from short follow-up time (that is, additional cases may have been observed in the control group if the study lasted longer). In summary, this trial demonstrated significantly increased lung cancer detection, resectability, and survivorship after detection in the group offered screening every four months compared with the control group. However, there was no significant difference in lung cancer mortality rate between the two groups. Contamination of the control group, together with 25 percent non-compliance in the screened group, limited the statistical power of this trial. The authors concluded that ''results do not justify recommending large-scale radiologic or cytologic screening for early lung cancer at this time (Fontana, *et al.,* 1984; Fontana, *et al.,* 1991).''

The term ''over-diagnosis'' refers to identifying through screening a disease that would otherwise remain undiagnosed during an individual's lifetime (*i.e.,* because symptoms do not present). Over-diagnosis is a serious potential risk of screening, as the evaluation and treatment of over-diagnosed cancer can lead to morbidity, and even to premature mortality (Black, 2000).

In order to assess whether over-diagnosis accompanies lung cancer CXR screening, Marcus *et al.* (2006) extended the follow-up of the same Mayo Clinic population studied by Fontana *et al.* for an additional 16 years using a randomized controlled trial with a stop-screen feature. A stop-screen study design (*i.e.,* one in which screening is terminated after a prespecified number of years but follow-up continues for ascertainment of cases of disease and deaths) provides the best setting in which to assess whether over-diagnosis accompanies screening (Marcus *et al.,* 2006). If over-diagnosis does not occur, the cumulative number of cases in each group will be equal after screening stops and the number of cancers in the control group identified through symptoms catches up with those identified earlier through screening (Marcus *et al.,* 2006).

At the start of the study in 1983, information on lung cancer status was available for 6,101 participants. From 1971 through the end of 1999, 585 participants in the more frequently screened group and 500 in the usual-care group were diagnosed with lung cancer. Because the number of lung cancers in the usual care group did not equalize with those in the more frequently screened group at the end of the study period, the study investigators concluded that ''the persistence of excess cases in the intervention [group] after 16 years of additional follow-up provides continued support for over-diagnosis in lung cancer screening'' (Marcus *et al.,* 2006).

OSHA identified one study that included men who were younger than 45. A Czech study, Kubic and Polak (1986), enrolled 6,364 smokers aged 40 to 64 years. This study compared semi-annual screening using x-ray and sputum cytology to screening at three-year intervals, and to no screening. Although it found more earlier-stage lung cancers in both screened groups, this study also found no significant difference in mortality rates. In 1993, the Prostate, Lung, Colorectal, and Ovarian (PLCO) Randomized Trial examined the question whether screening would reduce mortality rates from PLCO cancers. In a randomized controlled study conducted in ten screening centers in the US, 154,901 participants aged 55 through 74 years were assigned either to the group that received annual CXR for three or four years, or to the ''usual care'' (no radiographic intervention) group; 51.6 percent of the participants were current or former smokers. All diagnosed cancers, deaths, and causes of death were ascertained through 13 years of follow-up or until December 31, 2009, whichever event occurred earlier (Oken *et al.,* 2011). The study found no statistically significant differences in lung cancer mortality or incidence rates between the intervention and ''usual care'' groups, despite finding a higher proportion of early stage (potentially curable) lung cancers in the screened group (Hocking *et al.,* 2010). Of particular note is the rate of false positives in the study; of 13,038 participants with at least one positive CXR, 12,730, or 97.6 percent, did not test positive for lung cancer. Furthermore, 121 participants without cancer underwent an invasive surgical procedure (Hocking *et al.,* 2013).

An effective screening measure should detect a disease in its early stages before clinical signs and symptoms appear (Herman, 2006). Patients who are diagnosed while they are still asymptomatic tend to have better outcomes than those who are symptomatic (In, *et al.,* 2008). It is well documented in the radiology literature that initial CXR misses 19–50 percent of lung cancers (Quekel, 1999). In the past decades, several technological innovations have shown improved sensitivity in detecting lung cancer. Several small studies have shown that newer techniques (*e.g.,* dual-energy subtraction radiology, electronic bone suppression, temporal subtraction) may result in fewer missed diagnoses of pulmonary nodules. However, no large-scale randomized or non-randomized studies are available that assess the sensitivity of these radiological techniques.

Baseline screening of general populations for unsuspected lung cancer with CXR yields only a small fraction—less than one percent—of lung cancer cases (Hocking *et al.,* 2010; Kubik and Polak, 1986; Fontana *et al.,* 1984). Currently, the majority (approximately 85 percent) of patients with lung cancer present for clinical evaluation with symptoms (Mazzone, *et al.,* 2014); detection of lung cancer in the remaining (asymptomatic) patients frequently occurs when an x-ray or CT scan is done for another reason (Mazzone *et al.,* 2014; PubMed Health).

Several authoritative sources of health-information do not recommend CXR for wide-scale screening. For example, the National Cancer Institute (NCI) in its online Lung Cancer Screening PDQ (Physician's Data Query) concluded, ''Based on solid evidence, screening with chest x-ray and/or

sputum cytology does not reduce mortality from lung cancer in the general population or in ever-smokers.'' The NCI PDQ goes on to discuss the harm associated with false-positive screenings: ''Based on solid evidence, at least 95 percent of all positive chest x-ray screening exams (but not all) do not result in a lung cancer diagnosis. False-positive exams result in unnecessary invasive diagnostic procedures.'' The NCI PDQ refers to the Oken (2011) and Marcus (2006) studies when estimating the magnitude of over-diagnosis at 6 percent to 17 percent. The Cochrane Collaboration, a non-profit group that reviews health-care literature for the purpose of making empirical recommendations, updated its original review article, ''Screening for lung cancer,'' in 2013. This latest review included nine trials (eight randomized controlled studies and one controlled trial) with a total of 453,965 subjects. The review includes many of the studies discussed here. The authors concluded:

> The current evidence does not support screening for lung cancer with chest radiography or sputum cytology. Annual low-dose CT screening is associated with a reduction in lung cancer mortality in high-risk smokers but further data are required on the cost effectiveness of screening and the relative harms and benefits of screening across a range of different risk groups and settings.

(Manser *et al.,* 2013).

Screening workers exposed to lung carcinogens is a complex issue. Current tools, particularly CXR, have not been shown to be effective in reducing mortality in high-risk smoking populations, and have not been studied in worker populations (Fontana, 1984; Oken, 2011; Marcus *et al.,* 2011; Hocking *et al.,* 2010). However, workers exposed to lung carcinogens are at a higher risk for lung cancer than the general population. OSHA conducts risk analyses as part of its regulatory requirements, and has determined that occupational exposure to each of these: Inorganic arsenic, coke oven emissions, and acrylonitrile, was found to be associated with a ''significant risk'' of lung cancer (§§ 1910.1018, Inorganic Arsenic; 1910.1029, Coke Oven Emissions; and 1910.1045, Acrylonitrile).

OSHA has also preliminarily determined that the existing evidence is insufficient to justify using alternative screening methods to CXR. While the National Institute for Occupational Safety and Health (NIOSH) is currently evaluating the applicability of Low-Dose Computed Tomographic (LDCT) as a screening tool for workers exposed to lung carcinogens, it may be years before this research can provide a recommendation on the efficacy of LDCT. Additionally, research is needed on the risks associated with LDCT-associated radiation exposure occurring during a screening protocol for workers exposed to lung carcinogens in the workplace.

As noted earlier in this discussion, OSHA is proposing to remove the requirement to use periodic CXR as a screening tool for lung cancer from the following standards: §§ 1910.1018, Inorganic Arsenic; 1910.1029, Coke Oven Emissions; and 1910.1045, Acrylonitrile.

Although OSHA is proposing to remove periodic CXR requirements from the medical-surveillance sections of these three standards, the Agency emphasizes that the Access to Medical and Exposure Records standard (29 CFR 1910.1020) would still require employers to maintain all medical records, including records of CXRs previously administered. That is, this proposed rule would not relieve employers in general industry, maritime, and construction of the duty to maintain records of CXRs already administered under the requirements of §§ 1910.1018, 1910.1029, 1910.1045, 1915.1018, 1915.1045, 1926.1118, and 1926.1145 [6] in accordance with § 1910.1020.

OSHA is not proposing to remove the initial, baseline CXR requirement in these three standards. The Agency recognizes that requiring initial, baseline CXR at pre-placement or at the initiation of a medical-surveillance program provides benefits to workers exposed to lung carcinogens, their employers, and health-care professionals evaluating those workers. For example, even with known limitations, CXR can serve to document the absence of disease. Baseline CXR also can be useful in preventing additional testing after detecting an abnormality at a future date. In this regard, the PLCO Screening Trial found that ''evaluation stopped after comparison of the screening radiograph with a prior CXR in about one-third'' of those participants presenting with an abnormal follow-up CXR (Hocking *et al.,* 2013). When a worker receives a CXR prompted by symptoms, physical examination, or other indicator, and has an abnormality on that CXR, a baseline CXR from years before with the same lesion would reduce the need for additional evaluation (*e.g.,* CT scans, biopsy); such evaluations can be invasive, and lead to unnecessary irradiation for workers and additional costs for employers. However, workers receiving baseline CXR also may undergo invasive, potentially unnecessary work-ups and diagnostic testing for CXR-detectable lesions that may never progress to clinical significance. OSHA will continue to monitor the literature on baseline chest X-rays.

Updating Other Chest X-Ray Requirements

In recent years, improvements in medical technology permit screening with digital CXRs, also referred to as digital radiographs, in addition to traditional film-based CXRs. The medical community is rapidly adopting the technology, and both the International Labor Organization (ILO) and NIOSH recently published guidelines for digital radiographs (ILO, 2011; NIOSH, 2011).

OSHA is proposing to update the CXR requirements to allow the use of digital radiograph in the medical surveillance provisions of its Coke Oven Emissions, Acrylonitrile, and Inorganic Arsenic standards discussed above, and in its three asbestos standards and two cadmium standards. The latter standards are: §§ 1910.1001, Asbestos (General Industry); 1915.1001, Asbestos (Maritime); 1926.1101, Asbestos (Construction); 1910.1027, Cadmium (General Industry); and 1926.1127 Cadmium (Construction).[7] As noted previously, OSHA is proposing to add the option of digital radiography standards to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities. Another Department of Labor Program, the Office of Workers' Compensation Programs, published a final rule allowing the submission of digital radiographs in connection with benefit claims, and set out quality standards for administering and interpreting digital radiographs. (See 79 FR 21606; April 17, 2014). OSHA's proposal will codify current Agency policy as stated in a Letter of Interpretation dated September 24, 2012 to Dr. Michael Hodgson, in which OSHA confirmed that it ''will allow, but will not require, digital radiography in place of traditional chest roentgenograms for medical surveillance exams under the Asbestos Standards for

[6] The Construction and Maritime Inorganic Arsenic and Acrylonitrile standards, §§ 1915.1018, 1915.1045, 1926.1118, and 1926.1145, merely reference the respective general industry standards (§§ 1910.1018 and 1910.1045), so OSHA is not proposing to revise them.

[7] The Maritime Cadmium standard, § 1915.1027, is a reference to the general industry standard (§ 1910.1027), so OSHA is not proposing to revise it.

general industry, construction, and shipyards.''

Radiographic facilities and the physicians that are required by OSHA standards to classify CXR according to ILO's classification guidelines and that employ digital radiographs in their practice should follow the NIOSH Guidelines, ''Application of Digital Radiography for the Detection and Classification of Pneumoconiosis,'' or the most recent NIOSH guidance on using digital radiography to detect pneumoconiosis. In its current guidelines, NIOSH recommends that ''only authorized ILO standard digital images should be used for classifying digital chest images for pneumoconiosis.'' NIOSH does not recommend using film-based ILO reference radiographs for comparison with digital chest images or printed hard copies of the images. In this revision of the chest x-ray requirements, OSHA is also proposing to allow other reasonably-sized standard x-rays films, such as the 16 inch by 17 inch size, to be used in addition to the 14 inch by 17 inch film specified in some standards. In these standards, the phrase ''A 14- by 17-inch film or digital posterior-anterior chest X-ray'' (or similar) would be replaced by ''A 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray.'' This proposed change will affect the acrylonitrile standard (§ 1910.1045); the inorganic arsenic standard (§ 1910.1018); the coke oven standard (§ 1910.1029); and the asbestos standards (§§ 1910.1001, 1915.1001, and 1926.1101).[8] Updating this requirement ensures consistency across standards as well as conformance with current medical practice. This proposed change also would codify existing Agency policy outlined in a Letter of Interpretation (February 16, 1993 to David Lee Sirott) confirming that 16 inch by 17 inch X-rays are generally acceptable for the purpose of complying with OSHA standards.

Proposed updates also include replacement of ''roentgenogram'' with ''X-ray'' to reflect current terminology and corrections to remove references to semi-annual exams for certain employees in Coke Ovens Emissions appendices, § 1910.1029 App. A(VI) and App. B(II)(A), as these exams were eliminated in the second SIP rulemaking (70 FR 1112). In addition, the proposal makes changes to conform to the language used in the ILO's ''Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses,'' which specifically refers to a classification system as applying to CXR, while interpretation refers to the information translated by the physician to the employer. Finally, the proposed revisions include updating the version of the ILO Classification of Radiographs of Pneumoconioses to the 2011 version (from the 1980 version), and clarifying that classification must be accordance with the ILO classification system (rather than ''a professionally accepted Classification system'') in Appendix E of each of the three asbestos standards.

[8] And minor rewording to conform to the proposed language in the cadmium standards (1910.1027 and 1926.1127).

Statement of Reasonable Availability

As noted above, OSHA is incorporating the ILO Classification of Radiographs of Pneumoconioses, Revised Edition 2011, by reference. OSHA believes that this classification document is reasonably available to interested parties. It is available for purchase from the International Labour Organization (ILO), 4 route des Morillons, CH–1211 Genève 22, Switzerland; telephone: +41 (0) 22 799 6111; fax: +41 (0) 22 798 8685; Web site: *http://www.ilo.org/*. In addition, it is available in the docket for this rulemaking and in OSHA's docket office for review. If OSHA ultimately finalizes this rule, the classification document will be maintained in OSHA's national and regional offices for review by the public.

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3. Subpart Z of 1910—Toxic and Hazardous Substances, Pulmonary-Function Testing Requirements for Cotton Dust in 29 CFR 1910.1043

Background

In 1978, OSHA promulgated the standard for occupational exposure to cotton dust at 29 CFR 1910.1043 because workers exposed to cotton dust are at risk of developing the respiratory disease, byssinosis (43 FR 27350, June 23, 1978). As described in the preambles to the proposed and final rules, byssinosis is characterized by a continuum of effects (41 FR 56497, 56500–56501, December 28, 1976; 43 FR 27352–27354). Generally, workers who develop byssinosis first experience an acute stage (also called the reactor state), with mild and apparently reversible symptoms that occur on the first day of the work week, after one or more days away from the workplace. Symptoms include chest tightness, difficulty breathing, coughing, and possibly wheezing. Some of those workers also experience temporary acute declines in lung function over the course of a workshift as measured by pulmonary-function testing. As the disease progresses, workers may begin to experience symptoms on other days of the work week. Sometimes the disease progresses into a chronic, irreversible stage that involves permanent narrowing of bronchial tubes. Symptoms during the chronic stage are similar to symptoms observed with emphysema and chronic bronchitis, and include chronic cough with phlegm production and progressive shortness of breath. At this stage, impaired lung function associated with the disease is clearly detectable by pulmonary function testing. Byssinosis can lead to disability or death. Rates of progression depend on exposure levels and susceptibility of workers.

The Cotton Dust Standard contains medical-surveillance provisions at 29 CFR 1910.1043(h). These provisions require initial and periodic medical-surveillance examinations that include administration of a medical questionnaire to determine if workers are experiencing symptoms (§§ 1910.1043(h)(2)(ii) and (h)(3)(i)). Medical surveillance requirements also include pulmonary function testing (*i.e.,* spirometry testing) to objectively measure lung function and to assess changes in lung function (§ 1910.1043(h)(2)(iii)).

The preamble for the final Cotton Dust standard noted the poor accuracy and high variability of pulmonary function tests in the past, resulting from lack of uniform specifications for equipment calibration checks, test procedures, and personnel training (43 FR 27391). To improve the accuracy and consistency of pulmonary function testing, OSHA mandated specific requirements in the Cotton Dust Standard based on recommendations from the American Thoracic Society (ATS) and the National Institute for Occupational Safety and Health (NIOSH) (43 FR 27391; 29 CFR 1910.1043, Appendix D). Since 1978, pulmonary function testing procedures and technology have evolved significantly, and some of the mandates in the Cotton Dust Standard now are outdated. OSHA is proposing to update the lung function testing requirements for the Cotton Dust Standard to make them consistent with current practices and technology.

Proposed Revisions

OSHA based the proposed revisions to the Cotton Dust Standard pulmonary function testing requirements on current recommendations from the American Thoracic Society/European Respiratory Society (ATS/ERS), NIOSH, and the American College of Occupational and Environmental Medicine (ACOEM). Each of these organizations is a recognized authority on generally accepted practices in pulmonary function testing. In the following discussion, references to generally accepted practices refer to only those practices recommended by ATS/ERS, NIOSH, or ACOEM.

Like other respiratory diseases, byssinosis can slow the speed of expired air and/or reduce the volume of air that can be inspired and then exhaled. To detect and monitor these impairments, spirometry measures the maximal volume and speed of air that is forcibly exhaled after taking a maximal inspiration. Forced Vital Capacity (FVC) is defined as total exhaled volume after full inspiration. Speed of expired air is determined by dividing the volume of air exhaled in the first second, *i.e.,* the Forced Expiratory Volume in One Second (FEV1), by the total FVC to give the FEV1/FVC ratio. Values obtained from accurate and repeatable spirometry testing are then compared to reference predicted values, which are averages expected for a person of the same gender, age, height, and race as the employee being tested. A spirometry result that is 100 percent of the predicted value for a person of the same gender, age, and height and race indicates that the individual being tested has average lung function (OSHA, 2013). Depending upon the race of the individual and the reference value group being used, an adjustment may need to be made on the basis of race. This issue is discussed at greater length later in this discussion. Values are also compared to the employees' previous measurements.

Currently, § 1910.1043(h)(2)(iii) requires that health care providers conducting medical surveillance compare the employees' values to the predicted values in Appendix C of the standard. Appendix C currently contains predicted values derived from equations published by Knudson *et al.* (1976).

OSHA is proposing to revise this provision to specify use of the third National Health and Nutrition Examination Survey (NHANES III) reference data set and to replace the values currently in Appendix C with the NHANES III values, derived from Spirometric Reference Values from a Sample of the General U.S. Population (Hankinson *et al.,* 1999), which will be incorporated by reference. Currently, NIOSH (CDC/NIOSH, 2003), ATS/ERS (Pellegrino *et al.,* 2005), and ACOEM (Townsend, 2011) all recommend NHANES III as the most appropriate reference data set for assessing spirometry results for individuals in the U.S. population. The data set from NHANES III is the most recent and most representative of the U.S. population (Hankinson *et al.,* 1999). It lists reference values for non-smoking, asymptomatic male and female Caucasians, African Americans, and Mexican Americans aged 8- to 80-years old. Strict adherence to ATS quality control standards ensured optimal accuracy in developing this data set of spirometry values (Hankinson *et al.,* 1999).

OSHA also proposes to make a correction to § 1910.1043, Appendix B–II, Section B, ''Occupational History Table''. The table's column titled ''Tenure of Employment'' contains boxes in which dates of employment are entered. To allow the entry of dates that occurred later than 1999, OSHA would change the column's two sub-headers to

read as follows: ''From 19__ or 20__'' and ''To 19__ or 20__''.

Statement of Reasonable Availability

As noted above, OSHA is incorporating the Spirometric Reference Values from a Sample of the General U.S. Population (Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine, 159(1):179–187, January 1999). These values are also available to interested parties at *http://www.cdc.gov/niosh/topics/spirometry/nhanes.htm.* In addition, they are available at *www.regulations.gov* in the docket for this rulemaking and in OSHA's docket office for review. If OSHA ultimately finalizes this rule, the data set will be maintained in OSHA's national and regional offices for review by the public.

Section 1910.1043(h)(2)(iii) currently specifies that FEV1 and FVC predicted values be multiplied by 0.85 to obtain reference values for blacks because the Knudson data set contains reference values only for Caucasians. However, such an adjustment for that race/ethnic group is no longer necessary because the NHANES III data set contains reference values for African Americans. However, the NHANES III data set does not contain reference values for Asian Americans, who typically have smaller lung volumes compared to Caucasians of the same age, height, and gender (Pellegrino *et al.,* 2005). To obtain Asian American reference values, ATS/ERS (Redlich *et al.,* 2014) and ACOEM (Townsend, 2011) recommend that Caucasian reference values for FVC and FEV1 be multiplied by a factor of 0.88. Therefore, OSHA is proposing use of a 0.88 correction factor to obtain Asian American reference values for the FVC and FEV1. Because race does not appear to affect FEV1/FVC (ratio), OSHA is not proposing to apply a correction factor to Caucasian values to derive a ratio for Asian Americans. If the NHANES data set is updated to include Asian American values in the future, and generally accepted practices endorse that data set for use in the U.S., OSHA will consider revising § 1910.1043(h)(2)(iii).

OSHA's proposal to replace the Knudson values currently in Appendix C with the NHANES III data set would simplify interpretation of spirometry results by providing reference values for more race/ethnic groups; however, neither the NHANES III nor the proposed correction factor addresses every race/ethnic group. Therefore, OSHA is proposing text that indicates comparison to ''appropriate'' race/ethnicity values for groups not included in NHANES III. For example, using Mexican-American values for non-Mexican-American Hispanic workers may be appropriate. Designations of race/ethnicity are self-reported by workers, and bi-racial or multi-racial workers should select the race category that best describes them. OSHA's guidance document provides some additional guidance on this topic, including a recommendation to use Caucasian reference values for Native American Indians (OSHA, 2013).

The software for most spirometers includes the NHANES III data set, which is identified as the Hankinson 1999 data set on some spirometers. If software for older spirometers does not include the NHANES III data set, users of those spirometers would be able to access the NHANES III values online through the NIOSH calculator (CDC/NIOSH, 2010). Tables of the NHANES III values are also available in an appendix to OSHA's spirometry guidance for healthcare professionals that is available online (OSHA, 2013). Therefore, NHANES III values are widely available to spirometry providers, including those providers using older spirometers.

Currently, paragraph (h)(2)(iii) requires an evaluation of pulmonary function testing values using predicted values of FVC and FEV1, which are the only reference values listed in the tables in current Appendix C. The NHANES III reference data set includes the lower limit of normal (LLN) as well as predicted values for FEV1, FVC, and the FEV1/FVC ratio. The LLN for these spirometry measurements represents the lower fifth percentile of a healthy (normal) population. That is, 95 percent of a healthy (normal) population should have spirometry values above the LLN, and spirometry values below the LLN could be abnormal (OSHA, 2013). Generally accepted practices by ATS/ERS, NIOSH, and ACOEM currently compare spirometry values to the LLN values to identify impaired pulmonary function.

In particular, ATS/ERS (Pellegrino *et al.,* 2005) defines airways obstruction as an FEV1/vital capacity (VC) below the LLN. ACOEM (Townsend, 2011) and NIOSH (CDC/NIOSH, 2003) define borderline airway obstruction as an FEV1/FVC below the LLN, with an FEV1 between the LLN and the predicted value; they define airways obstruction as both FEV1/FVC and an FEV1 below the LLN. ATS/ERS, NIOSH, and ACOEM indicate that an FVC or VC less than the LLN could indicate possible restrictive impairment (Pellegrino *et al.,* 2005; Townsend, 2011; CDC/NIOSH, 2003).

Therefore, OSHA is proposing to update (h)(2)(iii) to require an evaluation of FEV1, FVC, and FEV1/FVC against the LLN and percent predicted values to fully characterize possible pulmonary impairment in exposed workers, which is consistent with generally accepted current practices described above. OSHA's proposal to evaluate the FEV1/FVC ratio in addition to FEV1 and FVC will not affect triggers for changes in medical surveillance frequency or referral for a detailed pulmonary examination, because the standard bases those triggers solely on FEV1 values.

However, OSHA is also proposing to change the triggers for the frequency of medical surveillance. Currently, paragraphs (h)(3)(ii)(A) and (B) of the standard require frequency of medical surveillance based in part on whether the FEV1 is above or below 80 percent of the predicted value. OSHA is proposing that the basis for frequency of medical surveillance be whether the FEV1 is above or below the LLN. As noted above, generally accepted practices currently use the LLN as the basis for classifying possibly abnormal lung function. Pulmonary function normally declines with age, and the LLN better accounts for age-related declines than the current standard (Townsend *et al.,* 2011). There is evidence that the cut-off point used by the standard, 80 percent of the predicted value, can result in erroneous lung function interpretation in adults (Pellegrino *et al.,* 2005). Therefore, OSHA is proposing to use the LLN to determine the frequency of lung-function testing.

Section 1910.1043, Appendix D, sets standards for spirometric measurements of pulmonary function. OSHA is basing the proposed changes to Appendix D on the most recent spirometry recommendations from ATS/ERS (Miller *et al.,* 2005). Many of the proposed changes reflect advances in spirometry procedures or methods of interpretation.[9] Other proposed changes reflect technological changes associated with the current widespread use of flow-type spirometers, in addition to volume-type spirometers, which were in widespread use in 1978 when OSHA published the current standard, and remain in use today. The proposed

[9] Appendix D provides minimal standards that must be employed when making spirometry measurements. Users of Appendix D should also consult generally accepted practices from ATS/ERS (Pellegrino *et al.,* 2005; Miller *et al.,* 2005), NIOSH (CDC/NIOSH, 2003), and ACOEM (Townsend, 2011) for a complete list of current spirometry standards. OSHA's spirometry guidance also outlines those practices (OSHA, 2013).

changes would apply only to equipment purchased one year after OSHA publishes the final standard in the **Federal Register**. This would give time for distributors to exhaust existing stocks and allow medical providers to continue using the older spirometers until they buy new ones in the normal course of business.

Current Appendix D(I)(b) specifies volume capacity for spirometers, and the proposed revision would change it from seven to eight liters. Current Appendix D(I)(e) specifies flow rates for flow-type spirometers, and the proposed revision would change it from 12 to 14 liters per second. These proposed revisions to Appendix D(I)(b) and (e) reflect current recommendations by ATS/ERS (Miller *et al.,* 2005).

Current Appendix D(I)(g) requires either a tracing or display, and OSHA is proposing to revise this language to ''paper tracing or real-time display.'' When OSHA published the current standard in 1978, a pen linked to a physical strip chart generated tracings of expiration curves on graph paper during pulmonary testing. In contrast, most current flow-type and volume-type spirometers use computer-generated displays of expiration curves projected on the spirometer or on an attached computer screen.

OSHA is proposing to add size specifications for computer-generated displays, the technology most often used today (Miller *et al.,* 2005). An issue that was critical for tracings in 1978, and remains critical for both tracings and displays today, is that they be large enough to allow a technician to easily evaluate the technical acceptability of the expiration during testing. A large real-time display allows the technician to easily view a technically unacceptable expiration and coach the worker to achieve optimal expirations in subsequent attempts. Current Appendix D(I)(g) also specifies requirements for paper tracings of the expiration curve, and requires that the tracings be of sufficient size for hand measurements to conform to Appendix D(I)(a). OSHA is proposing to revise paragraph D(I)(g) to indicate ''If hand measurements will be made.'' OSHA is proposing these changes because hand measurements are currently rarely used, and the values currently shown in the expiration curve are usually computer generated today.

Appendix D(I)(g) also requires the spirometer to display flow versus volume or volume versus time tracings. The proposed revision would require the spirometer to display both flow-volume and volume-time curves or tracings during testing. The flow-volume curve emphasizes early expiration and allows the technician to detect problems early in the maneuver (OSHA, 2013). The volume-time curve emphasizes the end of the expiration and allows the technician to coach the patient to achieve a complete expiration (OSHA, 2013). OSHA is also proposing to update the paragraph to indicate that both types of curves or tracings must be stored and available for recall. This requirement to store curves will allow the assessment of results for acceptability and repeatability, once testing is concluded, and it will also make it possible to include the curves in reports to health care providers who interpret the results (OSHA, 2013).

Current Appendix D(I)(h) requires that instruments be capable of accumulating volume for a minimum of 10 seconds and not stop accumulating volume before (1) the volume change for a 0.5-second interval is less than 25 millimeters, or (2) the flow is less than 50 milliliters per second for a 0.5-second interval. As noted by ATS in 1987, these end-of-test criteria, which were first included in the 1979 ATS statement, caused premature termination of exhalation and FVCs that were falsely reduced by as much as 9 percent (ATS, 1987). To avoid such falsely reduced FVCs, ATS defined end-of-test criteria only according to volume change from 1987 onward (ATS 1987, 1994, 2005). Therefore, OSHA is proposing to update the first clause by specifying the currently recommended volume change of less than 25 milliliters for a 1-second interval (Miller et al, 2005) and is also proposing to remove the latter clause, *i.e.,* that the instrument shall not stop accumulating volume before the flow is less than 50 milliliters per second for a 0.5-second interval. The proposed changes make Appendix D consistent with current ATS/ERS recommendations for expiratory end-of-test criteria using volume increment only, since flow rate criteria were abandoned in 1987 (ATS, 1987; Miller *et al.,* 2005). OSHA is also proposing to update this provision by revising the time for which the instrument must be capable of accumulating volume to 15 seconds, the maximum time for which an exhalation should be done according to ATS/ERS (Miller *et al.,* 2005). In 1987, ATS stated that they encourage spirometer designs that allowed patients to continue exhaling for as long as possible (ATS, 1987).

Current Appendix D(I)(j), (II)(b), and (IV)(b) provide requirements for the calibration of spirometers, and the proposal updates several of these requirements. The proposed revisions to Appendix D(I)(j), (II)(b), and (IV)(b) clarify that the technician must always check the calibration of spirometers, and recalibrate them only if the spirometer requires the technician to do so. That change is consistent with recommendations by ATS/ERS (Miller *et al.,* 2005). The reason for the proposed change is that while technicians cannot recalibrate many spirometer models in current use, they nevertheless must check all spirometers regularly when in use to ensure that the spirometers are operating within calibration limits, *i.e.,* that the spirometers are accurate (OSHA, 2013).

OSHA is proposing to delete the following text from Appendix D(I)(j) because it is ambiguous and provides no useful information: ''. . . with respect to the FEV1 and FVC. This calibration of the FEV1 and FVC may be either directly or indirectly through volume and time base measurements.'' OSHA also is proposing to update paragraph D(I)(j) to include the current ATS/ERS requirements for calibration-syringe accuracy and volume displacement (Miller *et al.,* 2005). As noted above, OSHA is proposing to revise the term ''calibration'' to ''calibration check.'' Another proposed change to paragraph D(I)(j) is to revise the term ''calibration source'' to ''calibration syringe'' because a syringe is the only type of calibration source currently used, so specifying a syringe instead of a source would clarify the requirement.

In addition, OSHA proposes to change the word ''should'' in D(I)(j) to ''shall,'' so the new D(I)(j)(2) would read, ''the volume-calibration syringe shall provide a volume displacement of at least 3 liters and shall be accurate to within ± 0.5 percent of 3 liters (15 milliliters).'' The phrase ''should'' sounds advisory, and the current practices that OSHA proposes to adopt are based on the 3 liter size of the syringe. OSHA seeks comment on this change to ''shall.''

Current Appendix D(II)(b) provides that technicians should perform calibrations using a syringe or other source of at least two liters. The proposed change in the syringe volume to three liters is consistent with current practices. OSHA also is proposing to change the term ''syringe or other volume source'' to ''syringe'' for the reasons described above in the discussion of paragraph D(I)(j). Another proposed change to Appendix D(II)(b) would be to delete the phrase ''or method.'' The meaning of that phrase is unclear; the sentence is addressing calibration checks of an instrument (*i.e.,* spirometer), not a method. OSHA also is proposing calibration check procedures for flow-type and volume-type spirometers to determine whether a spirometer is recording 3 liters of air ±

3.5 percent (Miller *et al.,* 2005; OSHA, 2013). The check of flow-type spirometers would involve the injection of air at three different speeds, and the check of volume-type spirometers would involve a single injection of air and a check for spirometer leakage. Users should refer to generally accepted practices and other guidance for complete details about calibration checks (see, *e.g.,* Miller *et al.,* 2005; Townsend, 2011; OSHA, 2013). OSHA also proposes to change the term ''recalibration'' in this provision to ''calibration checks'' for the reasons stated above in the discussion of paragraph D(I)(j). Finally, OSHA proposes to change ''should'' to ''shall'' in the first sentence of D(II)(B) for the same reasons as discussed above regarding paragraph D(I)(j).

Appendix D(II)(a) currently contains requirements for measuring forced expirations, including having the patient make at least three forced expirations. OSHA is proposing to update this paragraph to have the patient perform at least three, but no more than eight, forced expirations during testing. This proposed change would clarify that up to eight forced expirations can be attempted to obtain three acceptable forced expirations (Miller *et al.,* 2005). The same paragraph currently states that ''The subject may sit, . . .'' OSHA proposes that ''subject'' be changed to ''patient'' because ''subject'' implies someone in an experimental trial, while patient is the more appropriate term for someone undergoing screening at a medical facility, and ''patient'' is the term used most often in the standard. OSHA also is proposing to clarify the text in paragraph D(II)(a) to indicate that the expiration must be repeatable. The term ''repeatability,'' now used by ATS/ERS, would be an update to the existing term ''reproducibility''; paragraph D(II)(a)(7) lists the criteria for repeatable (formerly, reproducible) results. In addition, Appendix D(II)(a) lists elements of ''unacceptable'' efforts in paragraphs (a)(1)–(a)(7); OSHA proposes to revise this language to ''technically unacceptable'' to make clear that the problem is not with the worker's lungs but with the flaws in how the test is conducted.

Appendix D(II)(a)(3) currently specifies that a worker's efforts during testing are unacceptable when the expiration does not continue for at least five seconds or until an obvious plateau in the volume-time curve occurs. The proposed revision to this paragraph clarifies that results may be acceptable if the worker *attempted to exhale* (versus actually exhaled) for at least six seconds *and* until an obvious plateau in the volume-time curve occurs (Miller *et al.,* 2005). Therefore, the expiration must meet both of these criteria for a spirometry result to be technically acceptable. Many workers who are young or have small lung volumes can complete an expiration in less than six seconds, and their results may be acceptable if the technician observes an obvious plateau in the volume-time curve (OSHA, 2013).

Appendix D(II)(a)(4) provides that the results are unacceptable when the worker coughs or closes the glottis during forced expiration. This proposed change clarifies that the results are unacceptable if coughing occurs in the first second of expiration, a condition that is consistent with current ATS/ERS recommendations (Miller *et al.,* 2005). Coughing in the first second interferes with measurement of the FEV1 (Miller *et al.,* 2005), but coughing toward the end of the expiration does not affect test results (OSHA, 2013). Glottis closure at any time may result in premature termination of the expiration (Miller *et al.,* 2005).

Appendix D(II)(a)(6) provides that the results are unacceptable when there is an unsatisfactory start to expiration characterized by excessive hesitation, *i.e.,* one with an extrapolated volume greater than 10 percent of the FVC on the volume-time curve. As noted in the 1987 ATS statement, a criterion of 10 percent could result in a falsely elevated FEV1 from a suboptimal effort (ATS, 1987). The proposed change would indicate that extrapolated volume must be less than 150 milliliters or 5 percent of the FVC, whichever is greater, to be unacceptable. It would update the provision to be consistent with the most recent ATS/ERS recommendation on criteria for start-of-test so that an accurate time zero is set (Miller et al, 2005). All ATS or ATS/ERS statements define acceptable start-of-test criteria according to volume, as well as percent FVC, using whichever criterion is larger for a given patient (ATS, 1979, 1987, 1994; Miller *et al.,* 2005), and it is not clear why the volume value was excluded from the current cotton dust standard. OSHA is proposing to include the 2005 ATS/ERS recommendations for volume, in addition to percentage of FVC, for consistency with ATS/ERS. Expressing the values as both percentage of FVC and as a volume, and using whichever approach gives the larger allowed extrapolated volume, aids in the interpretation of results for individuals with very small or very large lung volumes. For example, since 5 percent of FVC will be less than 150 milliliters in individuals with FVC < 3.00 L, the 150 milliliter criterion would be used for those patients. But 5 percent of FVC would exceed 150 milliliters in individuals with FVC > 3.00 L, so in that case the 5 percent of FVC criterion would be used to evaluate the start-of-test for these patients.

As stated above, Appendix D(II)(a)(7) contains criteria for acceptable repeatability. Editorial changes proposed in Appendix D(II)(a)(7) are for clarification. Notably, OSHA would remove the word ''three'' because technicians can examine up to eight acceptable curves to select the two highest FEV1 and FVC values (Miller *et al.,* 2005). OSHA is also proposing to change ''variation'' to ''difference'' because ''difference'' is the more appropriate mathematical term to use when comparing only two numbers.

In Appendix D(II)(a)(7), OSHA also is proposing to revise the maximum difference between the two largest FVC values and the two largest FEV1 values of a satisfactory test to 150 milliliters, a change from the current maximum difference of 10 percent or ±100 milliliters, whichever is greater. This proposed revision to the criteria for acceptable repeatability reflects current ATS/ERS recommendations (Miller *et al.,* 2005). In 2005, ATS/ERS stated that many patients are able to achieve repeatability of FEV1 and FVC to within 150 milliliters (Miller *et al.,* 2005). In 1994, the ATS changed its repeatability criterion from a volume and a percentage difference between values to a volume difference only, so that the criterion was equally stringent for all lung sizes, and also so that it was easy to compute during the test if hand-measurements were made (ATS, 1994). OSHA is also proposing editorial changes to make it clear that the difference between the two largest acceptable FVC values should not exceed 150 milliliters and the two largest acceptable FEV1 values should not exceed 150 milliliters.

The Agency discussed proposed changes to Appendix D(II)(b) above.

OSHA is proposing to remove Appendix D(III)(b). The paragraph refers to a NIOSH guideline that specifies an outdated evaluation criterion of FEV1/FVC ratio of 0.75 percent, and OSHA is unaware of an updated NIOSH cotton dust guideline that more appropriately compares the FEV1/FVC ratio to LLN. As noted above, generally accepted practices use the LLN as the basis for classifying possibly abnormal lung function because it accounts for age-related declines in lung function (Townsend, 2011). Appendix D(III)(b) also refers to a table that OSHA never included in the final Cotton Dust

Standard. That table was most likely Table XII–12 in the NIOSH criteria document for cotton dust (CDC/NIOSH, 1974). The lack of the table does not appear to be a pressing issue since no user complained about the missing table after OSHA promulgated the standard. In addition, the information is available to users in the NIOSH criteria document.

The proposed updates to paragraphs D(IV)(a) and (d) would change ''reproducibility'' to ''repeatability'' to conform to the terminology now used by ATS/ERS (Miller *et al.,* 2005). ''Repeatability'' would have the same meaning as ''reproducibility.'' OSHA also is proposing to change the term ''calibration'' in paragraph D(IV)(b) to ''calibration checks'' for the reasons stated above in the discussion of paragraph D(I)(j). OSHA also proposes to change ''subject'' to ''patient'' in paragraph D(IV)(c) for the reason discussed above in the discussion of paragraph D(II)(a).

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4. Subpart F of 1915—General Working Conditions, Definitions in 29 CFR 1915.80

Existing requirements in the sanitation standard for Shipyard Employment, § 1915.88(j)(1) and (j)(2), specify that employers must, to the extent reasonably practicable, clean and maintain workplaces in a manner that prevents vermin infestation. When employers detect vermin, they must implement and maintain an effective vermin-control program.

Paragraph (b)(33) of § 1915.80 defines the term ''vermin'' as ''insects, birds, and other animals, such as rodents and feral cats, that may create safety and health hazards for employees.'' OSHA included this definition in the proposal for 29 CFR part 1915, subpart F, General Working Conditions in Shipyard Employment, on December 20, 2007 (72 FR 72452). In that NPRM, OSHA requested comment on the proposed vermin-control provisions, as well as examples of vermin that are present and the types of controls employers use to prevent the harborage of vermin in shipyard worksites. *Id.* at 72484. The Agency cited the hazards associated with exposure to insects, birds, and rodents in the preamble discussion, but did not mention any hazards associated with feral cats. *Id.* The Agency received two comments on these provisions. One commenter stated that vermin did not pose a serious hazard to workers and that OSHA should remove these provisions from the rulemaking (Ex. 197.1, Docket No. OSHA–S049–2006–0675). The other commenter explained that the number and types of vermin are greater than OSHA indicated in the proposed discussion, and that ''[t]o 'implement and maintain an effective control program' as required in this section would probably be very expensive, near impossible or even illegal'' (Ex. 121.1, Docket No. OSHA–S049–2006–0675). Based on the general industry sanitation standard that applied to shipyard employment prior to the subpart F rulemaking, and these limited comments, the final standard adopted the proposed definition 76 FR 24576 (May 2, 2011). The final rule preamble also did not identify any hazards associated with feral cats. *Id.* at 24616.

Recently, stakeholders raised concerns about including feral cats in the definition of vermin. These stakeholders argue that while the possibility exists for feral cats to pose safety and health hazards for employees (*e.g.,* bites, scratches, fecal contamination), the threat is minor as the cats tend to avoid human contact. Further, these stakeholders expressed concern that including the term ''feral cats'' in the definition of vermin encourages cruel and unnecessary extermination. OSHA recognizes these concerns and, therefore, is proposing to remove the term ''feral cats'' from the definition in § 1915.80(b)(33). The revised provision would define the term ''vermin'' as ''insects, birds, rodents and other animals that may create safety and health hazards for employees.'' The Washington State Plan also removed the term ''feral cats'' from its definition of vermin, which is equivalent to OSHA's definition in § 1915.80(b)(33) (WAC 296–304–01001). The proposed revision also is consistent with the general industry sanitation standard provision on vermin, which describes vermin as ''rodents, insects, and other vermin'' (§ 1910.141(a)(5)). OSHA does not believe that removing the term ''feral

cats'' from the definition will reduce worker health and safety, and notes that feral cats may help reduce the presence of other vermin. To the extent feral cats pose a safety or health hazard at any particular shipyard, OSHA would consider the cats to be ''other animals'' under the standard.

5. Subpart D of 1926—Occupational Health and Environmental Controls, Medical Services and First Aid in 29 CFR 1926.50

Under 29 CFR 1926.50, employers must provide specified medical services and first aid to employees to address serious injuries that may occur on the job. Existing § 1926.50(f) requires the posting of telephone numbers of physicians, hospitals, or ambulances for worksites located in areas where 911 emergency service is not available. OSHA adopted this requirement in 1979 when 911 emergency service was still a relatively new concept, and was available only in certain parts of the country.

Today, 911 emergency service is available almost everywhere in North America. In nearly all locations in the United States and Canada, a 911 call over a land-line telephone will link the caller to an emergency-dispatch center. In the United States, most localities with 911 service also have so-called ''Enhanced 911,'' which will not only connect the land-line caller to a dispatcher, but also will automatically provide the caller's location to the emergency dispatcher. This automatic-location information is critical for emergency responders in cases when the 911 caller does not know his/her exact location, or does not have sufficient time to provide such information.

Although the automatic transmission of location information to emergency dispatchers is customary for land-line telephones, the task of automatically transmitting location information is more complex when the emergency call originates from a wireless telephone. Since 1996, the Federal Communications Commission (FCC) has been phasing in the requirement that wireless carriers adopt technologies that provide 911 caller-location information. However, carriers are not likely to complete the phase-in until 2019; consequently, the FCC established a procedure for exempting carriers from the location requirement. As a result, in some remote areas of the country, wireless-telephone carriers still are unable to provide accurate information about the location of the 911 caller to 911 answering centers. The proposed revision to § 1926.50(f) updates the 911 service-posting requirements consistent with the current status of land-line and wireless-telephone technologies.

The proposed standard addresses the problem of locating callers, usually cell-phone callers, in remote areas that do not have automatic-location capability. In such areas, the proposed standard requires employers to post in a conspicuous location either the latitude and longitude of the worksite or other location-identification information that effectively communicates the location of the worksite. OSHA notes that when ACCSH discussed this proposal, one member stated that he had seen a contractor provide latitude and longitude coordinates at a remote site on stickers given to employees. (ACCSH Aug. 23, 2013 transcript, p. 85.) Employers can obtain information about which counties, or portions of counties, are exempted from the 911 location accuracy requirements from FCC PS Docket No. 07–114, which is publicly available on the FCC's Electronic Comment Filing System (ECFS) Web page: *http://apps.fcc.gov/ecfs/proceeding/view?name=07-114.*

The proposed revision also requires employers to ensure that the communication system they use to contact ambulance service is effective. Under existing § 1926.50(e), employers are required to provide a communication system for contacting ambulance service, or proper equipment for transportation of an injured person. When using wireless telephones as a communication system, however, that system's availability varies based on the location of the caller. If an employer is relying upon a communication system at a worksite, it must be effective at the worksite. The Agency is retaining the requirement to post telephone numbers of physicians, hospitals, or ambulances for worksites located in areas where 911 emergency service is not available.

6. Subpart D of 1926—Occupational Health and Environmental Controls, Gases, Vapors, Fumes, Dusts, and Mists in 29 CFR 1926.55

The provisions of § 1926.55 establish permissible exposure limits for numerous toxic chemicals used during construction activities. These provisions are the construction counterpart to the general industry standard at § 1910.1000. However, OSHA believes that several of these provisions, notably paragraph (a), paragraph (c), and Appendix A to § 1926.55, need clarification. In this regard, OSHA believes, first, that the use of the phrase ''threshold limit values'' and the reference to the American Conference of Governmental Industrial Hygienists (ACGIH), in both paragraph (a) and Appendix A, are confusing. Since these are OSHA standards, the correct terminology to express these limits is ''permissible exposure limits,'' and the proposed revision makes this revision. Moreover, while OSHA originally adopted these limits from ACGIH recommendations, the limits are OSHA, not ACGIH, requirements. Therefore, the proposed revision deletes the references to ACGIH.

Second, the phrase ''shall be avoided'' in paragraph (a) has an advisory, rather than a mandatory, connotation and, therefore, is not appropriate in regulatory text. OSHA is proposing to revise this language to read, ''An employee's exposure . . . must at no time exceed the exposure limit given for that substance.''

Third, the words ''inhalation, ingestion, skin absorption, or contact'' in paragraph (a) are redundant and confusing. In addition, the concentrations listed are airborne values, and the standard addresses exposure through any route. Therefore, the proposed language deletes these words.

Fourth, Appendix A is not an appendix but an integral part of the standard. The proposal, therefore, would acknowledge this relationship by revising the heading to read, ''Table A.''

Fifth, Appendix A (proposed Table A) has a column labelled ''Skin Designation'' under which an ''X'' demarcates certain substances, although the appendix provides no definition of ''X.'' The 1970 ACGIH publication, however, notes that the ''X'' identifies substances that present a dermal hazard. The proposed revision adds a footnote to the proposed table that clarifies the meaning of this designation.

Sixth, Appendix A (proposed Table A) has two footnotes designated by asterisks. However, there are no asterisks in the body of the appendix referencing these footnotes. The first footnote, consisting of a single asterisk, says, ''The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit.'' The second footnote, consisting of two asterisks, states, ''As determined from breathing-zone air samples.'' The proposed revision deletes these two footnotes, and moves the content of the footnotes to proposed paragraphs (a)(1) and (a)(2) of § 1926.55.

Finally, OSHA is proposing to correct the cross-references to OSHA's construction asbestos standard in paragraph (c) and in Appendix A (proposed Table A). The correct cross reference is: § 1926.1101.

7. Subpart D of 1926—Occupational Health and Environmental Controls, Process Safety Management of Highly Hazardous Chemicals in 29 CFR 1926.64

To avoid unnecessary duplication, OSHA is proposing to replace the entire 31 pages of regulatory text for the Process Safety Management of Highly Hazardous Chemicals (PSM) Standard for construction at § 1926.64 with a cross reference to the identical general industry standard at § 1910.119. Other construction standards have similar cross references to corresponding general industry standards; for example, the Respiratory Protection Standard for construction at § 1926.103 refers to the general industry Respiratory Protection Standard at § 1910.134.

OSHA believes that it is unnecessary to reproduce the entire PSM Standard in 29 CFR part 1926 because construction employers rarely have a PSM program at their worksites. The PSM standard affects construction employers mainly through paragraph (h), *Contractors,* when they perform construction work at refineries or chemical-manufacturing plants; in these cases, the host employer generally will have a copy of the standard available. Should construction employers require a copy of the PSM Standard, they can obtain a copy readily at OSHA's Web page.

8. Subpart E of 1926—Personal Protective and Life Saving Equipment, Criteria for Personal Protective Equipment in 29 CFR 1926.95

Current § 1926.95(a) of the construction personal protective equipment (PPE) standard states that PPE ''shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary.'' PPE must fit properly in order to provide adequate protection to employees. This can be a particular issue for small-stature construction workers, including some females, who may not be able to use standard-size PPE. Section 1926.95(c)'s requirement that PPE to be ''of safe design'' implicitly precludes the use of ill-fitting equipment. However, OSHA's construction standard does not contain an explicit requirement for PPE used in construction to fit each affected employee, like the general industry PPE standard does (see 29 CFR 1910.132(d)(1)(iii)).

Several commenters responding to the request for information for this rulemaking, including the AFL–CIO and the International Safety Equipment Association, recommended that the Agency revise its construction PPE standards to ensure that PPE fits all construction employees (Exs. OSHA–2012–0007–0012 and –0018).

Revising § 1926.95(c) to require employers to select PPE that properly fits each employee will clarify the construction PPE requirements on this point and make them consistent with general industry PPE requirements. The Agency believes that providing clear and explicit language on this point will help ensure employers provide employees with properly fitting PPE, thereby adequately protecting employees exposed to hazards requiring PPE. The proposed language, therefore, merely clarifies, and makes explicit, the requirement that all PPE used in construction fit properly.

9. Subpart E of 1926—Personal Protective and Life Saving Equipment, Safety Belts, Lifelines, and Lanyards in 29 CFR 1926.104

OSHA is proposing to revise the minimum breaking-strength requirement for lifelines in the Safety belts, lifelines, and lanyards standard, § 1926.104(c), to 5,000 pounds. This proposed revision will bring § 1926.104(c) into conformity with the breaking-strength requirements for lanyards and vertical lifelines in the Fall protection systems criteria and practices (''Fall Protection'') standard at § 1926.502(d)(9). The Agency concludes that making identical specifications for the same equipment will avoid confusion and, thereby, improve compliance.

The breaking strength of a lifeline is the maximum load that it can carry without failing or breaking. Under existing § 1926.104(c), the minimum breaking-strength requirement is 5,400 pounds. As noted by OSHA in the proposed Fall Protection standard published on November 25, 1986 (51 FR 42718, 42726), the Agency based the 5,400-pound requirement on the breaking strength of the then-available ¾-inch diameter manila rope used for body-belt systems and not on the forces generated in a fall. The basis for the revised requirement of 5,000 pounds adopted in the final Fall Protection standard and proposed now for § 1926.104(c) is the force generated by a 250-pound employee experiencing a force 10 times the force of gravity, plus a two-fold margin of safety. *Id.* This proposed revision also is consistent with the most recent ANSI/ASSE standards Z359.1 2007 and A10.32.

10. Subpart G of 1926—Signs, Signals, and Barricades

The provisions regarding accident prevention signs, signals, and barricades in 29 CFR 1926.200(g), 201 and 202, subpart G (Signs, Signals, and Barricades), contain requirements for employers' use of accident prevention signs, tags, signaling and barricades. These provisions require that traffic control signs and devices used for the protection of workers, barricades used for the protection of workers, and signaling by flaggers and the use of flaggers, including warning garments worn by flaggers, comply with the mandatory provisions of either of two versions of Part VI of the MUCTD. Employers may comply with Part VI of the 1988 Edition, Revision 3, September 3, 1993, MUTCD (''1988 Edition'') or the Millennium Edition, December 2000 MUTCD (''Millennium Edition'').

Several commenters to the SIP–IV Request for Information (77 FR 72781), including the AFL–CIO (OSHA–2012–0007–0012), the Laborers' Health and Safety Fund of North America (OSHA–2012–0007–0011), and the American Road and Transportation Builders Association (OSHA–2012–0007–0025), asked OSHA to update subpart G because the Department of Transportation (DOT) updated the MUTCD in 2009. These revisions aimed to expedite traffic, promote uniformity, improve safety, and incorporate technology advances in traffic control device application (74 FR 66730). In addition, DOT issued two revisions to the MUTCD in 2012 (77 FR 28455 and 77 FR 28460).

OSHA is proposing revisions to Subpart G, including an update to the references to the MUTCD to the November 4, 2009 MUTCD (''2009 Edition''), including Revision 1 dated May 2012 and Revision 2 dated May 2012. Updating the reference to the 2009 Edition MUTCD will eliminate confusion as to which edition employers must comply with, and will inform employers that compliance with DOT regulations will not conflict with outdated OSHA regulations.

Statement of Reasonable Availability

OSHA believes that the Manual on Uniform Traffic Control Devices is reasonably available to interested parties. It is available from the Federal Highway Administration, United States Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590; telephone: 202–366–4000; Web site: *http://www.fhwa.dot.gov/.* In addition, it is available in the docket for this rulemaking and in OSHA's docket office for review. If OSHA ultimately finalizes this rule, the standards will be maintained in OSHA's national and regional offices for review by the public.

DOT requires that traffic control signs or devices conform to the 2009 Edition

(see 23 CFR 655.601 to .603). DOT regulations recognize that the MUTCD is the national standard for all traffic control devices installed on any street, highway, or bicycle trail open to public travel (§ 655.603(a)). DOT requires compliance with the 2009 Edition for all federal-aid construction areas (§ 655.603(d)(3)). In addition, each State must have a highway safety program that complies with DOT's designated national standard, and where State or other federal agency MUTCDs or supplements are required, they shall be in substantial conformance with the 2009 Edition(23 U.S.C. 402(a); 23 CFR 655.603(b)(1)). Substantial conformance means that the State MUTCD or supplement shall conform as a minimum to the standard statements included in the 2009 Edition (§ 655.603(b)).

The differences between OSHA's standards that reference the 1988 Edition and the Millennium Edition MUTCDs and DOT's regulations cause potential industry confusion and inefficiency, without advancing worker safety. Accordingly, in Directive CPL 02–01–054, dated October 16, 2012, OSHA stated that it would accept compliance with the 2009 Edition in lieu of compliance with the 1988 Edition or Millennium Edition MUTCDs referenced in § 1926.200(g) through its *de minimis* policy.

OSHA reviewed the differences between the 1988 Edition, the Millennium Edition, and the 2009 Edition, and concluded that the more recently published manual will provide greater employee safety benefits than the older versions. The 2009 revisions to the MUTCD largely make the document more accessible and account for advances in technology. A comparison of the 1988 and 2009 Editions shows few new requirements; rather, the document is easier to use, with more guidance and supporting material available. The MUTCD is a complex document comprised of standards, guidance, and supporting material. Under § 1926.6(a), OSHA's Subpart G provisions incorporate by reference only the mandatory provisions of the MUTCD, *i.e.,* those provisions containing the word ''shall'' or other mandatory language, and only those provisions that affect worker safety with regard to the use of signs, devices, barricades, flaggers and points of hazard. Often, it was difficult to locate these provisions, but the 2009 Edition clearly labels them ''standards.''

The revisions to the 1988 and Millennium Editions that affect worker safety are minimal. DOT identified the following areas as significant revisions that relate to work safety in the final rule (74 FR 66730):

- The needs and control of all road users through a temporary traffic-control (TTC) zone apply to all public facilities and private property open to public travel, in addition to highways.
- Federal Highway Administration (FHWA) allows non-compliant devices on existing highways and bikeways to be brought into compliance with the current edition of the MUTCD as part of the systematic upgrading of substandard traffic control devices (and installation of new required traffic control devices) required pursuant to the Highway Safety Program, 23 U.S.C. 402(a). If the FHWA establishes a target compliance date for upgrading such devices, traffic control devices shall be in compliance by that date. (These target compliance dates established by the FHWA are shown in Table I–2 of the 2009 Edition.)
- Workers within the public right-of-way must use high-visibility safety apparel.
- There is a new section titled ''Automated Flagger Assistance Devices'' (AFAD). These optional devices enable a flagger to assume a position out of the lane of traffic when controlling road users through TTC zones.
- New requirements that flaggers shall use a ''STOP/SLOW'' paddle, flag, or AFAD to control road users; the 2009 Edition prohibits the use of hand movements alone. In the previous editions, it was not clear that hand signals alone were insufficient.
- All devices used for lane channelization (*i.e.,* directing vehicles in a particular direction) must be crashworthy.
- Temporary traffic barriers, including their end treatments (such as an impact attenuator), must be crashworthy.

There was one major revision to the MUTCD, the 2003 Edition, between the Millennium Edition and the 2009 Edition. OSHA is providing a list of the changes between the 2003 Edition and the 2009 Edition in the record (find 2009 Edition figure changes at *regulations.gov* in Docket No. OSHA–2012–0007).

Section 1926.200(g)—Traffic signs. Current paragraph (g)(1) of § 1926.200 states, ''[c]onstruction areas shall be posted with legible traffic control signs at points of hazard.'' Accordingly, current paragraph (g)(1) does not explicitly require protection by traffic control devices. However, existing paragraph (g)(1) requires legible signs at points of hazard and paragraph (g)(2) prohibits misuse of both signs *and devices,* by requiring their use to conform to the MUTCD. Not requiring employers to use, but prohibiting the *misuse* of, protective devices at points of hazard is an anomaly that causes unnecessary confusion. Additionally, current enforcement procedures allow OSHA to cite an employer for a violation under paragraph (g)(1) when the employer exposes an employee to a hazard resulting from the lack of protective devices at points of hazard when the devices (*i.e.,* channelization devices and warning devices) would essentially serve as signs. (CPL 02–01–054, Paragraph XIII.F.2).

The proposed revision explicitly requires that employers use traffic control devices at points of hazard. Accordingly, OSHA is proposing to revise paragraph (g)(1) to require employers to use both signs and devices at points of hazard. While paragraph (g)(2) would still cover the misuse of signs and devices, the proposal would revise this paragraph too. Proposed paragraph 200(g)(2) would clarify that it covers the design and use of traffic-control devices, and would add a list of those devices: Signs, signals, markings, barricades, and other devices. Consistent with these revisions, OSHA would also revise the headings of § 1926.200 and paragraph (g) by adding the term ''devices'' to these headings. The Agency would retain the requirement that signs be legible. These changes would clarify the requirements for signs and devices.

Section 1926.201—Signaling. The Agency is limiting proposed revisions to § 1926.201 to the 2009 Edition update discussed above.

Section 1926.202—Barricades. OSHA is proposing to delete this section because it would duplicate the requirements in the proposed revisions to paragraph (g)(1), which also would require the use of barricades as traffic control devices at points of hazard, and paragraph (g)(2), which would require that the design and use of barricades conform to the updated MUTCD.

Section 1926.203—Definitions applicable to this subpart. OSHA is proposing to delete this section because the MUTCD defines or describes most of the words defined in this section (*e.g.,* barricade, signs, signals). If OSHA retained this section, it would need to update these definitions to conform to the MUTCD. To the extent that other provisions of subpart G use the defined words but do not reference the MUTCD, OSHA believes that providing definitions for these words is unnecessary because the meanings of the words are either obvious or defined clearly in applicable consensus standards or in other OSHA standards;

for example, an adequate description of a ''tag'' is in § 1926.200(h).

In summary, OSHA is proposing to amend the safety and health regulations for construction to adopt and incorporate the 2009 Edition of the MUTCD and clarify the regulatory text. The revisions would delete the references in §§ 1926.200(g)(2) and 1926.201(a) to the 1988 Edition and Millennium Edition of the MUTCD and insert references to the 2009 Edition. The revisions also would amend the regulatory text of paragraphs (g)(1) and (g)(2) of § 1926.200 to eliminate confusion regarding OSHA's interpretation of the current text. The proposal deletes § 1926.202 because it duplicates the requirements in the proposed revisions to § 1926.200(g) and § 1926.203 because the proposed revisions make this section unnecessary.

11. Subpart H of Part 1926—Materials Handling, Storage, Use, and Disposal, General Requirements for Storage in 29 CFR 1926.250

Subpart H of OSHA's construction standards governs the handling, storage, use, and disposal of construction materials on a work site. Section 1926.250 addresses safe storage of building materials inside buildings under construction, and § 1926.250(a)(2) requires employers to post maximum safe load limits of floors in storage areas. This requirement is important in large buildings under construction because employers store large, heavy quantities of building materials in these structures to accommodate construction staging and schedules. However, requiring employers to post safe load limits is unnecessary in single-family home construction because employers do not use these structures for storing heavy materials that could endanger employees working at lower levels should the floor collapse. Therefore, OSHA is proposing to exclude detached, single-family residences and townhouses from the posting requirement.

OSHA finds that the proposed revision will lessen the compliance burden of employers without jeopardizing the safety of employees. While OSHA believes that employers involved in residential-building construction do not place heavy loads on the floors of these structures, the proposed revision does not relieve these employers of the duty to ensure that any loads placed on these floors do not exceed the maximum safe loads of the floors.

12. Subpart P of 1926—Excavations, Specific Excavation Requirements in 29 CFR 1926.651

Paragraphs (j)(1) and (j)(2) of § 1926.651 specify requirements for employers to protect employees from (1) loose rock or soil in excavations, and (2) excavated or other materials or equipment that could fall or roll into an excavation. Similar provisions were part of OSHA's subpart P Excavation standard originally issued under the Construction Safety Act in 1971 as 29 CFR 1518.651(h) and (i) (36 FR 7340, 7389, April 17, 1971), and OSHA retained them when it revised the standard in 1989 (54 FR 45894, Oct. 31, 1989). The original 1971 standard placed the burden on employers to ensure employees' safety from loose rock and soil, and excavated or other materials, in or around excavations (36 FR 7340, 7389). The 1989 revision added to the paragraphs (j)(1) and (j)(2) the phrase ''that could pose a hazard'' when referring to loose rock or soil and excavated or other materials or equipment (54 FR 45894, 45924–45925).

A number of decisions by administrative law judges of the Occupational Safety and Health Review Commission (OSHRC) have interpreted the added phrase in the standard as placing the burden on OSHA to establish that loose rock or soil or excavated or other material or equipment poses a hazard to employees before it can establish a violation of §§ 1926.651(j)(1) and (j)(2). (See, *e.g., Black Construction Corp.,* 19 BNA OSHC 1043 (2000) (ALJ) ((j)(1)); *Schaer Development of Central Florida, Inc.,* No. 11–0371, 2011 WL 3394942 (OSHRC ALJ June 2, 2011) ((j)(2))). These decisions are contrary to most of OSHA's standards, which presume that a hazard exists unless the employer can demonstrate otherwise (see, *e.g., Austin Bridge Co.,* 7 BNA OSHC 1761 (1979)). Moreover, the preamble to the 1989 revision does not indicate that OSHA intended to shift the burden when it revised the 1971 provisions, but only to clarify the language of the provisions (54 FR 45894, 45924). Thus, OSHA is proposing to remove the phrase ''that could pose a hazard'' from § 1926.651(j)(1) and (j)(2). This revision would clarify, as originally intended, employers must protect their employees from loose rock or soil and excavated or other materials or equipment, and that OSHA does not have the burden of demonstrating the existence of a hazard. Therefore, the standards presume a hazard unless an employer complied with the protections required by §§ 1926.651(j)(1) and (j)(2).

Section 1926.651(j)(1) applies to loose rock or soil that can fall from the face of the excavation. The preamble to the 1989 revision states that this provision does not apply to all excavations, only those excavations with loose rock or soil of ''sufficient volume [to] endanger an employee'' (54 FR 45894, 45924). It is the employer's duty to assess whether (1) the rock or soil is loose and (2) of sufficient volume to potentially endanger or injure employees in the excavation. The proposed revision would remove the phrase ''that could pose a hazard,'' but would keep the language limiting this provision to loose rock or soil. As noted in the previous paragraph, removing the language ''that could pose a hazard'' from the provision would preserve the duty of employers to protect workers from the hazard, while relieving OSHA of the initial burden of demonstrating that a hazard exists. OSHA also is proposing to remove the language ''by falling or rolling from an'' from the provision as that language is unnecessary to describe the hazard; however, OSHA is proposing to retain the term ''excavation face'' in the provision to clarify the location of the hazard.

Section 1926.651(j)(2) applies to excavated materials (''spoil piles'') or other materials or equipment that are on the surface near the excavation. Employers must keep these piles, and other materials or equipment, at least two feet from the edge of the excavation, or prevent them from moving by using retaining devices. Excavated soil is loose and may present a hazard to workers in an excavation. As explained in the preamble to the 1989 revision:

> The intent of this requirement is to protect employees from materials, equipment, and spoil piles which might fall into excavations. Obviously, materials such as excavated soil and stored construction supplies can superimpose loads on the walls of an excavation. Such loads can be the cause of cave-ins and must be considered when determining what protection is necessary to safeguard employees.

(54 FR 45894, 45925).

The proposed revision would remove the phrase ''that could pose a hazard by falling or rolling into excavations,'' but would retain the language ''excavated or other materials or equipment,'' from the first sentence in paragraph (j)(2). The proposed language would keep the remaining language in the paragraph, including the two-foot rule, and would remove from OSHA the burden of demonstrating that a hazard exists, while retaining the employers' duty to protect employees from the hazards of excavated or other materials or

equipment placed less than 2 feet from the edge of the excavation.

13. Subpart S of 1926—Underground Construction, Caissons, Cofferdams and Compressed Air, Underground Construction in 29 CFR 1926.800

Existing regulatory language in § 1926.800(k)(10)(ii) requires that mobile diesel-powered equipment used in ''other than gassy operations'' underground be approved by the Mine Safety and Health Administration (MSHA) in accordance with the provisions of 30 CFR part 32, or that the employer that demonstrate the equipment is ''fully equivalent'' to MSHA-approved equipment. In 1996, MSHA revoked part 32 and replaced it with updated provisions in 30 CFR part 7, subpart E and 30 CFR 75.1909 Non-permissible diesel-powered equipment;[10] design and performance requirements, 75.1910 Non-permissible diesel-powered equipment; electrical system design and performance requirements, and 75.1911 Fire suppression systems for diesel-powered equipment and fuel transportation units (61 FR 55411). In 2001, MSHA issued 30 CFR 57.5067, which permits operators to use engines that meet Environmental Protection Administration (EPA) requirements for engines as an alternative to seeking MSHA approval under part 7, subpart E (66 FR 5706). The Agency proposes to update the regulatory language in § 1926.800(k)(10)(ii) to cross-reference these updated provisions.

OSHA's existing regulatory language in § 1926.800(i)(2) requires that mobile diesel powered equipment used in ''gassy operations'' underground be approved by MSHA in accordance with the provisions of 30 CFR part 36, or that the employer demonstrate that the equipment is ''fully equivalent'' to MSHA-approved equipment. MSHA has also updated part 36. However, the reference in § 1926.800(i)(2) remains correct, and OSHA does not need to change the language to ensure employers are following MSHA's updated requirements.

Under 30 CFR 57.5067, all engines used in underground mines must have an affixed plate evidencing approval of the engine pursuant to 30 CFR part 7, subpart E or meet or exceed the applicable requirements of the EPA listed in MSHA Table 57.5067–1. To use equipment with non-permissible engines in non-gassy operations, the employer must ensure it meets the requirements listed in 30 CFR 75.1909, 75.1910, and 75.1911 for other machine features. If the employer wishes to use equipment with permissible engines, in gassy operations, it must ensure the equipment meets the requirements listed in 30 CFR part 36 for other machine features.

When MSHA revoked 30 CFR part 32 in 1996, it directed state and federal agencies that reference 30 CFR part 32 to 30 CFR part 7, subpart E and 30 CFR 75.1909 and 75.1910 (61 FR 55416). Accordingly, the proposal substitutes references to those sections for the reference to part 32. OSHA has also proposed including 30 CFR 75.1911(a)–(i) in the cross-reference because § 75.1909 requires certain equipment to have fire suppression systems in accordance with § 75.1911. To maintain the scope of 29 CFR 800(k)(10)(ii), OSHA is not proposing to incorporate § 75.1911 paragraphs (j) and (k) (regarding fire suppression systems on diesel-powered equipment), which are training and recordkeeping requirements that were not contained in the original 30 CFR part 32. In addition, OSHA is not proposing to incorporate § 75.1911(l), which addresses the interaction of that section with other MSHA requirements not relevant here. Thus, OSHA has not included paragraphs (j)–(l) in the cross reference.

If adopted, these changes will allow employers to use diesel-powered engines on mobile equipment in underground construction that meets current MSHA requirements.

The existing OSHA standard allows employers to use non-MSHA approved engines if they can demonstrate that they are fully equivalent. The existing standard and OSHA give no guidance how employers can make such a demonstration. OSHA believes that the allowance for engines that meet or exceed EPA requirements in MSHA Table 57.067–1 is a much more effective and simple way to allow the use of non-MSHA approved engines. OSHA solicits comments on whether employers do make such demonstrations and whether the use of EPA requirements will better effectuate a safe and healthful workplace.

For other machine features, the proposal requires that equipment with non-approved engines meeting the applicable EPA requirements must also meet the requirements of 30 CFR 75.1909, 75.1910, and 75.1911(a)–(i) for non-permissible engines used in ''other than gassy'' operations. Because these requirements list features, the only way for an employer to demonstrate equivalency is to show that the equipment has the required features, rendering the ''fully equivalent'' clause unnecessary as to ''other machine features.'' Therefore, because OSHA believes that the function of the current ''fully equivalent'' clause is captured by the updates to the referenced MSHA regulations, the Agency has not retained the language in the proposal.

Based on available information, OSHA has determined that currently manufactured equipment meets the proposed requirements and is generally compliant with the more stringent EPA Tier 3 and Tier 4 emission requirements (ERG, 2015). The Agency has therefore preliminarily concluded that all applicable new equipment currently available for in the market meets the proposed requirements. OSHA recognizes that there may be some employers using equipment that predates the newer MSHA standards, and the EPA requirements referenced in them. To avoid the costs of replacing existing equipment in use and are complaint with the current Standard, the Agency proposes to allow equipment purchased before the effective date of the final rule to continue to comply with the terms of existing § 1926.800(k)(10)(ii) (including having been approved by MSHA under 30 CFR part 32 (1995) or be determined to be equivalent to such MSHA-approved equipment). OSHA solicits comment on whether there are engines in use that meet the existing standard but will not meet the requirements of current MSHA standard and, if so, whether continued use of such equipment presents a serious safety or health hazard. OSHA also seeks comment on whether this proposed grandfathering is workable.

14. Subpart S in 1926—Underground Construction, Caissons, Cofferdams and Compressed Air, Compressed Air in 29 CFR 1926.803

OSHA is proposing to revise subpart S—Underground Construction, Caissons, Cofferdams, and Compressed Air by replacing the decompression tables currently found in Appendix A to subpart S with the 1992 French Air and Oxygen decompression tables. OSHA is also requesting comment on whether the following decompression tables should also be permitted as substitutes for the existing tables in Appendix A: The Edel-Kindwall (NIOSH) tables, the Blackpool (British) tables, and the German Standard Decompression tables. OSHA has preliminarily concluded that the French tables provide safer decompression practices than the OSHA decompression tables currently found in Appendix A to subpart S. OSHA proposes to revise § 1926.803(f)(1) to require employers to follow the 1992

[10] Non-permissible equipment may not be used in gassy operations.

French Air and Oxygen decompression tables to decompress employees exposed to compressed air environments. OSHA proposes to adopt the French tables with an incorporation by reference, while deleting Appendix A.

The current decompression tables in OSHA's subpart S standard were developed by Washington state. According to a NIOSH Request for Information (77 FR 74193), the Washington state Decompression Tables were used by several states prior to 1971, when OSHA adopted them as the federal requirement in Appendix A to subpart S. These tables were adopted under section 6(a) of the OSH Act, which permitted the Agency, for a two-year period, to adopt then-current consensus standards as its own without notice and comment rulemaking. The tables in Appendix A prescribe decompression by reducing the pressure that workers are exposed to at intervals in accordance with the schedule in the tables. The current tables address exposures ranging from half an hour to over eight hours, with only one decompression schedule for exposures of greater than eight hours. Subpart S prohibits employee exposures to compressed air environments of greater than 50 pounds per square inch (p.s.i) (§ 1926.803(e)(5)).

Employers in the tunneling construction industry have requested variances from the underground construction standards in subpart S from federal OSHA as well as states with State Plans. The requests seek a variance to use decompression tables other than those found in Appendix A to subpart S as well as other provisions in the underground standards. In their requests, employers in the industry assert that using other decompression tables is safer than using OSHA's current decompression tables. Also of note, many of the tunneling projects have working pressures ahead of the drill head higher than 50 p.s.i.—so none of the tables in Appendix A would be appropriate or safe. The variance requests suggest that using tables that provide for decompression from environments under pressure greater than 50 p.s.i. and provide staged decompression (stopping workers at set depths and pressures to prevent decompression illness (DCI)), with an enriched oxygen atmosphere, provide greater protection to employees from DCI. The decompression tables that were developed after the 1970s use elevated levels of oxygen to aid in the decompression process.

The ineffectiveness of the current OSHA tables for preventing DCI is discussed in a 1986 study by Gregory J. Downs and Edel P. Kindwall. During a tunneling project in Milwaukee where pressures ranged from 28 psig to 43 psig and the current OSHA tables were used for decompression, 33 percent of tunneling workers examined experienced aseptic necrosis, a form of DCI also known as dysbaric osteonecrosis that causes portions of the bone tissue to die.[11] The study explains that parts of the current OSHA tables ''poorly facilitates total nitrogen elimination,'' resulting in instances of aseptic necrosis for a substantial number of workers decompressed in accordance with the tables at the Milwaukee tunneling project.[12] Downs and Kindwall concluded that the OSHA tables are ''considered inadequate in efficiently eliminating nitrogen from the body, and allow bone disease at pressures in excess of 36.5 psig.'' [13] Kindwall mentioned in a subsequent study that there were inconsistencies in the OSHA tables. For example, the decompression times at 26 and 44 psig are the same for six and eight hour exposures. He believes that this is the result of a mistake made during the transcription of the tables.[14]

On May 23, 2014 OSHA granted a permanent variance to an underground construction contractor allowing, among other things, the employer to use the 1992 French decompression tables (79 FR 29809). In granting this variance, OSHA found that if the employer followed the requirements of the variance, including the French decompression tables, the working conditions for employees would be at least as safe as following OSHA's standard (79 FR 29816). OSHA granted similar variances for other projects on March 27, 2015 (80 FR 16440), and August 20, 2015 (80 FR 50652). On July 27, 2015, OSHA published a **Federal Register** notice seeking comment on an employer's variance request to use the 1992 French decompression tables for all future tunneling projects it performs, subject to certain conditions (80 FR 44386). (Note that ''at least as safe'' is the main criterion OSHA follows to evaluate variance requests.)

On December 15, 2011, the Seattle Tunnel and Tail Team gave a presentation to the Advisory Committee on Construction Safety and Health (ACCSH), titled *Tunnel Advances* (OSHA–2011–0124–0066). The presentation discussed how technology and work practices have changed in the underground construction industry, particularly since the promulgation of subpart S. They illustrated this point by showing the number of variances that were needed to complete underground construction projects safely, as many of the requirements of subpart S have become outdated. One of the common variance requests asks to use decompression tables other than the current OSHA decompression tables.

1992 French Air and Oxygen Decompression Tables

The 1992 French decompression tables replaced an older series of tables from 1974. The French Ministry of Labor revised the earlier tables when a number of cases of DCI occurred during an underground construction project.[15] OSHA conducted a review of the scientific literature on DCI during work under higher air pressure to determine whether use of the decompression methods in the 1992 French Decompression Tables was more effective or safer than following the tables currently in the standard. Based on this review, OSHA has preliminarily concluded that decompression recoveries performed with these tables will result in a fewer cases of DCI than the decompression tables specified by the current standard.

The review conducted by OSHA found several studies supporting the determination that the 1992 French Decompression Tables result in a lower rate of DCI than the decompression tables specified by the standard. For example, H. L. Andersen studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark in 1992–1996.[16] This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events, or a frequency of 0.0008 (0.08 percent). The DCI incidence in the study by Andersen is substantially less than the DCI incidence reported by Eric Kindwall for the decompression tables specified in Appendix A of the current standard. In his study, Kindwall reported 60 treated cases of DCI among

[11] Downs GJ, Kindwall EP (1986) ''Aseptic necrosis in caisson workers: A new set of decompression tables,'' p. 570.

[12] *Id.*

[13] *Id.*

[14] Kindwall, EP (1997). Compressed air tunneling and caisson work decompression procedures: Development, problems, and solutions. Undersea and Hyperbaric Medicine, 24(4), p. 342.

[15] Le Pechon, JC, Barre, P, Baudi, JP, Ollivier, F (1992). Compressed Air Work—French Tables 1992 Operational Results. p. 285.

[16] Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. Undersea and Hyperbaric Medicine, 29(3), pp. 172–188.

4,168 exposures between 19 and 31 p.s.i.g., resulting in a DCI incidence of 1.44 percent using the current OSHA tables.[17] OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables. The results of these studies show that the French tables do a better job of minimizing the significant risks of decompression illness than the current OSHA tables.

During decompressions under the May 23, 2014 variance to Tully/OHL USA Joint Venture, which allowed use of the French decompression tables during hyperbaric operations, the Tully/OHL reported no instances of DCI using the French tables.[18] Likewise, during decompressions under the variance to Traylor/Skanska/Jay Dee Joint Venture, which also allowed use of the French decompression tables, Traylor/Skanska/Jay Dee reported no instances of DCI. (Traylor 2015). The French tables also address decompression at greater pressures than 50 p.s.i and for durations longer than eight hours.

State-Plan states have also granted variances to entities asking to use the 1992 French Air and Oxygen Decompression tables. On June 25, 2007, Washington state granted a permanent variance to VCGP/Parsons RCI/Frontier-Kemper, JV that allowed, among other things, the use of the 1992 French Air and Oxygen decompression tables. Based on its research, the state of Washington determined that ''decompression using oxygen is much more effective in purging the body of residual nitrogen,'' concluding that the French tables were at least as effective as the decompression tables in their standard (OSHA–2012–0036–0009). Similarly, Nevada (OSHA–2012–0036–0006) and Oregon (OSHA–2012–0036–0007) approved variance requests to use the French tables.

Based on a review of available evidence, the experience of State-Plan states (discussed above) that granted variances (Nevada, Oregon, and Washington) for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and OSHA's previously issued variance allowing use the French Decompression Tables, OSHA is proposing to replace the tables in Appendix A with the 1992 French Decompression Tables, which will be incorporated by reference into § 1926.803(f)(1).

Other Tables

In 2003, Valerie Flook published ''*A comparison of oxygen decompression tables for use in compressed air work,*'' a Health and Safety Executive study comparing several oxygen decompression tables, including the British, French, German, and Edel-Kindwall tables. The study ''was commissioned to compare a number of tables used for oxygen decompression from compressed air work in order to identify the safest set of tables. . . .'' The study used a mathematical model to predict the maximum gas volume in bubbles in the central venous blood at the end of decompression using each set of tables. The report noted that the model used had been verified by comparison to actual nitrogen gas bubble counts (measured using Doppler technology) after various compression decompression trials in both animal and human subjects. As explained by NIOSH, nitrogen gas bubbles in the body are a precursor to DCI.[19]

The Flook study concluded that ''[t]he range of gas volumes predicted for most exposures is small and it is unlikely that the different [decompression] profiles could be distinguished. . . .'' (Flook, 2003, 34). The British, French, Edel-Kindwall, and German tables, among others, all achieved a quantity of nitrogen gas bubbles that was within the same range. Similar to the French tables, the British and German tables also address decompression at greater pressures than 50 p.s.i. and for durations longer than eight hours, while the Edel-Kindwall tables do not. OSHA is seeking comment on whether the Edel-Kindwall, British, and/or German tables should be included as options in the OSHA standard. OSHA also seeks any scientific information beyond the Flook study demonstrating the effectiveness of these tables in preventing DCI. If OSHA were to add any of these tables (British, Edel-Kindwall, and/or German) to § 1926.803 in addition to the French tables, then employers would be able choose any of the added tables to decompress employees. OSHA provides more information about each below.

Edel-Kindwall Tables

OSHA asks for comment on whether the Edel-Kindwall decompression tables should (also) be included as a replacement for the tables in Appendix A of subpart S. The Edel-Kindwall tables were developed in response to several tunneling workers experiencing DCI using the current OSHA decompression tables. Between 1971 and 1973 during a tunneling project in Milwaukee, Wisconsin, workers experienced aseptic necrosis, when using the current OSHA decompression tables. This incident prompted NIOSH to determine if alternate decompression tables could be developed.[20]

NIOSH awarded a contract to Eric Kindwall to develop staged decompression tables. The tables, later known as the Edel-Kindwall decompression tables, included the use of oxygen because it shortened decompression time considerably, from over 10 hours to less than four hours. A 1986 study by Kindwall and Gregory J. Downs tested the effectiveness of the Edel-Kindwall tables to eliminate nitrogen from the body and reduce instances of DCI. Six human subjects were compressed for this experiment. While compressed, each subject simulated work conditions for four hours. After performing many activities to establish baseline information for each subject, they were decompressed in accordance with the OSHA or Edel-Kindwall air and oxygen tables. The comparison of the OSHA tables and the Edel-Kindwall air table ability to eliminate nitrogen from the body resulted in ''no statistical difference'' between the two tables. The comparison of the OSHA tables and the Edel-Kindwall oxygen table showed that the Edel-Kindwall oxygen table was ''more efficient in eliminating nitrogen'' than the OSHA tables. Kindwall and Downs concluded that their ''data is definitive enough to for immediate acceptance of this table for use by the construction industry.'' Although Kindwall and Downs expressed some concerns regarding the cost of equipment, oxygen toxicity and flammability, they did not believe these potential concerns outweighed the ''shorter decompression times and reduced morbidity'' offered by the Edel-Kindwall tables.[21]

The Edel-Kindwall tables have been approved as part of variance requests in some State Plan states. In its December 15, 2011 presentation, the Seattle Tunnel and Tail Team presented permanent variances—one from Oregon in 2004 and another from Washington in 2007—that approved the use of the Edel-Kindwall tables for underground

[17] Kindwall, EP (1997). Compressed air tunneling and caisson work decompression procedures: Development, problems, and solutions. Undersea and Hyperbaric Medicine, 24(4), pp. 337–345.

[18] Email from Luis Alonso to Stefan Weisz, RE: Tully Variance End of Project Effectiveness Evaulation Report—Reminder, January 21, 2015.

[19] CDC—Decompression Sickness and Tunnel Workers, *http://www.cdc.gov/niosh/topics/decompression/default.html.*

[20] CDC—Decompression Sickness and Tunnel Workers, *http://www.cdc.gov/niosh/topics/decompression/history.html.*

[21] Downs GJ, Kindwall EP ''Aseptic necrosis in caisson workers: A new set of decompression tables,'' 1986.

construction projects within those states (OSHA–2011–0124–0066).

German Decompression Tables

OSHA asks for comment on whether to (also) include the German decompression tables as a replacement for the tables in Appendix A of subpart S. These decompression tables were developed by Dr. Max Hahn.[22] These tables were approved for use in Oregon, along with the French tables, in 2006 (OSHA–2012–0036–0007). The information from the Flook study discussed above resulted in the German decompression tables being approved by the Health and Safety Executive for use in the United Kingdom, ''the first time non-UK tables had been used on a UK contract.'' [23]

British Blackpool Tables

OSHA asks for comment on whether the British Blackpool decompression tables should (also) be included as a replacement for the tables in Appendix A of subpart S. The Blackpool decompression tables were published in 1973 with air as the breathing gas for decompression.[24] The Blackpool decompression tables are included in the United Kingdom's Health and Safety Executive's ''A Guide to Compressed Air Work 1996,'' The Guide updated the ''Work in Compressed Air Special Regulations 1958.'' [25] In 2001, oxygen decompression became mandatory in the United Kingdom, using a modified Blackpool table that required ''oxygen breathing from 0.6 bar downwards.'' [26] A year later, the Health and Safety Executive reprinted ''A Guide to Compressed Air Work 1996'' to reflect the change in policy. The modified Blackpool Tables were compared to other oxygen decompression tables in the Flook study discussed above.

Insofar as the Agency can find, underground projects which incorporate new tunneling technology have not followed OSHA's existing decompression tables, but have followed more recently developed tables. In each case, federal OSHA or a State Plan state has been persuaded by the available research and studies on the matter that the newer decompression methods better protect underground workers. (The states have either granted variances (discussed above) or promulgated a new standard (California [27])). Many of these tunneling projects also require work in atmospheres above the 50 p.s.i. limit in OSHA's construction subpart S, as current tunneling technology, when there are gaseous or wet underground conditions particularly, require higher pressures. (OSHA is not proposing to change the 50 p.s.i. limit in the SIP–IV rulemaking.)

SIP–IV Request for Information

Given the evidence suggesting that other decompression tables are at least as safe and in many cases safer than OSHA's current decompression tables, OSHA asked for comment on this topic in its Standards Improvement Project—Phase IV, Request for Information (77 FR 72781; Dec. 6, 2012). OSHA received comments from various groups requesting that OSHA update or revise its decompression tables (OSHA–2012–0007–0011, –0016, –0017). All of the commenters stated that OSHA's current decompression tables were outdated and did not address the hazard of DCI as well as more recently developed decompression tables. NIOSH argues that updating the decompression tables in Appendix A will shorten the time needed for decompression and reduce the instances of decompression sickness (OSHA–2012–0007–0017). NIOSH recommended that OSHA take the following steps when updating its decompression tables: Require staged decompression, allow 100 percent oxygen use during decompression, vary the decompression schedule based on exposure time, and allow for greater pressures in underground construction projects. NIOSH also recommended that OSHA adopt the Edel-Kindwall tables. The Laborers' Health and Safety Fund of North America recommended that OSHA adopt the French and Tri-mix [28] tables, with a certifying physician and variances from OSHA above 8 bars (116 p.s.i.) of pressure (OSHA–2012–0007–0011).

OSHA must set safety standards that provide a high degree of worker protection (*Int'l Union, UAW* v. *OSHA,* 37 F.3d 665,669 (D.C. Cir. 1994); 58 FR 16612, 16615 (Mar. 30, 1993)). Such standards must also be feasible and cost-effective. Based on the evidence discussed above, OSHA preliminarily determines that the best available evidence shows that the decompression tables in Appendix A to subpart S are not highly protective and that the French tables are more protective of worker health. OSHA is seeking comment on whether the Edel-Kindwall, British, and German tables should be included as options in the OSHA standard. In addition, OSHA requests comment on NIOSH's statement that staged decompression will shorten the time needed for decompression.

Therefore, OSHA proposes to remove the decompression tables found in Appendix A of Subpart S and replace them with the 1992 French Air and Oxygen decompression tables. The French tables have been used most often in the U.S., and the Agency has collected more information on their safety. Regarding the request for comment on other identified tables, OSHA also asks whether it would be less confusing and easier for the tunneling industry to use one set of tables, rather than include more alternatives in the OSHA standard?

The tables will be posted in the docket of this proposal for commenters to view.

Alternative Regulatory Structure

OSHA seeks comment on an alternative regulatory structure for regulating which decompression tables will be used to decompress workers from a compressed air environment. Under this structure, in addition to removing its current decompression tables, OSHA would also revise § 1926.803(f) to allow employers to use any decompression table that a qualified person determines will protect workers from instances of DCI on the project. The table used would have to meet accepted industry practices for prevent DCI in workers.

As discussed earlier, OSHA adopted the Washington state decompression tables into its regulations under section 6(a) of the Occupational Safety and Health Act. Although used by several states prior to their adoption, few, if any, studies regarding the effectiveness of the Washington state decompression tables were done prior to their adoption by OSHA. Instances of DCI using the current OSHA tables led NIOSH to support research that resulted in the creation of the Edel-Kindwall tables. Since then, several other tables have been developed that when used result in a lower incidence of DCI.

[22] Huggins, Karl E ''The Dynamics of Decompression Workbook'', 1992.

[23] Lamont, DR, Flook, V ''A Comparison of Oxygen Decompression Tables for Use in Hyperbaric Tunnelling''.

[24] Lamont, DR, Flook, V ''A Comparison of Oxygen Decompression Tables for Use in Hyperbaric Tunnelling''.

[25] A guide to the Work In Compressed Air Regulations 1996, Health and Safety Executive.

[26] Lamont, DR, Flook, V ''A Comparison of Oxygen Decompression Tables for Use in Hyperbaric Tunnelling''.

[27] California incorporates the Navy Diving Manual by reference. Because these tables are specifically for diving, conversions are necessary to use the tables in a non-diving application. See *http://www.dir.ca.gov/title8/6085.html.* For this reason, OSHA is not proposing to add, or seeking comment on, the Navy Diving Manual.

[28] Tri-mix is a mixture of three breathing gases: Oxygen, nitrogen, and helium. The mixture of the gases is usually proprietary.

OSHA has granted variance requests from members of the underground construction industry asking, among other things, to use decompression tables that they believe are at least as effective as the current OSHA tables found in Appendix A of subpart S. On May 23, 2014, OSHA granted the variance request of Tully/OHL USA Joint Venture (79 FR 29809). Tully/OHL USA requested to use the 1992 French decompression tables, which permit both air and oxygen decompression. OSHA granted a variance to Traylor/Skanska/Jay Dee Joint Venture in which they also requested to use the 1992 French decompression tables, as well as the proprietary Trimix tables, in their variance application (80 FR 16440).[29] OSHA also granted a permanent variance to Impreglio Healy Parsons Joint Venture on August 20, 2015 (80 FR 50652). Their variance application also requested to use the 1992 French decompression tables (OSHA–2014–0011–0001). Several occupational safety and health programs have approved of various decompression tables for underground construction work. In the Seattle Tunnel and Tail Team's presentation to ACCSH, they included variances from Washington that approved the use of the 1992 French decompression tables, Trimix tables, and modified NIOSH (Edel-Kindwall) tables (OSHA–2011–0124–0066). The presentation also included a variance from Oregon that approved the use of the DCIEM Oxygen Decompression tables, also known as the Canadian Navy Tables, the 1992 French Decompression Tables, and the NIOSH (Edel-Kindwall) Oxygen Decompression tables (OSHA–2011–0124–0066). In their comment to the Request for Information, the Laborer's health and Safety Fund of North America recommended OSHA adopt the French tables, but listed four other decompression tables—the Edel-Kindwall tables, the U.S. Navy Tables (Revision 6), the Canadian Navy Tables (1992), and the Trimix tables (for pressures over 4.8 bar)—that had been approved by variance in several states. (OSHA–2012–0007–0011). Furthermore, the Flook study suggests that many of the oxygen decompression tables provide virtually the same protection from DCI.

[29] Although Traylor/Skanska/Jay Dee Joint Venture requested the use of Trimix tables in their variance application for the Blue Plains Tunneling (BPT) project, they later explained to OSHA that ''[a]t the Blue Plains Tunnel, Traylor will not experience hyperbaric pressures greater than 3.6 bar. Therefore we do not plan on using trimix at the BPT project.'' OSHA–2012–0035–0013.

Given the numerous decompression tables that employers requests to use in variance applications, it appears that the industry does not believe there is one table that is applicable for all underground construction projects where workers may need to be decompressed. OSHA believes using a performance standard rather than specifying which table an employer must use may allow employers greater flexibility in providing safe decompression for their workers. OSHA requests comment on this regulatory approach.

Statement of Reasonable Availability

OSHA believes that the 1992 French Decompression Tables included in this proposal are reasonably available to interested parties. The tables are published in the Official Journal of the French Republic, titled ''Travaux en milieu hyperbare, measures particulières de prevention'' (Work in hyperbaric environment, specific prevention measures). J. O. Rep. Franç. Brochure n° 1636, June 1992. The tables are available for purchase from the French government at *http://www.journal-officiel.gouv.fr/.* In addition, it is available in the docket for this rulemaking and in OSHA's docket office for review. If OSHA ultimately finalizes this rule, the tables will be maintained in OSHA's national and regional offices for review by the public.

Subpart S—Underground Construction, Caissons, Cofferdams and Compressed Air also has several provisions that limit the quantities of oxygen that may be taken below ground and kept there. OSHA asks for comment on providing an exception to those requirements for purposes of maintaining oxygen on hand for decompression purposes, which would be necessary in a final rule as the updated tables discussed above require the use of oxygen.

15. Subpart W of 1926—Rollover Protective Structures; Overhead Protection

Provisions in subpart W specify minimum performance criteria for rollover protective structures (ROPS) and overhead protection on construction equipment. The Agency is proposing to amend the existing standards 29 CFR 1926.1000, 1926.1001, 1926.1002 and 1926.1003 by removing the provisions that specify the test procedures and performance requirements, and replacing those provisions with references to the underlying consensus standards from which they were derived. The substantive differences between the consensus standards and OSHA's standards are minimal. The Agency is also proposing to remove irrelevant text from § 1926.1000.

The original source standards for the current subpart W requirements are the Society of Automotive Engineers Standards (''SAE'') J320a–1971, J394–1971, J395–1971, J396–1971, J334a–1970, J167–1970, J168–1970, and J397–1969. The American National Standards Institute and SAE subsequently canceled these standards. To design and develop new equipment the industry now uses the most recent International Organization for Standardization (''ISO'') standards: ISO 3471–2008; ISO 5700–2013; and ISO 27850–2013. Though the names of the construction equipment covered by the consensus standards have changed over time, OSHA believes that all the equipment listed in current § 1926.1001(a) is covered by one of those ISO standards. A comment from a representative of Caterpillar, Inc. stated that the SAE standards have either been cancelled or superseded by new ISO standards (OSHA–2012–0007–0009). OSHA reviewed the relevant standards and believes that the standards identified in the proposed revisions reflect the current design and development of ROPS for equipment covered by subpart W. OSHA preliminarily concludes that using the proposed ISO standards will be as protective as using the current OSHA standards. Therefore, OSHA is proposing that, for new equipment manufactured after the effective date of the revised standard, the performance measures for testing ROPS meet the ISO standards. This proposed incorporation by reference will eliminate over 20 pages of text and diagrams in the CFR.

OSHA proposes to rename § 1926.1000 as ''Scope'' because this more accurately describes what follows in this section. Proposed paragraph (a) lists the types of equipment currently covered by subpart W. It also adds compactors and rubber-tired skid-steer equipment manufactured after the effective date of the final rule, which existing § 1926.1000(a)(2) anticipates as a possible expansion of the scope. The most recent ISO standards apply to compactors and skid-steer loaders as well as the equipment included in the current standard, and based on interviews with several manufacturers OSHA preliminarily concludes that all compactors and skid steer loaders currently produced meet those requirements. Proposed paragraph (b) states which standards apply to equipment manufactured before the publication of a final rule. Proposed paragraph (c) states which standards

apply to equipment manufactured after the publication of a final rule. Paragraphs (d) through (f) remain unchanged in the proposal, but OSHA solicits comment on whether paragraphs (d), ''*Remounting,''* (e), ''*Labeling,''* and (f), ''*Machines meeting certain existing governmental requirements''* are necessary or are obsolete (due to adoption of modern consensus standards) and should be deleted.

Currently, § 1926.1000(c) limits the application of the requirements of §§ 1926.1001 and 1926.1002 to equipment manufactured after July 1, 1969. The proposal eliminates this limitation because it is OHSA's understanding that there are not any pieces of covered equipment in operation today that are more than 45 years old and do not meet the SAE standards. OSHA seeks comment on whether this is so, and any data on the types and numbers of pre-1969, non-SAE compliant equipment currently in use.

Current § 1926.1001 provides ROPS requirements for rubber-tired self-propelled scrapers, rubber-tired front end loaders, rubber-tired dozers, crawler tractors, crawler-type loaders, and motor graders. The proposed rule deletes the current ROPS specifications for this equipment, and replaces it with a requirement that covered equipment manufactured before the effective date of the final rule comply with SAE J397–1969—Critical Zone—Characteristics and Dimensions for Operators of Construction and Industrial Machinery, SAE 320a–1970—Minimum Performance Criteria for Roll-Over Protective Structure for Rubber-Tired, Self-Propelled Scrapers, SAE J394–1970—Minimum Performance Criteria for Roll-Over Protective Structures for Rubber-Tired Front End Loaders and Rubber-Tired Dozers, SAE J395–1970—Minium Performance Criteria for Roll-Over Protective Structure for Crawler Tractors and Crawler-Type Loaders, and SAE J396–1970—Minimum Performance Criteria for Roll-Over Protective Structure for Motor Graders, as applicable. The proposal requires equipment manufactured after the effective date of the final rule (including compactors and rubber-tired skid steer equipment) to meet the requirements of ISO 3471–2008, Earth-moving machinery—Roll-over protective structures—Laboratory tests and performance requirements. This standard contains specifications for ROPS to protect employees. Because, as noted above, OSHA believes that covered equipment is already being manufactured to the requirements of ISO 3471–2008, the proposal provides the option for equipment manufactured before the effective date of the final rule to comply with the ISO standard rather than the SAE standards.

Current § 1926.1002 provides ROPS requirements for wheel-type agricultural equipment and industrial tractors used in construction. The proposed rule deletes the current ROPS specifications for this equipment, and replaces it with a requirement that covered equipment manufactured before the effective date of the final rule comply with SAE J168–1970-Protective Enclosures—Test Procedures and Performance Requirement and SAE J334a-1970-Protective Frame Test Procedures and Performance Requirements, as applicable. The proposal requires equipment manufactured after the effective date of the final rule meet the requirements of ISO 5700–2013, Tractors for agriculture and forestry—Roll-over protective structures—Static test method and acceptance conditions. This standard contains specifications for ROPS to protect employees. Because, as noted above, OSHA believes that covered equipment is already being manufactured to the requirements of ISO 5700–2013, the proposal provides the option for equipment manufactured before the effective date of the final rule to comply with the ISO standard rather than the SAE standards.

OSHA solicits comment on whether any equipment covered by § 1926.1002 that complies with ISO 3471–2008, the standard for earth-moving machinery should be considered in compliance for ROPS. OSHA asks this because ISO 3471–2008 requires testing at higher levels of energy than ISO–5700.

Current § 1926.1003 provides design and installation requirements for the use of overhead protection for operators of agricultural and industrial tractors used in construction. The proposed rule deletes the current overhead protection specifications for this equipment, and replaces it with a requirement that covered equipment manufactured before the effective date of the final rule comply with SAE J167–1970-Overhead Protection for Agricultural Tractors-Test Procedures and Performance Requirements when using overhead protection. The proposal requires equipment manufactured after the effective date of the final rule meet the requirements of ISO 27850–2013, Tractors for agriculture and forestry—Falling object protective structures—Test procedures and performance requirements when using overhead protection. This standard contains specifications for overhead protection to protect employees. Because, as noted above, OSHA preliminarily concludes that overhead protection, when used, is manufactured to the requirements of ISO 27850–2013, the proposal provides the option for equipment manufactured before the effective date of the final rule to comply with the ISO standard rather than the SAE standards.

Statement of Reasonable Availability

As noted above, OSHA is continuing to incorporate by reference Society of Automotive Engineers (SAE) standards. OSHA believes that these standards are reasonably available to interested parties. They are available for purchase the Society of Automotive Engineers (SAE), 400 Commonwealth Drive, Warrendale, PA 15096; telephone: 1–877–606–7323; fax: 724– 776–0790; Web site: *http://www.sae.org/*. OSHA proposes to incorporate by reference International Organization for Standardization (ISO) standards. OSHA believes that these standards are reasonably available to interested parties. They are available for purchase from the International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH–1211 Geneva 20, Switzerland; telephone: +41 22 749 01 11; fax: +41 22 733 34 30; Web site: *http://www.iso.org/*. In addition, it is available in the docket for this rulemaking and in OSHA's docket office for review. If OSHA ultimately finalizes this rule, the standards will be maintained in OSHA's national and regional offices for review by the public.

16. Subpart Z of 1926—Toxic and Hazardous Substances, Coke Oven Emissions in 29 CFR 1926.1129.

Section 1926.1129 regulates exposure to coke oven emissions in construction. OSHA incorporated this standard into part 1926 in 1993 (58 FR 35256, June 30, 1993) and revised it to be just a reference to the identical general industry standard in 1996 (61 FR 31428, June 20, 1996). In neither rulemaking did OSHA discuss, in particular, the application of the coke oven standard to construction, as it was only one of many standards involved in each rulemaking.

However, the provisions of this standard do not fit construction work. Much of the standard regulates exposure in the ''regulated area.'' (See 29 CFR 1910.1029(d)). But this ''regulated area'' is limited, including only ''[t]he coke oven battery including topside and its machinery, pushside and its machinery, coke side and its machinery, and the battery ends; the wharf; and the screening station [and the] beehive oven and its machinery'' (§ 1910.1029(d)(2)(i) and (ii)). As stated in an interpretation issued nearly contemporaneously with the general industry coke oven

emissions standard, ''[t]he ground level around the base of the coke oven battery is not generally considered in the regulated area unless work related to coke oven operations take place. The coke oven regulation, 29 CFR 1910.1029, does not apply to employees walking past coke ovens or between them.'' (Interpretation memorandum to White, May 17, 1977). Any work operating the coke ovens would be general industry work, and it is unlikely that any workers doing construction work, even if within a facility with an operating coke oven, would be so close to the coke oven as to be covered under the standard. OSHA recognized this issue in the 1990s, when it stated that the coke oven construction standard was ''invalid,'' and would be removed from the Code of Federal Regulations. (Interpretation letter to Katz, June 22, 1999). OSHA also advised its Regional Offices of this interpretation and that they should not enforce § 1926.1129 in 2005. OSHA's inspection database contains no record of a citation under this standard since 1997.[30]

Since, in effect, the standard does not address construction worker exposures to coke oven emissions, there would be no reduction in the level of protection. To the extent any construction workers would in the future be exposed to coke oven emissions, OSHA could cite the employer under the General Duty Clause (29 U.S.C. 654(a)(1)). Thus, OSHA is now proposing to delete § 1926.1129. OSHA is also proposing to delete the reference to § 1926.1129 in § 1926.55, Appendix A (proposed Table A).

17. Additional Proposed Revisions to Paragraphs and Appendices in 29 CFR Parts 1910, 1915, and 1926 To Remove Social Security Number Collection Requirements

In addition to the revisions described above, OSHA is proposing a series of revisions to various standards in 29 CFR parts 1910, 1915, and 1926, to remove the requirements that employers include an employee's social security number (SSN) on exposure monitoring, medical surveillance, and other records. OSHA believes that these revisions will protect employees' privacy and prevent identity fraud.

Many of OSHA's standards—particularly, its substance-specific standards—require that exposure monitoring, medical surveillance, and other records include the employee's SSN. OSHA has historically required SSNs on these records because SSNs, which are assigned at birth and do not change over time, are unique and constant personal identifiers that offer a useful method for linking records with individual employees. OSHA explained in a 1999 letter of interpretation regarding the asbestos standard for construction that only using an employee's name to match a record with an employee is undesirable because ''[m]any employees have identical or similar names.'' (Mr. Shawn T. Christon, April 16, 1999). Similarly, in the preamble to the final methylene chloride standard (62 FR 1494, January 10, 1997), OSHA explained that a SSN is a more useful identifier than an employer-generated employee identification number because each SSN is ''unique to an individual for a lifetime and does not change as an employee changes employers.'' (62 FR 1494, 1598).

However, increasingly widespread concerns about identity theft have prompted OSHA to reexamine whether requiring SSNs on records is still appropriate. Identity theft has emerged as one of the fastest growing crimes in the United States, and the Social Security Administration (SSA) has alerted the public that repetitive use and disclosure of SSNs in organizational recordkeeping systems should be avoided, as doing so multiplies the susceptibility of persons to potential identity theft (SSA, *Identity Theft and Social Security,* SSA Publication No. 05–10064 (Sept. 2015)), available at: *https://www.ssa.gov/pubs/EN-05-10064.pdf*). OSHA recognizes that limiting the use and transmission of SSNs is a key strategy for preventing identity theft, and acknowledges that requiring employers to include employee SSNs on exposure monitoring, medical surveillance, and other records does not further that effort.

OSHA previously requested public comments on its SSN collection requirements in the Standards Improvement Project Phase II (SIP II) proposal (67 FR 66494–66501, October 31, 2002), and the comments that the Agency received reflected mixed opinions on the usefulness of, and the privacy risks created by, including employee SSNs on monitoring and surveillance records. As discussed in the SIP II final rule (70 FR 1112, January 5, 2005), several commenters supported maintaining the requirements to collect employee SSNs, citing, among other reasons, SSNs' common use in other employee records and their suitability for tracking employees in large epidemiological studies of workplace populations (*e.g.,* Exs. 3–9, 3–16, 3–14, OSHA Docket No. S–778–A). Several other commenters, however, expressed interest in replacing SSNs with alternative identification numbers that would pose a less serious risk to employee privacy and security if acquired by a third party (*e.g.,* Exs. 3–1, 3–7, 3–28, 4–7, OSHA Docket No. S–778–A). OSHA ultimately decided not to take action in the SIP II final rule concerning the use of SSNs in its standards, concluding that the Agency needed to further investigate the issue (70 FR 1112, 1126–27).

OSHA subsequently clarified in two letters of interpretation that employers are permitted under its current standards to maintain a second set of records that use alternative identification numbers in place of SSNs (Mr. Sutherland, Feb. 5, 2007; Mr. Mayo, March 27, 2008). In the 2008 letter, which responded to an inquiry about the SSN requirements in the recordkeeping provisions of the lead standard (29 CFR 1910.1025(d)(5)), OSHA clarified that employers are permitted to keep a second set of records with alternative identification numbers in place of SSNs so long as ''those unique identification numbers [can] be easily cross referenced to the employee's SSN,'' because ''such a system would ensure that the employees' privacy is maintained, while also satisfying the intent of the Lead Standard'' (Mr. Mayo, March 27, 2008). The letter also emphasized that the lead standard only requires employers to assure access to complete exposure records that contain SSNs when requested by an employee, a designated employee representative, or a representative of OSHA or NIOSH.

OSHA also considered its SSN collection requirements after it published the Notice of Proposed Rulemaking for Occupational Exposure to Respirable Crystalline Silica (78 FR 56273, September 12, 2013). OSHA received many comments on the recordkeeping provisions in the proposed paragraphs (j)(1)(ii)(G) (Air monitoring data) and (j)(3)(i)(A) (Medical surveillance) which, consistent with the recordkeeping requirements in OSHA's other health standards, required the employer to include the employee's SSN in the standard's monitoring and surveillance records. More than a dozen commenters addressed the SSN collection requirements and all of those commenters expressed opposition to including the requirements in the standard (*e.g.,* Document ID 1772, p.1; 1785, pp. 9–10; 2185, pp. 8; 2267, p. 7; 2270, p. 3; 2291, p. 26; 2301, Attachment 1, pp. 80–81; 2311, p. 3; 2315, p. 7; 2348, Attachment 1, p. 39;

[30] There were a few citations between 1993 and 1997.

2357, pp. 36–37; 2363, p. 7; 2379, Appendix 1, p. 73; 2107, p. 4; 1963, p. 3, Docket No. OSHA–2010–0034). Commenters generally viewed the inclusion of a SSN on the records as creating an unnecessary risk to employee privacy and security, and sought the flexibility to use alternate personal identifiers in place of SSNs. Several commenters explained that companies currently use alternative identifiers—such as employee identification numbers—to link monitoring and surveillance records with specific employees, and stated that these identifiers can be internally linked back to an employee's SSN if that information is needed (*e.g.,* Docket ID 2379, Appendix 1, p. 73; 2357, pp. 36–37; 2270, p.3, 2348, Attachment 1, p. 39; 2301, Attachment 1, pp. 80–81; 2291, p. 26, Docket No. OSHA–2010–0034). Commenters acknowledged that SSNs must be used on some government reports (*e.g.,* payroll reports to the IRS) and are therefore present in some employer records, but stated that access to those records is usually more restricted than to air monitoring records.

OSHA ultimately decided to retain the requirements to include the employee's SSN in the recordkeeping paragraphs of the silica final rule, stating that including the employee SSNs on such records is ''long-standing OSHA practice, based on the fact that it is a number that is both unique to an individual and is retained for a lifetime, and does not change as an employee changes employers'' (81 FR 16285, 16852, March 25, 2016). OSHA acknowledged the commenters' concerns about employee privacy and identity theft, but explained that any change to the Agency's requirements for including employee SSNs on exposure records should be done comprehensively, rather than on a standard-by-standard basis. OSHA stated that it intended to examine the SSN requirements in all of its substance-specific health standards in a future rulemaking.

OSHA originally required collection of employee SSNs in its standards because SSNs are assigned at birth and do not change over time, which makes SSNs useful for linking records with individual employees. As unique and constant personal identifiers, SSNs are also suitable for researchers who track employees in large epidemiological studies of workplace populations. However, other tracking methods have emerged that allow researchers to conduct these studies without the use of SSNs.

OMB requires all federal agencies to identify and eliminate unnecessary collection and use of SSNs in agency systems and programs (see Memorandum from Clay Johnson III, Deputy Director for Management, Office of Management and Budget, to the Heads of Executive Departments and Agencies Regarding Safeguarding Against and Responding to the Breach of Personal Identifiable Information (M–01–16), May 22, 2007 (available at: *www.whitehouse.gov/omb/memoranda/fy2007/m07-16.pdf*). Recognizing the seriousness of the threat of identity theft and the availability of other methods for tracking employees for research purposes, if needed, OSHA has reexamined the SSN collection requirements in its standards, and now proposes to comprehensively remove all requirements to include employee SSNs on exposure monitoring, medical surveillance, or other records. Specifically, OSHA proposes to delete the requirement to include an employee's SSN in records employers must maintain under the following standards:

- Hazardous Waste Operations and Emergency Response—§§ 1910.120(f)(8)(ii)(A) and 1926.65(f)(8)(ii)(A);
- Asbestos—§§ 1910.1001(m)(1)(ii)(F), (m)(3)(ii)(A), and Appendix D, 1915.1001(n)(2)(ii)(F), (n)(3)(ii)(A), and Appendix D, and 1926.1101(n)(2)(ii)(F), (n)(3)(ii)(A), and Appendix D;
- Vinyl Chloride—§ 1910.1017(m)(1);
- Inorganic Arsenic—§ 1910.1018(q)(1)(ii)(D) and (q)(2)(ii)(A);
- Lead—§§ 1910.1025(d)(5), (n)(1)(ii)(D), (n)(2)(ii)(A), (n)(3)(ii)(A), and Appendix B, and 1926.62(d)(5), (n)(1)(ii)(D), (n)(2)(ii)(A), (n)(3)(ii)(A), and Appendix B;
- Chromium (VI)—§§ 1910.1026(m)(1)(ii)(F) and (m)(4)(ii)(A), 1915.1026(k)(1)(ii)(F) and (k)(4)(ii)(A), and 1926.1126(k)(1)(ii)(F) and (k)(4)(ii)(A);
- Cadmium—§§ 1910.1027(n)(1)(ii)(B), (n)(3)(ii)(A), and Appendix D, and 1926.1127(d)(2)(iv), (n)(1)(ii)(B), and (n)(3)(ii)(A);
- Benzene—§§ 1910.1028(k)(1)(ii)(D) and (k)(2)(ii)(A);
- Coke Oven Emissions—§§ 1910.1029(m)(1)(i)(a) and (m)(2)(i)(a);
- Bloodborne Pathogens—§ 1910.1030(h)(1)(ii)(A);
- Cotton Dust—§§ 1910.1043(k)(1)(ii)(C), (k)(2)(ii)(A), and Appendices B–I, B–II, and B–III;
- 1,2 Dibromo-3-Chloropoane—§§ 1910.1044(p)(1)(ii)(d) and (p)(2)(ii)(a);
- Acrylonitrile—§ 1910.1045(q)(2)(ii)(D);
- Ethylene Oxide—§§ 1910.1047(k)(2)(ii)(F) and (k)(3)(ii)(A);
- Formaldehyde—§§ 1910.1048(o)(1)(vi), (o)(3)(i), (o)(4)(ii)(D), and Appendix D;
- Methylenedianiline—§§ 1910.1050(n)(3)(ii)(D), (n)(4)(ii)(A), and (n)(5)(ii)(A), and 1926.60(o)(4)(ii)(F) and (o)(5)(ii)(A).
- 1,3-Butadiene—§§ 1910.1051(m)(2)(ii)(F), (m)(4)(ii)(A), and Appendix F;
- Methylene Chloride—§§ 1910.1052(m)(2)(ii)(F), (m)(2)(iii)(C), (m)(3)(ii)(A), and Appendix B;
- Respirable crystalline silica—§§ 1910.1053(k)(1)(ii)(G) and (k)(3)(ii)(A), and 1926.1153(j)(1)(ii)(G) and (j)(3)(ii)(A).

The Agency believes that removing these requirements will facilitate employers' efforts to safeguard employee privacy. Based on the comments that it received in response to the SIP II request and the proposed silica rule, OSHA understands that some employers use a unique employee identification number to identify employees, and because these numbers are not used in commerce, they pose a less serious risk to employee privacy than SSNs if they are acquired by an authorized third party. Alternatively, some employers use other personal identifying information, either alone or in combination, to identify employees, such as first and last name, date of birth, government issued identification or driver's license number, passport number, or the last four digits of the SSN. Although some of this personal information, such as date of birth, may be used in commerce, exposure of that information may also be less damaging to employee privacy than exposure of an employee's SSN.

The proposed revisions would not otherwise alter OSHA's requirements for maintaining records, and employers would thus be expected to continue handling previously-generated records that contain SSNs as they currently do. The proposal does not require the deletion of employee SSNs from existing records, and it does not require employers to use an alternative unique employee identifier on those records. The proposal allows employers, who wish to do so, to continue using SSNs on records developed in compliance with the standards noted above. Accordingly, OSHA believes that these proposed revisions will not increase an employer's compliance burden under any of the revised standards.

OSHA sought and received a recommendation from the Advisory Committee on Construction Safety and

Health (ACCSH) to proceed with its proposal to remove the SSN collection requirements from its standards. At a public meeting held on December 2, 2015, ACCSH unanimously recommended that OSHA proceed with the proposal (ACCSH Dec. 2, 2016 transcript, pp. 83–98, available at Docket No. OSHA–2015–0002–0113). However, members of ACCSH also requested that OSHA provide guidance to employers whether they could continue using SSNs, and as noted above the proposal would allow them to do so.

OSHA seeks comments on all aspects of this proposal. In addition, the Agency seeks comments on potential alternative approaches, including a requirement that the employer implement an alternative unique employee identifier, and that the employer remove all employee SSNs from all existing records maintained under the standards noted above. In particular, OSHA seeks comments on whether employers currently use alternatives to SSNs to identify employees in the records required by OSHA's standards, and if so, which alternative identifiers employers use, and whether employers maintain two sets of records or just a single set. OSHA would appreciate detailed information on any alternatives to SSNs. The Agency also requests comments on how removing the SSN requirements from exposure monitoring and surveillance records would affect employers' ability to identify employees on records, and whether the proposed revisions would affect the way that employers conduct business.

Regarding the handling of existing records, OSHA requests information on whether employers currently maintain the records required under OSHA's standards electronically, in hard copy, or both. For those employers that store records electronically, OSHA seeks information on whether employers store those records in a database, and if so, whether OSHA's proposed revisions would require employers to modify or reprogram their databases. OSHA also requests information on the feasibility of removing SSNs from existing records, including any obstacles that might prevent employers from removing SSNs from electronic records, and whether it would be practicable to remove SSNs from existing hard copy records.

This proposal would impact several forms that are contained in appendices to OSHA's standards, and when reviewing those forms to remove their SSN collection requirements, OSHA noticed that several forms from older standards do not comport with OMB's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, as updated on October 30, 1997 (62 FR 58782–58790). The Agency is considering revising the forms to either update the language to ensure compliance with OMB's standards or remove the question altogether. For example, Part 1 (''Initial Medical Questionnaire'') of Appendix D of the asbestos standard for general industry (29 CFR 1910.1001) includes a question (currently, #15) that states:

Race:
1. White ____
2. Black ____
3. Asian ____
4. Hispanic ____
5. Indian ____
6. Other____

To reflect a combined race and ethnicity format (*see* 62 FR 58782, 58789), OSHA is considering revising the language to state:

Race:
1. White ____
2. Black or African American ____
3. Asian ____
4. Hispanic or Latino ____
5. American Indian or Alaska Native ____
6. Native Hawaiian or ____
Other Pacific Islander ____

Other forms impacted by the removal of SSN collection requirements that have questions that would be similarly affected are: Asbestos in Construction (§ 1926.1101, Appendix D) and Maritime (§ 1915.1001 Appendix D); Cotton Dust (§ 1910.1043, Appendix B–1, Appendix B–II, and Appendix B–III) and Methylene Chloride (§ 1910.1052, Appendix B)

OSHA requests comments on revising the appendices as indicated above and particularly on whether revising the language of race and ethnicity questions would impose any additional burden hours or costs on the respondents.

IV. Preliminary Economic Analysis and Regulatory Flexibility Act Certification

A. Overview

Executive Orders 12866 and 13563 require that OSHA estimate the benefits, costs, and net benefits of proposed regulations. Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) also require OSHA to estimate the costs, assess the benefits, and analyze the impacts of certain rules that the Agency promulgates. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The proposed rule is not an ''economically significant regulatory action'' under Executive Order 12866 or UMRA, and it is not a ''major rule'' under the Congressional Review Act (5 U.S.C. 801 *et seq.*). This proposed rule has estimated annual costs of $27,899 and would lead to approximately $3.2 million per year in cost savings to regulated entities. Thus, neither the benefits nor the costs of this rule exceed $100 million. In addition, it does not meet any of the other criteria specified by UMRA or the Congressional Review Act for a significant regulatory action or major rule. This Preliminary Economic Analysis (PEA) addresses the costs, cost savings benefits, and potential economic impacts of the proposed rule.

The purpose of the proposed provisions in this standard was to reduce the burden on employers, or provide employers with compliance flexibility, by removing or revising confusing, outdated, duplicative, or inconsistent requirements, while maintaining the same level of protection for employees. This proposed standard deletes and revises a number of provisions in existing OSHA standards. In most instances, the Agency chose to revise outdated provisions to improve clarity, as well as consistency, with standards more recently promulgated by the Agency or current consensus standards. In other instances, the proposed provisions revise standards to improve consistency with current technology or research, and to restore OSHA's original intent to standards. Because of the reduction or removal of current requirements and because many of the updates reflect what is already practiced in the applicable industry, OSHA has preliminarily concluded that the proposed rule is technologically feasible.

B. Costs, Cost Savings, and Benefits

Work-Related Hearing Loss

OSHA is proposing to add a specific cross-reference to 29 CFR 1904.5—Determination of Work-Relatedness—in § 1904.10—Recording Criteria for Cases Involving Occupational Hearing Loss—paragraph (b)(6). This cross-reference specifies that employers must comply with the provisions of § 1904.5 when making a determination as to whether a worker's hearing loss is work-related. OSHA is not changing any requirements of 29 CFR 1904.10, but merely clarifying the Agency's intent. Since this change does not change the requirements of this standard, OSHA has preliminarily determined that neither new costs nor compliance burdens would be incurred.

Lockout/Tagout

OSHA is proposing to remove the word ''unexpected'' from the phrase ''unexpected energization'' in its general industry standard regulating the control of hazardous energy (lockout/tagout) at 29 CFR 1910.147. As described in the Summary and Explanation, because removing the word ''unexpected'' from the language of this standard would not represent any revision in OSHA policy, but instead clarify the Agency's original meaning of the term ''energization'' in the standard, OSHA preliminary concludes that this action would not result in any costs, compliance burdens, or additional employer responsibility other than what the Final Economic Analysis already considered for original § 1910.147 (OSHA, 1989).

This revision would respond to the interpretation of the lockout/tagout of the Occupational Safety and Health Review Commission and the U.S. Court of Appeals for the Sixth Circuit in Reich v. General Motors Corp., Delco Chassis Div. (GMC Delco), 17 BNA OSHC 1217 (Nos. 91–2973, 91–3116, 91–3117, 1995); aff'd 89 F.3d 313 (6th Cir. 1996). In that case, both OSHRC and the Court of Appeals found that a machine with a multi-step procedure, time delays, and a warning system before reenergization was not covered by the standard because its reenergization was not ''unexpected.'' OSHA does not agree with this decision, and its consistent interpretation of the standard is that such equipment is covered by the standard. As explained in the summary and explanation, the phrase ''unexpected energization'' was intended to mean any re-energization or startup that was not authorized by the servicing employee removing her personal lockout/tagout device from the energy isolation device or equivalent energy control mechanism. Moreover, to implement the *GMC Delco* decision, OSHA's directive on the lockout/tagout standard lists 11 different factors for compliance officers to use to evaluate and document whether equipment is covered by the standard or not. This case-by-case analysis creates a degree of uncertainty about the applicability of the standard for the regulated community that OSHA did not intend. Though this proposed revision may change the frequency or number of violations cited and the amount of fines assessed due to improved employer understanding of the revised language, these are not material effects that would serve as a basis for estimating new costs to comply with the standard, and such costs can be avoided by adherence to the standard, whose costs OSHA has already estimated.

In addition, removing the word ''unexpected'' from the text of § 1910.147 also would harmonize this standard with a recent OSHA lockout/tagout standard which does not include the term ''unexpected.'' See OSHA's General Working Conditions in Shipyard Employment standard at 29 CFR 1915.89.

Chest X-Ray Requirements

Medical surveillance requirements in health standards are designed primarily to detect the early onset of adverse health effects so that appropriate interventions can be taken. In certain OSHA standards, the Agency currently requires periodic chest X-rays (CXRs) as a form of early lung cancer detection. At the time these standards were promulgated, routine screening for lung cancer with CXR was considered appropriate; however, recent studies with many years of follow-up have not shown a benefit from CXR screening for either lung cancer incidence or mortality. As a result, OSHA is proposing to remove the requirement for periodic CXR in the following standards: § 1910.1029—Coke Oven Emissions, § 1910.1045—Acrylonitrile, and § 1910.1018—Inorganic Arsenic.

As OSHA has become increasingly aware of the ineffectiveness of CXR in reducing lung cancer mortality, the Agency has moved to decrease CXR requirements to eliminate unnecessary radiation to workers as well as reduce the cost to employers to provide CXR as part of medical examinations, which it did previously in the first phase of the Standards Improvement Process (63 FR 33450, June 18, 1998). Not only does OSHA preliminarily conclude that the removal of this requirement would result in a cost savings to employers, but the Agency also believes it would prove to be beneficial to employees by decreasing their exposure to radiation as well as decreasing the rate of false positive results. Although OSHA has not attempted to quantify these benefits in this preliminary analysis, the Agency invites comment from the public on these issues.

To estimate the annual cost savings to employers if the requirement for periodic CXRs were removed from the listed standards, OSHA, with the assistance of Eastern Research Group (ERG), estimated the number of unnecessary CXRs that would be eliminated by this proposed change by drawing on estimates of the affected number of workers for each standard in the Agency's most recent Information Collection Requests for each affected standard (ERG, 2015). OSHA then analyzed data from the Centers for Medicare and Medicaid Services' (CMS) Physician Fee Schedule. Summarizing data from around the United States indicated a national average price of $68.42 for a CXR (ERG, 2015). Finally, the Agency multiplied the average price of a CXR by the number of CXRs to be eliminated, providing an estimate of $245,148 of exam cost savings. This information is detailed as follows:

Coke Oven Emissions (§ 1910.1029):
  Reduced Exam Costs: 2,324 exams × $68.42 CXR cost per exam = $159,008
Acrylonitrile (§ 1910.1045):
  Reduced Exam Costs: 467 exams × $68.42 CXR cost per exam = $31,952
Inorganic Arsenic (§ 1910.1018):
  Reduced Exam Costs: 792 exams × $68.42 CXR cost per exam = $54,188
Total Reduced Exam Cost:
  $159,008+$31,952+$54,188 = $245,148

Reducing the time of the medical exam, by removing the CXR requirement, would also save employers money because the employee is away from work for a shorter period of time. Based on information from RadiologyInfo.org, the Agency conservatively estimates that the time employees would be away from work is reduced by 15 minutes when the CXR component of the exam is eliminated (ERG, 2015). OSHA seeks comment on this time estimate. As indicated, OSHA estimates this change would save 896 hours of worker time that would have been spent during their recurring exams. Multiplying the reduced exam time by employee hourly wages of $24.05,[31] the Agency estimates a cost savings of $21,549 in employee time. This information is detailed as follows:

Coke Oven Emissions (§ 1910.1029):
  Time saved: 2,324 exams × .25 hours = 581 hours [32]
  Reduced Cost: 581 hours × $24.05 employee wage = $13,973
Acrylonitrile (§ 1910.1045):
  Time saved: 467 exams × .25 hours = 117 hours
  Reduced Cost: 117 hours × $24.05 employee wage = $2,814
Inorganic Arsenic (§ 1910.1018):

[31] Wages are based on data from the May 2013 National Occupational Employment and Wage Estimates for Standard Occupational Classification Code 51–000—Production Operation, which lists average base compensation of $16.79. A private industry Fringe Benefit rate of 30.20 percent was from Source: Bureau of Labor Statistics. Employer Costs for Employee Compensation—June 2014. (*http://www.bls.gov/news.release/archives/ecec_09102014.htm*). The multiplier applied to base compensation to determine loaded wages is 1.43 [1/(1–30.20 percent)]. Applying the multiplier (1.43) to base compensation ($16.79) results in loaded wages of $24.05.

[32] Numbers rounded to the nearest whole dollar here and elsewhere in the Preliminary Economic Analysis.

Time saved: 792 exams × .25 hours = 198 hours
Reduced Cost: 198 hours × $24.05 employee wage = $4,762
Total Employee Time Savings from fewer CXRs:
581 hours + 117 hours + 198 hours = 896 hours
Total Value of Time Savings from fewer CXRs:
$13,973 + $2,814 + $4,762 = $21,549

Combining the value of saved worker time of $21,549 with the decreased exam cost of $245,148 nets a total potential cost savings to employers of $266,697. OSHA seeks comment on these estimates.

OSHA is also proposing to update other CXR requirements in its Coke Oven Emissions, Acrylonitrile, and Inorganic Arsenic standards discussed above, as well as in its three Asbestos standards—§ 1910.1001 Asbestos (General Industry), § 1915.1001 Asbestos (Maritime), and § 1926.1101 Asbestos (Construction)—and two Cadmium standards—§ 1910.1027 Cadmium (General Industry), and § 1926.1127 Cadmium (Construction).

In recent years, innovation in medical technology has allowed for screening with digital CXRs. Reflecting this, OSHA is proposing to add the option of digital radiography to its existing standards. As a practical matter, digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.

There are cost savings to using digital CXRs over analog CXRs. Traditional analog film-based CXRs are much larger than standard-sized office documents and weigh more than a piece of paper of the same size. As such, storing traditional CXRs requires an investment in specialized storage cabinets, which in turn may require reinforcement of the floor. Digital CXRs, however, can be stored on a computer. Due to continuing advances in technology and the emergence of inexpensive and large-capacity storage devices, digital CXRs can be stored for just a fraction of a cent each. Digital CXRs also save time and materials because they can be instantly processed and ready for use as soon as the CXR is taken.

OSHA believes that digital storage of CXRs is so common that most employers are already realizing this cost savings and would thus not incur any additional savings as a result of this proposal. As a practical matter, OSHA already allows digital storage of CXRs as a matter of enforcement discretion. In a letter of interpretation released on September 24, 2012, entitled ''OSHA's position on the acceptability of digital radiography in place of traditional chest roentgenograms,'' OSHA stated: ''OSHA would allow, but would not require, digital radiography in place of traditional chest roentgenograms for medical surveillance exams under the Asbestos Standards for general industry, construction, and shipyards.'' Although OSHA has not released interpretations specifically allowing for digital storage of CXRs in other standards, it has become the Agency's practice not to cite or otherwise penalize employers for storing CXRs digitally. Because it is now current OSHA enforcement practice to waive the formal requirement for employers to keep analog copies of CXRs when they store them digitally, the Agency preliminarily concludes that there would be no realized cost savings by changing this requirement. This proposed change simply formalizes and thereby clarifies what the Agency has already accommodated in practice.

Revisions in these standards also include replacements of antiquated terminology such as ''roentgenogram,'' correction of misspellings in the existing standards, an update to the current ILO classification guidance, and revisions where inaccuracies exist in clinical diagnostic language. OSHA is proposing to update the regulatory text to better distinguish between the appropriate uses of classification and interpretation of CXRs. The Agency believes these changes are merely editorial in nature and reflect current practices, and therefore would not create new costs or cost savings for employers.

Cotton Dust—Pulmonary Function Testing

As explained in greater detail in the Summary and Explanation, OSHA is proposing to make revisions to its medical surveillance program requirements—more specifically, its pulmonary function testing requirements of the Cotton Dust standard (29 CFR 1910.1043). Exposure to cotton dust places employees at risk of developing the respiratory disease byssinosis. Since the publication of the Cotton Dust standard in 1978, OSHA has not updated its pulmonary function testing requirements to match those of current technology and practices. As a result, OSHA is basing its proposed revisions on current recommendations from organizations recognized as authorities on generally accepted practices in pulmonary-function testing: The American Thoracic Society/European Respiratory Society (ATS/ERS), the National Institute for Occupational Safety and Health (NIOSH), and the American College of Occupational and Environmental Medicine (ACOEM).

OSHA is proposing to revise paragraph (h) and Appendix D of its Cotton Dust standard. Many of the revisions are simply editorial, to clarify existing language, as well as to update outdated pulmonary function measurements. However, for those revisions that may suggest a potential need to upgrade pulmonary testing equipment, OSHA investigated the characteristics of equipment currently available in the United States and whether such equipment met the specifications of OSHA's proposed revisions.

Paragraphs 1043(h)(2)(iii) and (h)(3)(ii)(A) and (B) give instructions for pulmonary function testing, measuring forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) against the Spirometry Prediction Tables for Normal Males and Females (Appendix C), adjusting those measurements based on ethnicity, and from the outcome of such measurements, determining the frequency of medical surveillance provided to employees. OSHA is proposing to revise this provision to specify use of the National Health and Nutrition Examination Survey (NHANES) III reference data set and to replace the values currently in Appendix C with the NHANES III values.

Software for most spirometers includes the NHANES III data set, which is identified as the Hankinson data set on some spirometers. If software for older spirometers does not include the NHANES III data set, users of those spirometers would be able to access the NHANES III values online through the NIOSH calculator. Tables of the NHANES III values are also available in an appendix of OSHA's spirometry guidance for healthcare professionals that is also available online. Therefore, NHANES III values are widely available to spirometry providers, including those providers using older spirometers.

OSHA's proposal to use the NHANES III data set in place of the Knudson values currently in Appendix C would simplify interpretation of spirometry results by providing reference values for more race/ethnic groups, thereby reducing the need to adjust values for race/ethnic groups not included in the Knudson data set. This revision as to how pulmonary functioning should be tested and measured falls in line with current generally accepted practices; therefore OSHA does not believe this proposed revision should pose a compliance burden to affected employers.

OSHA is also proposing to update paragraph (h)(2)(iii) to require an evaluation of FEV1, FVC, and FEV1/FVC against the lower limit of normal (LLN) for each race/ethnic group, by age. Similarly, OSHA is proposing that the basis for frequency of medical surveillance in paragraphs (h)(3)(ii)(A) and (B) be whether the FEV1 is above or below the LLN. This would technically change the required triggers for medical surveillance from the existing standard, but is consistent with generally accepted current practices. The Agency believes the changes would reduce confusion and have little other practical effect. The proposed revision to evaluate the FEV1/FVC ratio in addition to FEV1 and FVC would not affect the triggers for other medical monitoring requirements such as changes in medical-surveillance frequency or referral for a detailed pulmonary examination because the standard bases those triggers solely on FEV1 values.

Proposed revisions to Appendix D address updates to the specifications of spirometry equipment used in performing pulmonary functioning tests. To assess whether current readily available spirometry equipment met the Agency's proposed specifications, OSHA investigated the market for spirometry equipment, with the assistance of its contractor, Eastern Research Group (ERG). OSHA found that the market has been adapting to similar consensus standards in this area as far back as 1994. In its research of spirometry product specifications collected through internet searches, interviews with manufacturers, and the consultation of peer-reviewed literature and voluntary standards published by respiratory health groups, the Agency found that spirometry models currently sold in the United States, Europe and Australia meet the potential specification revisions of spirometry equipment to be used in the cotton dust standard. More specifically, ERG looked at a sample of 12 spirometry models from various manufacturers and found that 11 out of the 12 models were already complaint with the volume, accuracy, and minimum duration requirements of the 2005 spirometry specification standard jointly published by ATS/ERS (ERG, 2015).

The Agency estimates that this spirometry equipment has a working life of approximately ten years. To prevent a potential burden to employers from having to prematurely purchase new equipment, OSHA is proposing that the revised spirometry specifications apply only to equipment newly purchased one year or more after OSHA publishes the final standard in the **Federal Register**. Combined with evidence that the large majority of the equipment already on the market is already compliant, OSHA does not believe that the proposed revisions to the spirometry equipment specifications would impose additional costs or compliance burdens to employers. OSHA welcomes comment on the possible impacts of these requirements.

Shipyard Employment: Feral Cats

As stated in the Summary and Explanation, OSHA is proposing to remove feral cats from its definition of vermin in paragraph (b)(33) of § 1915.80—Subpart F—Shipyard General Working Conditions. 29 CFR 1915.88—Sanitation, paragraphs (j)(1) and (j)(2), specify that employers must, to the extent reasonably practicable, clean and maintain workplaces in a manner that prevents vermin infestation. When employers detect vermin, they must implement and maintain an effective vermin-control program.

OSHA has determined that, although the possibility exists for feral cats to pose safety and health hazards for employees, the threat is minor as the cats tend to avoid human contact. Further, stakeholders have expressed concern that including the term ''feral cats'' in the definition of vermin encourages cruel and unnecessary extermination. OSHA does not believe that removing the term ''feral cats'' from the definition would reduce worker health and safety, and notes that feral cats may help reduce the presence of other vermin. To the extent feral cats pose a safety or health hazard at any particular shipyard, OSHA would consider the cats to be ''other animals'' under the standard. Removing a perceived obligation to exterminate feral cats should not have any costs to employers.

911 Emergency Medical Services

OSHA is proposing to revise paragraph (f) in 29 CFR 1926.50—Medical Services and First Aid. Existing § 1926.50(e) requires employers to provide a communication system for contacting ambulance service, or proper equipment for transportation of an injured person. Existing § 1926.50(f) requires the posting of telephone numbers of physicians, hospitals, or ambulances for work sites located in areas where 911 emergency service is not available. OSHA is proposing to retain both of these this requirements. The Agency would add to paragraph (f) a requirement that when an employer uses a communication system for contacting 911 services, the employer must ensure that the communication system can effectively do so, and, if the system is in an area that does not automatically supply the caller's latitude and longitude to the 911 dispatcher, post or otherwise provide to employees the latitude and longitude of the work site or other information that communicates the location of the worksite.

OSHA has preliminarily concluded that this proposed requirement would result in annual costs of $27,899 until 2019, when the FCC expects enhanced 911 wireless services to be universal, at which time these costs would disappear.

OSHA calculated the burden hours and wage hour costs for employers to post the latitude and longitude of the work site location based on the number of new construction projects started in a given year. To estimate the number of project sites, OSHA reviewed the most recent data provided by request from Dodge Data and Analytics.[33] The Dodge data show a total of 660,469 new construction projects starts in 2012 of which 537,997 were residential buildings, 58,754 were non-residential buildings, and 63,718 were non-buildings. Of the 537,997 residential buildings, 516,363 were single-family homes, 7,388 were two-family houses, and 14,246 were apartments.[34]

OSHA notes that more than one single-family home may be built at a project site. The Agency determined that construction contractors build approximately one-half of single-family houses at single house project sites and the other half at project sites holding multiple single-family homes. As a result, OSHA estimated the number of single-family homes completed at single house project sites in 2012 to be 258,182, and 129,091 to be the total of project sites holding two single family-homes (one-half of single-family houses at single project sites: 516,363/2 =

[33] For the purpose of this section, in conformance with previous ICRs on this provision, OSHA deems the Dodge data to be the best source of information for new construction projects. This stands in contrast to U.S. Census construction data used later in the PEA in the context of Load Limit Posting provision because OSHA is interested in *all* construction projects started, but not necessarily completed, in a given year. While Census construction data provides lists more detailed information on residential housing starts and completions, and total value of construction put in place, it does not provide information on the total number of construction projects started in a given year.

[34] Dodge defines single-family homes as single-family detached, stand-alone units. Single-family attached structures, including such buildings as condominiums and townhomes, are included in Dodge's multi-family category.

258,182; one-half of single-family homes at project sites holding two houses: 258,182/2 = 129,091).

As shown below in Table IV–1, the total number of construction project sites covered by this provision is: 531,379.

TABLE IV–1—ESTIMATED TOTAL CONSTRUCTION SITES IN THE UNITED STATES, 2012

Type of construction site	Total number of construction projects
Non-Residential Buildings	58,754
Non-Buildings Construction Projects	63,718
Residential Buildings	408,907
One Single-Family Home Per Site	258,182
Multiple Single-Family Homes Per Site	129,091
Multi-Family Residential Buildings	21,634
Two-Family Houses	7,388
Apartments	14,246
Total Construction Sites	531,379

In the United States, when a 9–1–1 call is made from a traditional telephone or wireline, the call is routed to a Public Safety Answering Point (PSAP) that is responsible for assisting people in a particular geographic area or community. Depending on the type of 9–1–1 service available, the telephone number of the caller and the location or address of the emergency is either communicated by the caller to the emergency dispatcher (Basic 9–1–1); or automatically displayed to the dispatcher through the use of equipment and database information (Enhanced 9–1–1). According to a 2001 report produced by the RCN Commission and the National Emergency Number Association (NENA) titled, *Report Card to the Nation: The Effectiveness, Accessibility and Future of America's 9–1–1 Service*,[35] wireline 9–1–1 coverage is available to 97.8 percent of the U.S. population; however only 93 percent of all U.S. counties have either Basic or Enhanced wireline 9–1–1 coverage while 7 percent of U.S. counties are without any 9–1–1 services. NENA reported that these areas without any wireline 9–1–1 coverage are primarily rural in character with sparse population and generally high poverty levels; as well as inclusive of Native American lands and military installations (NENA, 2001).

In the December 5, 2014 version of the Federal Communications Commission's (FCC) 911 Wireless Service Guide, it was estimated that about 70 percent of 9–1–1 calls were placed from wireless phones (FCC, 2014). The FCC finds using wireless phones create unique challenges for emergency response personnel because wireless or mobile phones are not associated with one fixed location or address. Although the location of the cell site closest to the 9–1–1 caller may provide a general indication of the caller's location, the FCC finds that the information is not always specific enough for rescue personnel to deliver assistance to the caller quickly (FCC, 2014). As a result, the FCC is now requiring wireless service carriers to implement its wireless Enhanced 9–1–1 program which will provide 9–1–1 dispatchers with additional information on wireless 9–1–1 calls. The FCC is allowing the implementation of its wireless Enhanced 9–1–1 program in two parts—Phase I and Phase II. Phase I requires carriers to provide the PSAP with the telephone number of the 9–1–1 wireless caller as well as the location of the cell site or base station transmitting the call. Phase II however, requires carriers to provide more precise information to the PSAP, such as the latitude and longitude of the caller whereby the accuracy of the geographical coordinates must be within 50 to 300 meters of the caller's location (FCC, 2014).

With the implementation of the wireless Enhanced 9–1–1 program, the total number of U.S. counties with 9–1–1 coverage has increased from 93 percent to nearly 97 percent. As of March 2015, NENA reported a total number of 3,135 U.S. counties, which include parishes, independent cities, boroughs and Census areas. Of these counties, 96.9 percent (3,038) of them are now capable of receiving some [36] Phase I location information and 95.7 percent (3,000) are capable of receiving some Phase II. All wireless carriers, however, are expected to comply with Phase II of the FCCs requirements by 2019.[37]

Since all 9–1–1 emergency calls made are routed to a PSAP or call center based on the geographic location in which the call was made, for the purpose of this analysis, OSHA is interested in those U.S. counties where Enhanced 9–1–1 is neither available by wireline nor wireless device. Using the data provided by NENA, OSHA estimates that of the 3,135 recorded U.S. counties, 4.3 percent (135) neither have wireline nor wireless Enhanced 9–1–1 capabilities. By extension, for this analysis, OSHA further assumes that 4.3 percent of all construction project sites (22,849 of 531,379 construction project sites) are located within those counties without wireline and wireless Enhanced 9–1–1 capabilities and would therefore be covered by this provision whereby employers must either post the latitude and longitude of the work site or other location-identification information that effectively communicates the location of the work site to the 9–1–1 emergency medical service dispatcher. The Agency believes this is likely an overestimate of the number of construction sites affected by this provision of the proposal, as construction activity will generally parallel population concentration. Enhanced cell service, in turn, is more concentrated around population centers. NENA estimates that 98.4 percent of the population now has Phase II wireless service; 98.1 percent of PSAPs have Phase II service. The Agency, however, requests comment on this aspect of analysis, as well as the distribution of wireline and wireless service at construction sites.

OSHA estimates that it takes the average construction employee affected by this requirement 3 minutes (.05 hour) to obtain the latitude and longitude of worksite locations, write the information on material, and then to prominently post the information, as required by proposed § 1926.50(f). This would not pose an issue of technological feasibility as the information could be easily downloaded from the Internet before the crew leaves for the site; in the large majority of cases this information should be also be available onsite via common applications for smartphones. The Bureau of Labor Statistics' (BLS) 2013 Occupational Employment Statistics (OES) data indicate that the most common construction occupation is ''construction laborer.'' Partly for that reason, the Agency believes this occupation is most representative of the workers actually posting the latitude and longitude load requirements at construction project sites. Consistent with that, OSHA, based on the OES

[35] Report Card to the Nation (RCN)—An RCN Commission was formed by the National Emergency Number Association (NENA) to review and grade the performance of 9–1–1. NENA serves its members and the greater public safety community as the only professional organization solely focused on 9–1–1 policy, technology, operations, and education issues.

[36] The term 'some,'' as defined by the National Emergency Number Association, means that some or all wireless carriers have implemented either Phase I or Phase II service in the County or the PSAPs. In order for any carrier to provide service, the County or PSAP must be capable of receiving the service. In most cases, all carriers are implemented in a County or PSAP, but one or more may be in the process of completing the implementation. See *http://www.nena.org/?page=911Statistics.*

[37] See 47 CFR 20.18—911 Service

data, estimates a wage of $16.84 per hour for the average affected construction worker (BLS, 2013a). BLS also estimates in their 2013 Employer Cost for Employee Compensation report that employers pay an additional 45 percent in employee benefits,[38] implying a total employer cost for employee compensation of $24.42 per hour.

Therefore, the estimated annual burden hours and wage hour cost of this proposed requirement are:

Burden hours: 22,849 construction project sites × .05 hour = 1,142.45 hours.

Cost: 1,142.45 hours × $24.42 = $27,899.

Based on these costs, OSHA preliminary determines that the proposed provision is economically feasible. OSHA notes that a member of ACCSH stated that he had seen a firm provide location information at remote sites. (ACCSH Aug. 23, 2013 transcript, p. 85.) As noted previously, the task of communicating relevant site information to rescue services is gradually being made easier by the spread of advanced telecommunications technology, such that in the near future the existing burden should be eliminated. However, OSHA seeks comments on this estimate and how long the costs will remain in effect.

Permissible Exposure Limits Table

As discussed in the Summary and Explanation, 29 CFR 1926.55—Gases, Vapors, Fumes, Dusts, and Mists—is the Construction counterpart to 29 CFR 1910.1000—Air Contaminants, which enumerates hundreds of Permissible Exposure Limits (PELs) in its Z tables. Because 29 CFR 1926.55 is not as clear as its General Industry counterpart, OSHA is proposing to update section 1926.55(a) and Appendix A to help clarify the construction PELs. These proposed changes would: (1) Change the term ''Threshold Limit Values'' to ''Permissible Exposure Limits''; (2) eliminate language that sounds advisory; (3) eliminate confusing language; (4) correct several noted errors in Appendix A; and (5) correct cross-references to the asbestos standard. OSHA deems these changes to be simple clarifications which would not change the substantive effect this rule. Therefore, OSHA has preliminarily concluded that these revisions would not result in changes to the cost or impact of 29 CFR 1926.55; however, OSHA seeks comment on this preliminary conclusion.

Process Safety Management of Highly Hazardous Chemicals

OSHA is proposing to replace the regulatory text of its Process Safety Management (PSM) of Highly Hazardous Chemicals construction regulation, § 1926.64, with a cross-reference to the corresponding general industry regulation in 29 CFR 1910.119. The requirements applicable to construction work in 29 CFR 1926.64 are identical to those set forth in 29 CFR 1910.119. This change would only serve to eliminate duplicative regulatory text and as such, OSHA has preliminarily determined that it has no cost.

Personal Protective Equipment Fit

OSHA is proposing to amend Section § 1926.95—Criteria for Personal Protective Equipment (PPE), paragraph (c), to clarify that PPE must properly fit each employee. The existing regulatory text states that PPE ''shall be of safe design and construction for the work to be performed'' and current paragraph (a) states that PPE ''shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary. . . .'' It is the agency's opinion that for PPE to provide protection against the hazards for which it is designed, it must fit properly. OSHA views this change as a clarification of the existing language and thus preliminarily determines that it would not increase costs or compliance burdens to employers.

Lanyard/Lifeline Break Strength

OSHA is proposing to lower the minimum breaking strength requirement in § 1926.104—Safety Belts, Lifelines and Lanyards, paragraph (c)—from 5,400 pounds to 5,000 pounds. As discussed in the Summary and Explanation of that section, the Agency believes a 5,000 pound requirement would still provide a more than sufficient safety factor. Because this change lowers the minimum requirement, employers would not be required to purchase new equipment. When employers do replace their equipment, they could continue to purchase lifelines with a breaking strength of 5,400 pounds, or with a breaking strength of 5,000 pound. This proposed revision also would bring § 104(c) into conformance with the lanyard and lifeline breaking strength requirement in the Fall Protection standard, at § 1926.502(d)(9). As a result, OSHA has preliminarily concluded that this change would not add any new compliance costs for employers.

Manual on Uniform Traffic Control Devices

Under 29 CFR part 1926 subpart G—Signs, Signals, and Barricades, OSHA requires that employers comply with the mandatory provisions of Part VI of the Manual on Uniform Traffic Control Devices (MUTCD). Currently, employers comply with Part VI when they use one of two versions of MUCTD: the 1988 Edition, Revision 3, September 3, 1993 MUTCD (''1988 Edition'') or the Millennium Edition, December 2000 MUTCD (''Millennium Edition''). Since OSHA's last published update to subpart G, requiring employers to follow one of the two MUTCD editions above, the Department of Transportation (DOT) has then updated 23 CFR 655.601 through 655.603 to require adherence to the 2009 Edition, November 4, 2009, MUTCD (''2009 Edition''). The Agency is proposing to update subpart G to require employers to follow the MUTCD 2009 Edition.

23 CFR 655.603 states that the MUTCD is the national standard for all traffic control devices installed on any street, highway, or bicycle trail open to public travel. It also requires all States, within two years after a new national MUTCD edition is issued or any national MUTCD amendments are made, to adopt the new MUTCD in the State, adopt the national MUTCD with a State Supplement that is in substantial conformance with the new MUTCD, or adopt a State MUTCD that is in substantial conformance with the new MUTCD.

Each State enacts its own laws regarding compliance with standards for traffic control devices in that State. If the State law has adopted a State Supplement or a State MUTCD that the Federal Highway Administration (FHWA) has found to be in substantial conformance with the national MUTCD, then those State requirements are what the local road agencies (as well as the State DOT) must abide by. The exception is traffic control devices installed on a federally aided project, in which case 23 CFR 655.603(d)(2) specifically requires those devices to comply with the national MUTCD before the road can be opened or reopened to the public for unrestricted use.

The Agency believes any employer costs related to incorporating the updated MUCTD reference into subpart G are very limited because, first, the updated DOT rules are already currently

[38] BLS, 2013b. Employer costs for employee benefits (other than wage and salary) were estimated to be 31 percent of total compensation for workers employed in construction. The fringe benefit factor is calculated by 1/(1—percent of total compensation attributable to employee benefits, or 1/(1 − .3) = 1.45. Total employer cost for employee compensation is calculated by multiplying the base wages ($16.84) by the fringe benefits factor (1.45).

in force for all public roads. Second, even in the limited circumstances of construction on private roads, the MUCTD rules are already likely followed. Finally, the changes from the prior editions are minor and could easily be outweighed by eliminating the burden created by having conflicting DOT and OSHA requirements.

Private roads open to public travel are now subject to the same traffic control standards as public streets and highways. However, the FHWA does not require State and/or local highway agencies to have specific authority or enforcement responsibility for traffic control devices on private roads to ensure compliance with the MUTCD. Owners or parties responsible for such private roads are encouraged to bring the traffic control devices into compliance with the MUTCD and other applicable State Manuals, and those who do not may find themselves exposed to increased tort liability. State and local jurisdictions can encourage MUTCD compliance on private roads by incorporating pertinent language into zoning requirements, building and occupancy permits, and similar controls that they exercise over private properties.

As a practical matter, available data on private road construction indicate that it represents a very small portion of total road construction activity. Data from the Census Construction Spending Survey indicate that it represents less than 1 percent of all funds dedicated to highway and street construction (Census, 2014).[39] This leaves a very limited scope of construction signage not already governed by the updated DOT rules.

Since all contractors engaged in construction of public roads are now required to follow the current MUTCD, only those firms that work exclusively on private roads would incur costs associated with this proposal. Contractors that work on both public and private roads should not see an increased burden because they would already need to be in compliance with the MUTCD to work on public roads. Considering that there is pressure, both from a regulatory and liability perspective, for firms that work exclusively on private roads to follow the MUTCD, OSHA believes the total number of these firms potentially incurring costs as a result of this proposal would be very small. To better understand how often these situations occur, OSHA seeks comment on the number of contractors that work exclusively on private roads and are therefore not required to follow the MUTCD. To the extent that situation occurs, the Agency also seeks comment on the extent to which such contractors already follow the updated MUTCD.

For any firms not already complying with the updated MUTCD, the cost of compliance would be very limited. As explained in the Summary and Explanation, the revisions to the MUTCD make the document more user friendly and account for advances in technology. A comparison of the 1998 and 2009 updates shows fewer and less burdensome new requirements, but more guidance and support material which makes the document easier to use. This proposed change to the OSHA rule should decrease the burden on employers by eliminating confusion as to which edition they must comply with. It would also inform employers that compliance with DOT regulations would not run afoul of outdated OSHA regulations. Most of the new provisions provide more options to employers, which should either increase safety or reduce the burden to employers.

Nonetheless, the Agency has identified two proposed changes in the 2009 Edition that could have a very small cost for those employers doing construction work exclusively on private roads that are not already following the updated MUTCD for these items.

One change is a requirement to use a new symbol and additional sign for a shoulder drop-off. OSHA has estimated that the average price of a shoulder drop-off sign at $32.74, depending on size and finish. A second change prohibits contractors from relying on hand-signs alone to control traffic. This burden would only apply to a subset of contractors that use flaggers to control traffic (as opposed to something like automated flagger assistance device) and choose to only use hand signals to accomplish this task. Each of these contractors would need to purchase at least one stop sign or flag. OSHA has determined that a flag would cost, on average, $7.96 each, dependent on size (ERG, 2015).

The number of signs or flags a contractor needs for these situations would presumably be dependent on the number of simultaneous projects that the road construction firm engages in during a typical season, or how large and complex such projects are. While smaller contractors may be more likely to engage solely in private road operations, larger, more complex projects demanding more equipment would almost certainly fall to larger contractors also employed in public road construction. Considering the very limited number of contractors and situations that would likely be impacted by this proposal, the Agency believes that most of the potentially affected firms would not need more than a handful of either signs or flags. The Agency seeks comment on what the likely impact of these changes would be, both in terms of the number of signs and/or flags potentially affected contractors might need, as well as whether other changes to MUCTD might have a cost associated with them, or ultimately whether the clarity provided by a government-wide reference to a single set of standards may provide a cost savings to employers.

It is not clear whether any firm would incur new costs as a result of this this proposed update to the 2009 Edition, but as shown, any such costs would be very limited in nature and would be an insignificant portion of a contractor's annual profit. OSHA therefore does not believe these changes would have a significant impact to any firm or raise an issue of economic feasibility. The Agency, however, welcomes comment on this preliminary assessment.

Load Limit Postings

OSHA is proposing to remove the load limit posting requirement for single family dwellings or townhouses in 29 CFR 1926.250—General Requirements for Storage, paragraph (a)(2). OSHA has preliminarily estimated that removing the requirement for employers to post maximum safe load limits of floors in storage areas when constructing single family dwellings or townhouses would result in a cost savings to employers engaged in these construction activities of approximately $2,948,715.

OSHA estimates that it takes the average construction employee affected by this requirement 15 minutes (0.25 hours) to develop and post the currently required signs, assuming the information is readily available from current engineering estimates. The Bureau of Labor Statistics' (BLS) 2013 Occupational Employment Statistics (OES) data indicate that the most common construction occupation is ''construction laborer.'' Partly for that reason, the Agency believes this occupation is most representative of the workers actually posting the load limit requirement at such dwellings. Consistent with that, OSHA, based on the OES data, estimates a wage of $16.84

[39] Since private spending on Highway and Street construction is relatively small in comparison to other categories of spending, it does not appear as a separate item, but can be derived from subtracting Total Public Construction spending on Highway and Street construction from Total Construction spending on Highway and Street construction. 2013 data indicates private spending was well below 1 percent of total spending in this category. This pattern was consistent at least as far back as 2002.

per hour for the average affected construction worker (BLS, 2013a). BLS also estimates in their 2013 Employer Cost for Employee Compensation report that employers pay an additional 45 percent in employee benefits,[40] implying a total employer cost for employee compensation of $24.42 per hour. According to the U.S. Census, in 2012 there were 483,000 single family houses constructed, including townhouses (Census, 2012).[41] OSHA estimates, that on average, each project would have one storage area, producing one required posting. Using this data, OSHA preliminarily estimates that the yearly burden on employers affected by this proposed revision would be reduced by $6.105 ($24.42/hour × 0.25 hours) for a total cost savings of $2,948,715 ($6.105 cost per posting × 483,000 single family homes) to the industry. Therefore, the estimated reduction in burden hours and wage hour costs of this proposed requirement are:

Reduced burden hours: 483,000 houses × .25 hours = 120,750 hours.

Reduced cost: 120,750 hours × $24.42 = $2,948,715.

Excavation Hazards

In 1989, OSHA updated § 1926.651(j)—Specific Excavation Requirements—Protection of Employees from Loose Rock or Soil, to add the phrase ''that could pose a hazard'' when referring to loose rock or soil and excavated or other materials or equipment. A number of Administrative Law Judges of the Occupational Safety and Health Review Commission (OSHRC) later ruled that the added phrase in the standard shifts the burden of determining whether loose rock or soil and excavated or other material or equipment poses a hazard to employees to OSHA, before OSHA can establish a violation. These rulings are inconsistent with what OSHA intended, as the preamble to the 1989 revision does not indicate that OSHA intended to shift the burden when it revised the 1971 provisions, but rather intended to clarify the language of the provisions. Thus, the Agency is proposing to remove the phrase ''that could pose a hazard'' from § 1926.651(j)(1) and (j)(2).

OSHA believes that this revision would clarify its original intent that the burden is on employers to protect their employees from loose rock or soil and excavated or other materials or equipment, and that OSHA does not have the initial burden of demonstrating the existence of a hazard. Consistent with the Agency's intent, no estimated costs or cost savings were attributed to this additional language in the 1989 update to the original 1971 rule (54 FR 45894). Hence, OSHA has preliminarily determined that no cost or compliance burdens would be associated with the proposed removal of this language.

Decompression Tables

OSHA is proposing to replace the current decompression tables found in Appendix A to subpart S of part 1926—Underground Construction, Caissons, Cofferdams and Compressed Air—with the 1992 French Air and Oxygen decompression tables, which are an updated industry standard, and are therefore preferred over the Agency's existing tables. The information available to the Agency currently indicates that underground projects which incorporate new tunneling technology have not followed OSHA's existing decompression tables, but instead, have followed the French or other updated tables. In each case, federal OSHA or a state plan state had been persuaded by the available research and studies that the new decompression methods provide better protection for underground workers and has issued a variance.

Since underground tunneling projects currently already use these proposed tables, OSHA has preliminary determined that the replacement of its existing Decompression Tables in Appendix A to subpart S of part 1926 with the French tables would not result in an increase of cost to affected employers. OSHA seeks comment regarding any establishment that does not currently use the French tables and/or uses any other updated tables. This should provide some relief for employers who currently wish to use the newer tables, in that they would no longer need to apply for a variance from the Agency. The Agency however, has not quantified a cost savings associated with this reduced burden to employers.

Rollover Protective Structures

OSHA is proposing to amend the existing standards in 29 CFR part 1926 subpart W—Rollover Protective Structures; Overhead Protection (§ 1926.1001, 1002, and 1003). The existing standards, which are based on consensus standards from 1970, will be amended to remove the provisions that specify test procedures and performance requirements. The revised provisions will reference the 1970 consensus standards for equipment manufactured prior to the effective date of the final rule. They will also reference the most recent ISO standards: ISO 3471–2008, ISO 5700–2013 and ISO 3449–2005, for new equipment manufactured after the effective date of the final rule. It is OSHA's understanding that all industries affected by this change are already following the new ISO standards, and therefore has preliminarily concluded that this change would not create any new costs for employers. However, OSHA seeks comments on this conclusion and on current adherence to the ISO standards in the affected industries.

The Agency also proposes to expand the existing regulatory language of § 1926.1000 and 1001 to cover compactors and skid-steer loaders, as telegraphed previously by reserving existing paragraph 1000(a)(2). OSHA believes that this new equipment, as with the equipment currently covered by the existing standard, already adheres to the minimum performance criteria for ROPS as set forth in the recent ISO standards, but seeks further comment. If OSHA is correct about the current compliance for this new equipment, then OSHA preliminarily concludes that this change would not add any new compliance cost to employers. OSHA seeks comments on this issue as well.

Underground Construction—Diesel Engine

Existing regulatory language in § 1926.800(k)(10)(ii) requires that mobile diesel-powered equipment used underground comply with the Mine Safety Health Administration's (MSHA) provisions of 30 CFR part 32. In 1996, MSHA revoked part 32 and replaced it with updated provisions in 30 CFR part 7, subpart E and 30 CFR 75.1909 Non-permissible diesel-powered equipment; design and performance requirements, 75.1910 Non-permissible diesel-

[40] BLS, 2013b. Employer costs for employee benefits (other than wage and salary) were estimated to be 31 percent of total compensation for workers employed in construction. The fringe benefit factor is calculated by 1/(1—percent of total compensation attributable to employee benefits, or 1/(1 − .3) = 1.45. Total employer cost for employee compensation is calculated by multiplying the base wages ($16.84) by the fringe benefits factor (1.45).

[41] In the 911 Emergency Medical Services section of PEA presented earlier, the Agency examined total construction starts, which were estimated using Dodge data. Included within that total were new home starts. However, as has historically been the case when examining the paperwork burden for 29 CFR 1926.250, the Agency is using U.S. Census data rather than the Dodge report. The Dodge report does not include data on townhomes separate from condominiums; townhomes and condominiums are both grouped together in the Dodge report's multifamily category. For the purposes of analyzing the change to this provision, OSHA needs to be able to separate condominiums from townhomes; the U.S. Census' definition of a single family homes identically matches the new home constructions that the Agency needs to measure. Therefore, OSHA believes the data provided from the U.S. Census is the best available for analyzing the proposed update to 29 CFR 1926.250(a)(2).

powered equipment; electrical system design and performance requirements, and 75.1911 Fire suppression systems for diesel-powered equipment and fuel transportation units (61 FR 55411). In 2001, MSHA issued 30 CFR 57.5067 to allow engines that meet Environmental Protection Administration (EPA) requirements to be used as an alternative to seeking MSHA approval under part 7, subpart E (66 FR 5706). The Agency proposes to update the regulatory language in § 1926.800(k)(10)(ii) to cross-reference these updated provisions.

If adopted, these changes will allow employers who use diesel-powered engines on mobile equipment in underground construction to use current MSHA procedures to obtain approval plates to affix to the engines or meet or exceed the applicable EPA requirements listed at MSHA Table 57.5067–1, and meet the requirements for other machine features in 30 CFR 75.1909, 75.1910, and 75.1911(a)–(i) for non-permissible diesel-powered engines. Based on available information, OSHA has determined that currently manufactured equipment meets the proposed requirements and are generally compliant with the more stringent EPA Tier 3 and Tier 4 emission requirements (ERG, 2015). The Agency has therefore preliminarily concluded that all applicable new equipment currently available for in the market meets the proposed requirements.

OSHA recognizes that there may be some employers using equipment that predates the newer MSHA standards, and the EPA requirements referenced in them. To avoid the costs of replacing existing equipment in use, the Agency proposes to allow equipment purchased before the effective date of the final rule to continue to comply with the terms of existing § 1926.800(k)(10)(ii) (including having been approved by MSHA under 30 CFR part 32 (1995) or be determined to be equivalent to such MSHA-approved equipment). OSHA solicits comment on the number of engines in use that meet the existing standard but will not meet the requirements of the new MSHA standard and whether continued use of such equipment presents a serious safety or health hazard. OSHA also seeks comment on whether this proposed grandfathering is workable.

The Agency observes that some parts of the updated MSHA regulations have additional requirements, such as the potential need for training on fire suppression systems. However, as discussed in the Summary and Explanation, OSHA proposes to carry over the reference to only *equipment* requirements in the MSHA standards. Therefore, as explained, these other elements of the MSHA standards would not apply here and would therefore carry no cost.

In summary, because diesel equipment manufactured for underground construction apparently conforms with the newer MSHA standards, and the proposal would ''grandfather'' in existing equipment, the Agency believes employers will not have additional expenses in complying with the this proposed change to the Underground Construction standard. OSHA welcomes comments on this preliminary conclusion.

Coke Oven Emissions

Section 1926.1129 regulates exposure to coke oven emissions in construction. In the Summary and Explanation, the point was made that the provisions of this standard do not fit construction work. Therefore OSHA is proposing to delete 29 CFR 1926.1129 (and the reference to it in 29 CFR 1926.55).

An interpretation letter to Mr. Katz from Assistant Secretary Charles Jeffress on June 22, 1999 stated, ''We will remove 29 CFR 1926.1129 from OSHA's Internet Web site; the standard will be deleted from Part 1926 Code of Federal Regulations, and we [OSHA] will formally notify OSHA field offices that § 1926.1129 is not to be enforced.'' Since OSHA is not enforcing § 1926.1129 and it has no applicability to construction, this change will have no cost.

Removal of Social Security Number Collection Requirements From OSHA's Standards

As discussed in the Summary and Explanation, OSHA is proposing to delete the requirements in its standards for employers to use social security numbers to identify employees on exposure monitoring, medical surveillance, and other records. The Agency believes that while this change will help employers to protect their employees from identity theft, it will not impose new costs upon employers. The proposed changes would not require employers to delete social security numbers from existing records, nor would they prohibit employers from continuing to use them to identify employees; employers would simply no longer be required to include employee social security numbers on the records. The Agency believes that these changes have the potential to provide benefits to both employees and employers and potential cost savings, but OSHA has not quantified those potential benefits and savings for this preliminary analysis.

C. Summary

OSHA preliminarily concludes that the proposed provisions do not impose costs of any significance on any employer, and therefore concludes that the proposed rule is economically feasible. Table IV–2 provides a brief summary of the cost savings and benefits OSHA estimates would result from the proposed rule.

TABLE IV–2

Item	Cost savings/benefits
Cost Savings	
Remove the load limit posting requirement for single family dwellings or townhouses in § 1926.250 (a)(2).	$2,948,715.
Remove the requirement for periodic CXR in § 1910.1029, § 1910.1045, and § 1910.1018.	266,697.
Revise paragraph (f) in 29 CFR 1926.50—Medical Services and First Aid.	−27,899.
Total	3,187,513.
Allow digital storage of chest roentgenograms in § 1910.1029, § 1910.1045, § 1910.1018, § 1910.1001, § 1915.1001, § 1926.1101, § 1910.1027,and § 1926.1127.	Reduces storage costs, brings standard up to date, simplifies.

TABLE IV–2—Continued

Item	Cost savings/benefits
Benefits	
Remove the requirement for periodic CXR in § 1910.1029, § 1910.1045, and § 1910.1018.	Reduced radiation, fewer false positives.
Update required pulmonary function testing requirements in § 1910.1043.	Brings OSHA standards up to current technology and medical practices.
Revise decompression tables to require adherence to 1992 French Air and Oxygen Decompression tables in Subpart S of Part 1926.	Better protect employees, reduce cases of decompression illness, bring OSHA standard up to current medical guidelines.

D. Regulatory Flexibility Analysis

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (as amended), OSHA examined the regulatory requirements of the proposed rule to determine whether these proposed requirements would have a significant economic impact on a substantial number of small entities. This proposed rule has estimated annual costs of $27,899 and would lead to approximately $3.2 million per year in cost savings to regulated entities. Since the costs related to this proposal (from posting location information in limited circumstances) amount to a few dollars per construction project, and are widely dispersed geographically and throughout the industry, the Agency believes the proposed rule does not possess potential to have a significant impact on a substantial number of small entities. The Agency therefore certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

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V. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et al.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources . . .'' (29 U.S.C. 651(b).) To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards; authorized summary adoption of existing national consensus and established Federal standards within two years of the effective date of the OSH Act (29 U.S.C. 655(a)); authorizing promulgation of standards pursuant to notice and comment (29 U.S.C. 655(b)); and required employers to comply with OSHA standards (29 U.S.C. 654(b)).

An occupational safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' (29 U.S.C. 652(8)). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk. In addition, it must be technologically and economically feasible, cost effective, and consistent with prior Agency action, or a justified departure. A standard must be supported by substantial evidence, and be better able to effectuate the OSH Act's purposes than any national consensus standard it supersedes. (See 58 FR 16612–16616, March 30, 1993.)

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. (See *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981) (ATMI); *American Iron and Steel Institute* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991) (AISI).)

A standard is economically feasible if industry can absorb or pass on the costs of compliance without threatening its long-term profitability or competitive structure. See ATMI, 452 U.S. at 530 n. 55; AISI, 939 F.2d at 980. A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. ATMI, 452 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C. Cir. 1994) (LOTO II). Section 6(b)(7) of the OSH Act authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing, and other information-gathering and transmittal provisions. (29 U.S.C. 655(b)(7).) OSHA safety standards also must be highly protective. (See 58 FR at 16614–16615; LOTO II, 37 F.3d at 668–669.) Finally, whenever practical, standards shall ''be expressed in terms of objective criteria and of the performance desired.'' (29 U.S.C. 655(b)(5).)

VI. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

The purposes of the Paperwork Reduction Act 1995 (PRA), 44 U.S.C. 3501 *et seq.,* include enhancing the quality and utility of information the Federal government requires and minimizing the paperwork and reporting burden on affected entities. The PRA requires certain actions before

an agency can adopt or revise a collection of information (paperwork), including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information. PRA defines ''collection of information'' as ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format'' (44 U.S.C. 3502(3)(A)). Under PRA, a Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number (44 U.S.C. 3507). Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

The Standards Improvement Project-Phase IV (SIP–IV) proposal would modify a number of Information Collections currently approved by the Office of Management and Budget (OMB) under the PRA.

B. Solicitation of Comments

Concurrent with publication of this proposed rule, the Department is submitting a series of Information Collection Requests (ICRs) to revise the collections in accordance with this NPRM, as required by the PRA. *See* 44 U.S.C. 3507(d). Some of these revisions, if adopted, would result in changes to the existing burden hour and/or cost estimates. Other revisions may be less significant and would not change the ICR burden hour and cost estimates.[42]

The Agency solicits comments on the information collection requirements contained in this NPRM. The Agency is particularly interested in comments on the collections of information requirements that:

- Evaluate whether the proposed collection of information requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- Evaluate the accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information collected; and
- Minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

C. Proposed Revisions to the Collection of Information Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about the ICRs, including the changes in burden associated with the proposed revisions to information collection requirements.

1. *Title:* Standards Improvement Project-Phase IV (SIP–IV)

2. *Description of revisions to the ICRs:* The SIP–IV proposal adds, removes, or revises collection of information requirements, as further explained in Table 1(a) that identifies those ICRs where the proposal will change burden hours and costs. For those ICRs, Table 1(b) itemizes the responses, frequencies, time, burden hours, and cost as a result of the program change. Table 2 identifies those ICRs where the proposal will add to or revise the text of standards, but do not result in a burden or cost change as result.

TABLE 1(a)—ICRS WITH PROPOSED BURDEN HOUR CHANGES

ICR title	OMB control No.	Provisions being modified
Coke Oven Emissions (29 CFR 1910.1029).	1218–0128	OSHA is proposing to remove the requirement for periodic chest x-rays as part of the medical exams for employees. In addition, OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Acrylonitrile (29 CFR 1910.1045)	1218–0126	OSHA is proposing to remove the requirement for periodic chest x-rays as part of the medical exams for employees. OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Inorganic Arsenic (29 CFR 1910.1018)	1218–0104	OSHA is proposing to remove the requirement for periodic chest x-rays as part of the medical exams for employees. OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Construction Standards on Posting Emergency Telephone Numbers and Floor Load Limits (29 CFR 1926.50 and 29 CFR 1926.250).	1218–0093	OSHA is proposing to add to 29 CFR 1926.50(f) a requirement that when an employer uses a communication system for contacting 911 services, if the communication system is in an area that does not automatically supply the caller's latitude and longitude to the 911 dispatcher, the employer must post or otherwise provide to employees the latitude and longitude of the work site or other information that communicates the location of the worksite. In addition, OSHA is proposing to remove the load limit posting requirement for single family dwellings or townhouses in 29 CFR 1926.250.

[42] The proposal would revise to existing standard provisions that are not collections of information. These revisions are not addressed in this preamble section. However some revisions will modify language contained in a currently OMB approved information collection (paperwork analysis), though they will not change burden hour or cost estimates. These information collections, referenced by OMB Control number, are included in this section since the Agency will prepare and submit an ICR to OMB to incorporate the revised language into the existing information collection.

TABLE 1(b)—ESTIMATED BURDEN HOURS AND COST

ICR Title and paragraph modified	OMB control No.	Number of respondents	Number of responses	Frequency per response	Average time per response (hours)	Estimated burden hour /program change	Estimated cost (capital-operation and maintenance) change
Coke Oven Emissions (29 CFR 1910.1029) (§ 1910.1029(j))	1218–0128	2,324	2,324	Annual	1.42	−581	−$159,008
Acrylonitrile (29 CFR 1910.1045) (§ 1910.1045(n))	1218–0126	467	467	Annual	1.25	−117	−31,952
Inorganic Arsenic (29 CFR 1910.1018) (§ 1910.1018(n))	1218–0104	792	792	Annual	1.42	−198	−54,188
Construction Standard on Posting Emergency Telephone Numbers (29 CFR 1926.50)[43] (§ 1926.50(f)).	1218–0093	22,849	22,849	Annual	.05	1,142	27,899
Construction Standard on Floor Load Limits (29 CFR 1926.250) (§ 1926.250 (a)).	1218–0093	483,000	483,000	Annual	0.25	−120,750	−2,948,715
Grand Total	.....	509,432	509,432	.....	.....	−120,504	−3,165,964

TABLE 2—ICRS WITH NO PROPOSED BURDEN HOUR CHANGES

ICR title	OMB control No.	Provisions being modified
Asbestos in General Industry (29 CFR 1910.1001).	1218–0133	OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Asbestos in Construction (29 CFR 1926.1101).	1218–0134	OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Asbestos in Shipyards (29 CFR 1915.1001).	1218–0195	OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Cadmium in Construction (29 CFR 1926.1127).	1218–0186	OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Cadmium in General Industry (29 CFR 1910.1027).	1218–0185	OSHA is proposing to add the option of digital radiography to its existing standards because digital radiography systems are rapidly replacing traditional analog film-based systems in medical facilities.
Cotton Dust (29 CFR 1910.1043).	1218–0061	OSHA is proposing to revise paragraph (h) and Appendix D of its Cotton Dust standard. Many of the revisions are simply editorial, to clarify existing language, as well as to update outdated pulmonary function measurements. OSHA is also proposing to update paragraph (h)(2)(iii) to require a determination of the FEV1/FVC ration, and the evaluation of FEV1, FVC, and FEV1/FVC against the lower limit of normal (LLN) for each race/ethnic group, by age, which is consistent with generally accepted practices.

This proposal will also have an impact on the provisions in OSHA's standards that currently require employers to include employee SSNs on exposure monitoring, medical surveillance, and other records. As explained above in the *Summary and Explanation of the Proposed Rule* section (*see* Section III.B.17.), the Agency previously considered stakeholder comments regarding the SSN collection requirements in OSHA's standards during the SIP II (70 FR 1112, January 5, 2005) and Respirable Crystalline Silica (81 FR 16285, March 25, 2016) rulemakings. Eliminating SSN collection requirements from OSHA's standards will affect several of the ICRs covered under the PRA. Table 3 shows the control number, title, and paragraph or appendix modified for each of the ICRs that will be affected. The agency believes removing the social security numbers will have no measureable impact on employer burden.

TABLE 3—ICRS AFFECTED BY SOCIAL SECURITY REMOVAL

OMB control No.	Title	Paragraph/appendix modified
1218–0202	Hazardous Waste Operations and Emergency Response for General Industry (29 CFR 1910.120) and Construction (29 CFR 1926.65).	1910.120(f)(8)(ii)(A), 1926.65(f)(8)(ii)(A).
1218–0133	Asbestos in General Industry (29 CFR 1910.1001)	1910.1001(m)(1)(ii)(F), 1910.1001(m)(3)(ii)(A), Appendix D.
1218–0010	Vinyl Chloride Standard (29 CFR 1910.1017)	1910.1017(m)(1).
1218–0104	Inorganic Arsenic (29 CFR 1910.1018)	1910.1018(q)(1)(ii)(D), 1910.1018(q)(2)(ii)(A).

[43] Both 29 CFR 1926.50 and 1926.250 are covered by the same ICR, 1218–0093.

TABLE 3—ICRS AFFECTED BY SOCIAL SECURITY REMOVAL—Continued

OMB control No.	Title	Paragraph/appendix modified
1218–0092	Lead Standard in General Industry (29 CFR 1910.1025)	1910.1025(d)(5), 1910.1025(n)(1)(ii)(D), 1910.1025(n)(2)(ii)(A), 1910.1025(n)(3)(ii)(A), Appendix B.
1218–0252	Hexavalent Chromium Standards for General Industry (29 CFR 1910.1026), Shipyard Employment (29 CFR 1915.1026), and Construction (29 CFR 1926.1126).	1910.1026(m)(1)(ii)(F), 1910.1026(m)(4)(ii)(A), 1915.1026(k)(1)(ii)(F), 1915.1026(k)(4)(ii)(A), 1926.1126(k)(1)(ii)(F), 1926.1126(k)(4)(ii)(A).
1218–0185	Cadmium in General Industry Standard (29 CFR 1910.1027)	1910.1027(n)(1)(ii)(B), 1910.1027(n)(3)(ii)(A), Appendix D.
1218–0129	Benzene (29 CFR 1910.1028)	1910.1028(k)(1)(ii)(D), 1910.1028(k)(2)(ii)(A).
1218–0128	Coke Oven Emissions (29 CFR 1910.1029)	1910.1029(m)(1)(i)(a), 1910.1029(m)(2)(i)(a).
1218–0180	Bloodborne Pathogens Standard (29 CFR 1910.1030)	1910.1030(h)(1)(ii)(A).
1218–0061	Cotton Dust (29 CFR 1910.1043)	1910.1043(k)(1)(ii)(C), 1910.1043(k)(2)(ii)(A), Appendices B–I, B–II, B–III.
1218–0101	1,2-Dibromo-3-Choropropane (DBCP) Standard (29 CFR 1910.1044)	1910.1044(p)(1)(ii)(d), 1910.1044(p)(2)(ii)(a).
1218–0126	Acrylonitrile Standard (29 CFR 1910.1045)	1910.1045(q)(2)(ii)(D).
1218–0108	Ethylene Oxide (EtO) Standard (29 CFR 1910.1047)	1910.1047(k)(2)(ii)(F), 1910.1047(k)(3)(ii)(A).
1218–0145	Formaldehyde Standard (29 CFR 1910.1048)	1910.1048(o)(1)(vi), 1910.1048(o)(3)(i), 1910.1048(o)(4)(ii)(D), Appendix D.
1218–0184	4,4′-Methylenedianiline (MDA) for General Industry (29 CFR 1910.1050)	1910.1050(n)(3)(ii)(D), 1910.1050(n)(4)(ii)(A), 1910.1050(n)(5)(ii)(A).
1218–0170	1,3-Butadiene Standard (29 CFR 1910.1051)	1910.1051(m)(2)(ii)(F), 1910.1051(m)(4)(ii)(A), Appendix F.
1218–0179	Methylene Chloride (29 CFR 1910.1052)	1910.1052(m)(2)(ii)(F), 1910.1052(m)(2)(iii)(C), 1910.1052(m)(3)(ii)(A), Appendix B.
1218–0266	Respirable Crystalline Silica Standards for General Industry, Shipyard Employment and Marine Terminals (29 CFR 1910.1053) and Construction (29 CFR 1926.1153) 1910.1053(k)(1)(ii)(G), 1910.1053(k)(3)(ii)(A), 1926.1153(j)(1)(ii)(G), 1926.1153(j)(3)(ii)(A).	
1218–0195	Asbestos in Shipyards Standard (29 CFR 1915.1001)	1915.1001(n)(2)(ii)(F), 1915.1001(n)(3)(ii)(A), Appendix D.
1218–0134	Asbestos in Construction (29 CFR 1926.1101)	1926.1101(n)(2)(ii)(F), 1926.1101(n)(3)(ii)(A), Appendix D.
1218–0186	Cadmium in Construction Standard (29 CFR 1926.1127)	1926.1127(d)(2)(iv), 1926.1127(n)(1)(ii)(B), 1926.1127(n)(3)(ii)(A).
1218–0183	4,4′-Methylenedianiline (MDA) in Construction (29 CFR 1926.60)	1926.60(o)(4)(ii)(F), 1926.60(o)(5)(ii)(A).
1218–0189	Lead in Construction Standard (29 CFR 1926.62)	1926.62(d)(5), 1926.62(n)(1)(ii)(D), 1926.62(n)(2)(ii)(A), 1926.62(n)(3)(ii)(A), Appendix B.

In addition to the above-described changes, the Agency will make adjustments to the some of the ICRs to reflect on-going PRA interpretations that will result in changes to the burden hours and costs; these changes are not a result of this rulemaking.

D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the DOL–OSHA, Office of Management and Budget, Room 10235, Washington, DC 20503. You may also submit comments to OMB by email at *OIRA_submission@omb.eop.gov.* Please reference the ICR's OMB control number in order to help ensure proper consideration. The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA–2012–0007), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to these paperwork determination, including the ICR (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this notice titled **ADDRESSES.** You also may obtain an electronic copy of the complete ICRs by visiting the Web page at *http://www.reginfo.gov/public/do/PRAMain,* scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for

proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

VII. Federalism

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

Under Section 18 of the OSH Act, Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State Plan States.'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

While OSHA drafted this proposed rule to protect employees in every State, Section 18(c)(2) of the OSH Act permits State Plan States and Territories to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in this proposed rule.

In summary, this proposed rule complies with Executive Order 13132. In States without OSHA-approved State Plans, any standard developed from this proposed rule would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA-approved State Plans, this rulemaking would not significantly limit State policy options.

VIII. State Plans

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 28 States and U.S. territories with their own OSHA-approved occupational safety and health plans (''State Plan States'') must revise their standards to reflect the new standard or amendment. The State standard must be at least as effective as the final Federal standard or amendment, and must be promulgated within six months of the publication date of the final Federal rule (29 U.S.C. 667(c)(2); 29 CFR 1953.5(a)).

A State-Plan State may demonstrate that a standard change is unnecessary because the State standard is already the same as or at least as effective as the new or amended Federal standard. In order to avoid delays in worker protection, the effective date of the State standard and any of its delayed provisions must be the date of State promulgation or the Federal effective date, whichever is later. The Assistant Secretary may permit a longer time period if the State timely demonstrates that good cause exists for extending the time limitation (29 CFR 1953.5(a)). Of the 28 States and territories with OSHA-approved State plans, 22 cover public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Six States and territories cover only public-sector employees: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than the existing standard, State Plan States are not required to amend their standards, although OSHA may encourage them to do so.

OSHA concludes that this final rule, by revising confusing, outdated, duplicative, or inconsistent standards, will increase the protection afforded to employees while reducing the compliance burden of employers. Therefore, States and Territories with approved State Plans must adopt comparable amendments to their standards within six months of the promulgation date of this rule unless they demonstrate that such amendments are not necessary because their existing standards are at least as effective in protecting workers as this final rule.

IX. Unfunded Mandates Reform Act of 1995

OSHA reviewed this proposed rule in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (56 FR 58093). As discussed in section IV (''Preliminary Economic Analysis and Regulatory Flexibility Act Certification'') of this notice, the Agency determined that this proposed rule has one revision with estimated annual new costs of $27,899, but all proposed revisions would result in approximately $3.2 million per year in overall (net) cost savings to regulated entities.

As noted under section VIII (''State Plans'') of this notice, the Agency's standards do not apply to State and local governments except in States that elect voluntarily to adopt a State Plan approved by the Agency. Consequently, this proposed rule does not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5)). Therefore, for the purposes of the UMRA, the Agency certifies that this proposed rule does not mandate that State, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

X. Review by the Advisory Committee for Construction Safety and Health

OSHA must to consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees (29 CFR 1911.10, 1912.3). Accordingly, prior to the dates of meetings listed below, OSHA distributed to the ACCSH members for their review, a copy of the proposed revisions that applied to construction, as well as a brief summary and explanation of these revisions. At the regular meetings on December 15–16, 2011, May 10–11 2012, November 29, 2012, March 18, 2013, May 23, 2013, August 22, 2013, May 7–8 2014, December 3–4, 2014, and December 2, 2015, OSHA staff made presentations to the ACCSH members that summarized the material provided to them earlier, and then responded to their questions. The ACCSH subsequently recommended that OSHA publish the proposal.

XI. Public Participation

A. Submission of Comments and Access to the Docket

OSHA invites comments on the proposed revisions described, and the specific issues raised, in this notice. These comments should include supporting information and data. OSHA will carefully review and evaluate these comments, information, and data, as well as any other information in the rulemaking record, to determine how to proceed.

When submitting comments, parties must follow the procedures specified in the previous sections titled **DATES** and

ADDRESSES. The comments must provide the name of the commenter and docket number. The comments also should identify clearly the provision of the proposal each comment is addressing, the position taken with respect to the proposed provision or issue, and the basis for that position. Comments, along with supporting data and references, submitted on or before the end of the specified comment period will become part of the proceedings record, and will be available for public inspection and copying at *http://www.regulations.gov.*

B. Requests for an Informal Public Hearing

Under section 6(b)(3) of the OSH Act and 29 CFR 1911.11, members of the public may request an informal public hearing by following the instructions under the section of this **Federal Register** notice titled **ADDRESSES**. Hearing requests must include the name and address of the party requesting the hearing, and submitted (*e.g.,* postmarked, transmitted, sent) on or before December 5, 2016. All submissions must bear a postmark or provide other evidence of the submission date.

List of Subjects

29 CFR Part 1904

Recordkeeping.

29 CFR Part 1910

Chest X-ray requirements, Incorporation by reference, Lockout/tagout, Pulmonary-function testing, Reporting and recordkeeping requirements.

29 CFR Part 1915

Chest X-ray requirements, Reporting and recordkeeping requirements, Sanitation.

29 CFR Part 1926

Airborne contaminants, Construction, Chest X-ray requirements, Coke oven emissions, Diesel equipment, Decompression table, Excavations, Emergency services, Incorporation by reference, Lanyards, Load limits, Manual on Uniform Traffic Control Devices (MUCTD), Personal protective equipment, Process safety management, Reporting and recordkeeping requirements, Roll-over protective structures (ROPs).

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this notice pursuant to Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 1–2012 (77 FR 3912).

Signed at Washington, DC, on August 10, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendments to Standards

For the reasons stated in the preamble of this proposed rule, the Occupational Safety and Health Administration is proposing to amend 29 CFR parts 1904, 1910, 1915, and 1926 as set forth below:

PART 1904—RECORDING AND REPORTING OCCUPATIONAL INJURIES AND ILLNESSES

■ 1. Revise the authority citation for part 1904 to read as follows:

Authority: 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Orders No. 3–2000 (65 FR 50017) and 1–2012 (77 FR 3912), as applicable, and 5 U.S.C. 553.

Subpart C—Recordkeeping Forms and Recording Criteria

■ 2. Revise paragraph (b)(6) of § 1904.10 to read as follows:

§ 1904.10 Recording criteria for cases involving occupational hearing loss.

* * * * *

(b) * * *

(6) *If a physician or other licensed health care professional determines the hearing loss is not work-related, do I still need to record the case?* If a physician or other licensed health care professional determines, following the rules set out in § 1904.5, that the hearing loss is not work-related or that occupational noise exposure did not significantly aggravate the hearing loss, you do not have to consider the case work-related or record the case on the OSHA 300 Log.

* * * * *

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

■ 3. The authority section for part 1910 continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable.

Sections 1910.6, 1910.7, 1910.8, and 1910.9 also issued under 29 CFR 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Public Law 106–113 (113 Stat. 1501A–222); Public Law 11–8 and 111–317; and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

Subpart A—General

■ 4. Add paragraphs (aa) and (bb) to § 1910.6 to read as follows:

§ 1910.6 Incorporation by reference.

* * * * *

(aa) The following material is available for purchase at the American Thoracic Society (ATS), 25 Broadway, 18th Floor New York, NY 10004; Web site: *http://www.atsjournals.org/.*

(1) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine, 159(1):179–187, January 1999, IBR approved for § 1910.1043(h).

(2) [Reserved]

(bb) The following material is available for purchase from the International Labour Organization (ILO), 4 route des Morillons, CH–1211 Genève 22, Switzerland; telephone: +41 (0) 22 799 6111; fax: +41 (0) 22 798 8685; Web site: *http://www.ilo.org/.*

(1) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, Occupational safety and health series; 22 (Rev.2011), IBR approved for § 1910.1001, Appendix E.

(2) [Reserved]

Subpart J—General Environmental Controls

■ 5. The authority section for subpart J continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable.

■ 6. Amend § 1910.147 by:

■ a. Revising paragraphs (a)(1)(i), (a)(2)(iii)(A), and (a)(3)(i);

■ b. Revising the definition of ''Servicing and/or maintenance'' in paragraph (b);

■ c. Revising paragraphs (c)(1) and (c)(4)(i) note;

■ d. Revising paragraph (f)(4);

■ e. Revising Appendix A.

The revisions read as follows:

§ 1910.147 The control of hazardous energy (lockout/tagout).

(a) * * *

(1) * * *

(i) This standard covers the servicing and maintenance of machines and equipment in which the energization or

startup of the machines or equipment, or release of stored energy could cause injury to employees. This standard establishes minimum performance requirements for the control of such hazardous energy.

* * * * *

(2) * * *

(iii) * * *

(A) Work on cord and plug connected electric equipment for which exposure to the hazards of energization or startup of the equipment is controlled by the unplugging of the equipment from the energy source and by the plug being under the exclusive control of the employee performing the servicing or maintenance.

* * * * *

(3) * * *

(i) This section requires employers to establish a program and utilize procedures for affixing appropriate lockout devices or tagout devices to energy isolating devices, and to otherwise disable machines or equipment to prevent energization, startup or release of stored energy in order to prevent injury to employees.

* * * * *

(b) * * *

Servicing and/or maintenance. Workplace activities such as constructing, installing, setting up, adjusting, inspecting, modifying, and maintaining and/or servicing machines or equipment. These activities include lubrication, cleaning or unjamming of machines or equipment and making adjustments or tool changes, where the employee may be exposed to the energization or startup of the equipment or release of hazardous energy.

* * * * *

(c) * * *

(1) *Energy control program.* The employer shall establish a program consisting of energy control procedures, employee training and periodic inspections to ensure that before any employee performs any servicing or maintenance on a machine or equipment where the energizing, startup or release of stored energy could occur and cause injury, the machine or equipment shall be isolated from the energy source and rendered inoperative.

* * * * *

(4) * * *

(i) * * *

Note: *Exception:* The employer need not document the required procedure for a particular machine or equipment, when all of the following elements exist: (1) The machine or equipment has no potential for stored or residual energy or reaccumulation of stored energy after shut down which could endanger employees; (2) the machine or equipment has a single energy source which can be readily identified and isolated; (3) the isolation and locking out of that energy source will completely deenergize and deactivate the machine or equipment; (4) the machine or equipment is isolated from that energy source and locked out during servicing or maintenance; (5) a single lockout device will achieve a locked-out condition; (6) the lockout device is under the exclusive control of the authorized employee performing the servicing or maintenance; (7) the servicing or maintenance does not create hazards for other employees; and (8) the employer, in utilizing this exception, has had no accidents involving the activation or reenergization of the machine or equipment during servicing or maintenance.

* * * * *

(f) * * *

(4) *Shift or personnel changes.* Specific procedures shall be utilized during shift or personnel changes to ensure the continuity of lockout or tagout protection, including provision for the orderly transfer of lockout or tagout device protection between off-going and oncoming employees, to minimize exposure to hazards from the energization or startup of the machine or equipment, or the release of stored energy.

* * * * *

APPENDIX A TO §1910.147—TYPICAL MINIMAL LOCKOUT PROCEDURE

General

The following simple lockout procedure is provided to assist employers in developing their procedures so they meet the requirements of this standard. When the energy isolating devices are not lockable, tagout may be used, provided the employer complies with the provisions of the standard which require additional training and more rigorous periodic inspections. When tagout is used and the energy isolating devices are lockable, the employer must provide full employee protection (*see* paragraph (c)(3)) and additional training and more rigorous periodic inspections are required. For more complex systems, more comprehensive procedures may need to be developed, documented and utilized.

Lockout Procedure

Lockout procedure for

_____

(Name of Company for single procedure or identification of equipment if multiple procedures are used)

Purpose

This procedure establishes the minimum requirements for the lockout of energy isolating devices whenever maintenance or servicing is done on machines or equipment. It shall be used to ensure that the machine or equipment is stopped, isolated from all potentially hazardous energy sources and locked out before employees perform any servicing or maintenance where the energization or start-up of the machine or equipment or release of stored energy could cause injury.

Compliance with This Program

All employees are required to comply with the restrictions and limitations imposed upon them during the use of lockout. The authorized employees are required to perform the lockout in accordance with this procedure. All employees, upon observing a machine or piece of equipment which is locked out to perform servicing or maintenance shall not attempt to start, energize or use that machine or equipment.

Type of compliance enforcement to be taken for violation of the above.

Sequence of Lockout

(1) Notify all affected employees that servicing or maintenance is required on a machine or equipment and that the machine or equipment must be shut down and locked out to perform the servicing or maintenance.

Name(s)/Job Title(s) of affected employees and how to notify.

(2) The authorized employee shall refer to the company procedure to identify the type and magnitude of the energy that the machine or equipment utilizes, shall understand the hazards of the energy, and shall know the methods to control the energy.

Type(s) and magnitude(s) of energy, its hazards and the methods to control the energy.

(3) If the machine or equipment is operating, shut it down by the normal stopping procedure (depress stop button, open switch, close valve, etc.).

Type(s) and location(s) of machine or equipment operating controls.

(4) De-activate the energy isolating device(s) so that the machine or equipment is isolated from the energy source(s).

Type(s) and location(s) of energy isolating devices.

(5) Lock out the energy isolating device(s) with assigned individual lock(s).

(6) Stored or residual energy (such as that in capacitors, springs, elevated machine members, rotating flywheels, hydraulic systems, and air, gas, steam, or water pressure, etc.) must be dissipated or restrained by methods such as grounding, repositioning, blocking, bleeding down, etc.

Type(s) of stored energy—methods to dissipate or restrain.

(7) Ensure that the equipment is disconnected from the energy source(s) by first checking that no personnel are exposed, then verify the isolation of the equipment by operating the push button or other normal operating control(s) or by testing to make certain the equipment will not operate.

CAUTION: Return operating control(s) to neutral or "off" position after verifying the isolation of the equipment.

Method of verifying the isolation of the equipment.

(8) The machine or equipment is now locked out.

Restoring Equipment to Service. When the servicing or maintenance is completed and the machine or equipment is ready to return to normal operating condition, the following steps shall be taken.

(1) Check the machine or equipment and the immediate area around the machine or equipment to ensure that nonessential items have been removed and that the machine or equipment components are operationally intact.

(2) Check the work area to ensure that all employees have been safely positioned or removed from the area.

(3) Verify that the controls are in neutral.

(4) Remove the lockout devices and reenergize the machine or equipment.

Note: The removal of some forms of blocking may require reenergization of the machine before safe removal.

(5) Notify affected employees that the servicing or maintenance is completed and the machine or equipment is ready for use.

Subpart Z—Toxic and Hazardous Substances

■ 7. Revise the authority citation for subpart Z to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

■ 8. Amend § 1910.1001 by:
■ a. Revising paragraphs (l)(2)(ii) and (l)(3)(ii);
■ b. Revising the heading to Table 1;
■ c. Revising Appendix D;
■ d. Revising Appendix E;
■ e. Revising Appendix H, sections III and IV(iii).

The revisions read as follows:

§ 1910.1001 Asbestos.

* * * * *

(l) * * *

(2) * * *

(ii) Such examination shall include, as a minimum, a medical and work history; a complete physical examination of all systems with emphasis on the respiratory system, the cardiovascular system and digestive tract; completion of the respiratory disease standardized questionnaire in Appendix D to this section, part 1; a 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray; pulmonary function tests to include forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV(1.0)); and any additional tests deemed appropriate by the examining physician. Classification of all chest X-rays shall be conducted in accordance with Appendix E to this section.

(3) * * *

(ii) The scope of the medical examination shall be in conformance with the protocol established in paragraph (l)(2)(ii) of this section, except that the frequency of chest X-rays shall be conducted in accordance with Table 1, and the abbreviated standardized questionnaire contained in part 2 of Appendix D to this section shall be administered to the employee.

Table 1—Frequency of Chest X-ray

* * * * *

APPENDIX D TO § 1910.1001—MEDICAL QUESTIONNAIRES; MANDATORY

This mandatory appendix contains the medical questionnaires that must be administered to all employees who are exposed to asbestos above permissible exposure limit, and who will therefore be included in their employer's medical surveillance program. Part 1 of the appendix contains the Initial Medical Questionnaire, which must be obtained for all new hires who will be covered by the medical surveillance requirements. Part 2 includes the abbreviated Periodical Medical Questionnaire, which must be administered to all employees who are provided periodic medical examinations under the medical surveillance provisions of the standard.

Part 1
INITIAL MEDICAL QUESTIONNAIRE

1. NAME_____
2. CLOCK NUMBER_____

3. PRESENT OCCUPATION_____
4. PLANT _____
5. ADDRESS_____
6. _____
   (Zip Code)
7. TELEPHONE NUMBER_____
8. INTERVIEWER_____
9. DATE _____
10. Date of Birth _____
    Month Day Year
11. Place of Birth _____
12. Sex 1. Male ___ 2. Female ___
13. What is your marital status? 1. Single ___ 2. Married ___ 3. Widowed ___ 4. Separated/ Divorced ___
14. Race 1. White ___ 2. Black ___ 3. Asian ___ 4. Hispanic ___ 5. Indian ___ 6. Other ___
15. What is the highest grade completed in school? _____
    (For example 12 years is completion of high school)

OCCUPATIONAL HISTORY

16A. Have you ever worked full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 16A:

B. Have you ever worked for a year or more in any dusty job? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

Specify job/industry _____ Total Years Worked ___

Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

C. Have you ever been exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

Specify job/industry _____ Total Years Worked ___

Was exposure: 1. Mild ____ 2. Moderate ___ 3. Severe ___

D. What has been your usual occupation or job -- the one you have worked at the longest?

1. Job occupation _____
2. Number of years employed in this occupation _____
3. Position/job title _____
4. Business, field or industry _____

(Record on lines the years in which you have worked in any of these industries, e.g. 1960-1969)

Have you ever worked:	YES	NO
E. In a mine?	_____	_____
F. In a quarry?	_____	_____
G. In a foundry?	_____	_____
H. In a pottery?	_____	_____
I. In a cotton, flax or hemp mill?....	_____	_____
J. With asbestos?	_____	_____

17. PAST MEDICAL HISTORY	YES	NO
A. Do you consider yourself to be in good health?	_____	_____

If "NO" state reason _____

B. Have you any defect of vision? _____ _____

If "YES" state nature of defect _____

C. Have you any hearing defect? _____ _____

If "YES" state nature of defect _____

D. Are you suffering from or have you ever suffered from:	YES	NO
a. Epilepsy (or fits, seizures, convulsions)?	_____	_____
b. Rheumatic fever?	_____	_____
c. Kidney disease?	_____	_____
d. Bladder disease?	_____	_____
e. Diabetes?	_____	_____
f. Jaundice?	_____	_____

18. CHEST COLDS AND CHEST ILLNESSES

18A. If you get a cold, does it "usually" go to your chest? (Usually means more than 1/2 the time)	1. Yes ___ 2. No ___ 3. Don't get colds ___
19A. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed?	1. Yes ___ 2. No ___

IF YES TO 19A:

B. Did you produce phlegm with any of these chest illnesses?	1. Yes ___ 2. No ___ 3. Does Not Apply ___
C. In the last 3 years, how many such illnesses with (increased) phlegm did you	Number of illnesses ___ No such illnesses ___

have which lasted a week or more?

20. Did you have any lung trouble before the age of 16? 1. Yes ___ 2. No ___

21. Have you ever had any of the following?

1A. Attacks of bronchitis? 1. Yes ___ 2. No ___

IF YES TO 1A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age was your first attack? Age in Years ___ Does Not Apply ___

2A. Pneumonia (include bronchopneumonia)? 1. Yes ___ 2. No ___

IF YES TO 2A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did you first have it? Age in Years ___ Does Not Apply ___

3A. Hay Fever? 1. Yes ___ 2. No ___

IF YES TO 3A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did it start? Age in Years ___ Does Not Apply ___

22A. Have you ever had chronic bronchitis? 1. Yes ___ 2. No ___

IF YES TO 22A:

B. Do you still have it? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

D. At what age did it start? Age in Years ___ Does Not Apply ___

23A. Have you ever had emphysema? 1. Yes ___ 2. No ___

IF YES TO 23A:

B. Do you still have it? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

D. At what age did it start? Age in Years ___ Does Not Apply ___

24A. Have you ever had asthma? 1. Yes ___ 2. No ___

IF YES TO 24A:

B. Do you still have it? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

D. At what age did it start? Age in Years ___ Does Not Apply ___

E. If you no longer have it, at what age did it stop? Age stopped ___ Does Not Apply ___

25. Have you ever had:

A. Any other chest illness? 1. Yes ___ 2. No ___

If yes, please specify _____

B. Any chest operations? 1. Yes ___ 2. No ___

If yes, please specify _____

C. Any chest injuries? 1. Yes ___ 2. No ___

If yes, please specify _____

26A. Has a doctor ever told you that you had heart trouble? 1. Yes ___ 2. No ___

IF YES TO 26A:

B. Have you ever had treatment for heart trouble in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

27A. Has a doctor told you that you had high blood pressure? 1. Yes ___ 2. No ___

IF YES TO 27A:

B. Have you had any treatment for high blood pressure (hypertension) in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

28. When did you last have your chest X-rayed? (Year) ___ ___ ___ ___

29. Where did you last have your chest X-rayed (if known)? _____

What was the outcome? _____

FAMILY HISTORY

30. Were either of your natural parents ever told by a doctor that they had a chronic lung condition such as:	FATHER			MOTHER		
	1. Yes	2. No	3. Don't know	1. Yes	2. No	3. Don't know
A. Chronic Bronchitis?	___	___	___	___	___	___
B. Emphysema?	___	___	___	___	___	___
C. Asthma?	___	___	___	___	___	___
D. Lung cancer?	___	___	___	___	___	___
E. Other chest conditions?	___	___	___	___	___	___
F. Is parent currently alive?	___	___	___	___	___	___
G. Please Specify	___ Age if Living ___ Age at Death ___ Don't Know			___ Age if Living ___ Age at Death ___ Don't Know		
H. Please specify cause of death	_____			_____		

COUGH

31A. Do you usually have a cough? (Count a cough with first smoke or on first going out of doors. Exclude clearing of throat.) (If no, skip to question 31C.)	1. Yes ___	2. No ___
B. Do you usually cough as much as 4 to 6 times a day 4 or more days out of the week?	1. Yes ___	2. No ___
C. Do you usually cough at all on getting up or first thing in the morning?	1. Yes ___	2. No ___

D. Do you usually cough at all during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF ABOVE (31A, B, C, OR D), ANSWER THE FOLLOWING. IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO NEXT PAGE

E. Do you usually cough like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had the cough? Number of years ___ Does not apply ___

32A. Do you usually bring up phlegm from your chest? Count phlegm with the first smoke or on first going out of doors. Exclude phlegm from the nose. Count swallowed phlegm.) (If no, skip to 32C) 1. Yes ___ 2. No ___

B. Do you usually bring up phlegm like this as much as twice a day 4 or more days out of the week? 1. Yes ___ 2. No ___

C. Do you usually bring up phlegm at all on getting up or first thing in the morning? 1. Yes ___ 2. No ___

D. Do you usually bring up phlegm at all on during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF THE ABOVE (32A, B, C, OR D), ANSWER THE FOLLOWING:

IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO 33A

E. Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had trouble with phlegm? Number of years ___ Does not apply ___

EPISODES OF COUGH AND PHLEGM

33A. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year?
*(For persons who usually have cough and/or phlegm)

1. Yes ___ 2. No ___

IF YES TO 33A

B. For how long have you had at least 1 such episode per year?

Number of years ___
Does not apply ___

WHEEZING

34A. Does your chest ever sound wheezy or whistling

1. When you have a cold? 1. Yes ___ 2. No ___

2. Occasionally apart from colds? 1. Yes ___ 2. No ___

3. Most days or nights? 1. Yes ___ 2. No ___

B. For how many years has this been present?

Number of years ___
Does not apply ___

35A. Have you ever had an attack of wheezing that has made you feel short of breath? 1. Yes ___ 2. No ___

IF YES TO 35A

B. How old were you when you had your first such attack?

Age in years ___
Does not apply ___

C. Have you had 2 or more such episodes? 1. Yes ___ 2. No ___ 3. Does not apply ___

D. Have you ever required medicine or treatment for the(se) attack(s)? 1. Yes ___ 2. No ___ 3. Does not apply ___

BREATHLESSNESS

36. If disabled from walking by any condition other than heart or lung disease, please describe and proceed to question 38A.

Nature of condition(s)
_____
_____

37A. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?

1. Yes ___ 2. No ___

IF YES TO 37A

B. Do you have to walk slower than people of your age on the level because of breathlessness?

1. Yes ___ 2. No ___
3. Does not apply ___

C. Do you ever have to stop for breath when walking at your own pace on the level?

1. Yes ___ 2. No ___
3. Does not apply ___

D. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level?

1. Yes ___ 2. No ___
3. Does not apply ___

E. Are you too breathless to leave the house or breathless on dressing or climbing one flight of stairs?

1. Yes ___ 2. No ___
3. Does not apply ___

TOBACCO SMOKING

38A. Have you ever smoked cigarettes?
(No means less than 20 packs of cigarettes or 12 oz. of tobacco in a lifetime or less than 1 cigarette a day for 1 year.)

1. Yes ___ 2. No ___

IF YES TO 38A

B. Do you now smoke cigarettes (as of one month ago)	1. Yes ___ 2. No ___ 3. Does not apply ___
C. How old were you when you first started regular cigarette smoking?	Age in years ___ Does not apply ___
D. If you have stopped smoking cigarettes completely, how old were you when you stopped?	Age stopped ___ Check if still smoking ___ Does not apply ___
E. How many cigarettes do you smoke per day now?	Cigarettes per day ___ Does not apply ___
F. On the average of the entire time you smoked, how many cigarettes did you smoke per day?	Cigarettes per day ___ Does not apply ___
G. Do or did you inhale the cigarette smoke?	1. Does not apply ___ 2. Not at all ___ 3. Slightly ___ 4. Moderately ___ 5. Deeply ___
39A. Have you ever smoked a pipe regularly? (Yes means more than 12 oz. of tobacco in a lifetime.)	1. Yes ___ 2. No ___

IF YES TO 39A:
FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started to smoke a pipe regularly?	Age ___
2. If you have stopped smoking a pipe completely, how old were you when you stopped?	Age stopped ___ Check if still smoking pipe ___ Does not apply ___

C. On the average over the entire time you smoked a pipe, how much pipe tobacco did you smoke per week?	___ oz. per week (a standard pouch of tobacco contains 1 1/2 oz.) ___ Does not apply
D. How much pipe tobacco are you smoking now?	oz. per week ___ Not currently smoking a pipe ___
E. Do you or did you inhale the pipe smoke?	1. Never smoked ___ 2. Not at all ___ 3. Slightly ___ 4. Moderately ___ 5. Deeply ___

40A. Have you ever smoked cigars regularly? 1. Yes ___ 2. No ___

(Yes means more than 1 cigar a week for a year)

IF YES TO 40A

FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started smoking cigars regularly?	Age ___
2. If you have stopped smoking cigars completely, how old were you when you stopped smoking cigars?	Age stopped ___ Check if still ___ Does not apply ___
C. On the average over the entire time you smoked cigars, how many cigars did you smoke per week?	Cigars per week ___ Does not apply ___
D. How many cigars are you smoking per week now?	Cigars per week ___ Check if not smoking cigars currently ___

E. Do or did you inhale the cigar smoke?

1. Never smoked ___
2. Not at all ___
3. Slightly ___
4. Moderately ___
5. Deeply ___

Signature _____ Date _____

.

Part 2

PERIODIC MEDICAL QUESTIONNAIRE

1. NAME _____
2. CLOCK NUMBER ___ ___ ___ ___ ___ ___ ___
3. PRESENT OCCUPATION _____
4. PLANT _____
5. ADDRESS _____
6. _____
   (Zip Code)
7. TELEPHONE NUMBER _____
8. INTERVIEWER _____
9. DATE _____
10. What is your marital status? 1. Single ___ 2. Married ___ 3. Widowed ___ 4. Separated/ Divorced ___

11. OCCUPATIONAL HISTORY

11A. In the past year, did you work full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 11A:

11B. In the past year, did you work in a dusty job? 1. Yes ___ 2. No ___ 3. Does not Apply ___

11C. Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11D. In the past year, were you exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

11E. Was exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11F. In the past year, what was your:
1. Job/occupation? _____
2. Position/job title? _____

12. RECENT MEDICAL HISTORY

12A. Do you consider yourself to be in good health? Yes ___ No ___

If NO, state reason _____

12B. In the past year, have you developed:

	Yes	No
Epilepsy?	___	___
Rheumatic fever?	___	___
Kidney disease?	___	___
Bladder disease?	___	___
Diabetes?	___	___
Jaundice?	___	___
Cancer?	___	___

13. CHEST COLDS AND CHEST ILLNESSES

13A. If you get a cold, does it "usually" go to your chest? (usually means more than 1/2 the time)
1. Yes ___ 2. No ___
3. Don't get colds ___

14A. During the past year, have you had any chest illnesses that have kept you off work, indoors at home, or in bed?
1. Yes ___ 2. No ___
3. Does Not Apply ___

IF YES TO 14A:

14B. Did you produce phlegm with any of these chest illnesses?
1. Yes ___ 2. No ___
3. Does Not Apply ___

14C. In the past year, how many such illnesses with (increased) phlegm did you have which lasted a week or more?
Number of illnesses ___
No such illnesses ___

15. RESPIRATORY SYSTEM

In the past year have you had:

	Yes or No	Further Comment on Positive Answers
Asthma	_____	
Bronchitis	_____	
Hay Fever	_____	
Other Allergies	_____	

	Yes or No	Further Comment on Positive Answers
Pneumonia	_____	
Tuberculosis	_____	
Chest Surgery	_____	
Other Lung Problems	_____	
Heart Disease	_____	

Do you have:

	Yes or No	Further Comment on Positive Answers
Frequent colds	_____	
Chronic cough	_____	
Shortness of breath when walking or climbing one flight or stairs	_____	

Do you:

Wheeze	_____	
Cough up phlegm	_____	
Smoke cigarettes	_____	Packs per day ____ How many years ___

Date _____ Signature _____

APPENDIX E TO § 1910.1001—CLASSIFICATION OF CHEST X-RAYS—MANDATORY

(a) Chest X-rays shall be classified in accordance with the International Labour Organization (ILO) Classification of Radiographs of Pneumoconioses (revised edition 2011) (incorporated by reference, see § 1910.6), and recorded on a classification form following the format of the CDC/NIOSH (M) 2.8 form. As a minimum, the content within the bold lines of this form (items 1 through 4) shall be included. This form is not to be submitted to NIOSH.

(b) All X-rays shall be classified only by a B-Reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses.

(c) Whenever classifying chest X-rays made under this section, the physician shall have immediately available for reference a complete set of the ILO Classification of Radiographs for Pneumoconioses (revised edition 2011) and the Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses (revised edition 2011).

* * * * *

APPENDIX H TO § 1910.1001—MEDICAL SURVEILLANCE GUIDELINES FOR ASBESTOS

NON-MANDATORY

* * * * *

III. Signs and Symptoms of Exposure-Related Disease

The signs and symptoms of lung cancer or gastrointestinal cancer induced by exposure to asbestos are not unique, except that a chest X-ray of an exposed patient with lung cancer may show pleural plaques, pleural calcification, or pleural fibrosis, and may also show asbestosis (i.e., small irregular parenchymal opacities). Symptoms characteristic of mesothelioma include shortness of breath, pain in the chest or abdominal pain. Mesothelioma has a much longer average latency period compared with lung cancer (40 years versus 15-20 years), and mesothelioma is therefore more likely to be found among workers who were first exposed to asbestos at an early age. Mesothelioma is a fatal disease.

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. Symptoms include shortness of breath, coughing, fatigue, and vague feelings of sickness. When the fibrosis worsens, shortness of breath occurs even at rest. The diagnosis of asbestosis is most commonly based on a history of exposure to asbestos, the presence of characteristic radiologic abnormalities, end-inspiratory crackles (rales), and other clinical features of fibrosing lung disease. Pleural plaques and thickening may be observed on chest X-rays. Asbestosis is often a progressive disease even in the absence of continued exposure, although this appears to be a highly individualized characteristic. In severe cases, death may be caused by respiratory or cardiac failure.

IV. Surveillance and Preventive Considerations

* * * * *

(iii) A physical examination including a chest X-ray and pulmonary function test that includes measurement of the employee's forced vital capacity (FVC) and forced expiratory volume at one second (FEV(1)).

* * * * *

■ 9. Amend § 1910.1018 by:
■ a. Revising paragraphs (n)(2)(ii)(A) and, (n)(3)(i) and (ii);
■ b. Revising Appendix A, section VI;
■ c. Revising Appendix C, sections I(2) and (4).

The revisions read as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(n) * * *

(2) * * *

(ii) * * *

(A) A standard film or digital posterior-anterior chest X-ray;

* * * * *

(3) * * *

(i) Examinations must be provided in accordance with paragraphs (n)(2)(i) and (n)(2)(ii)(B) and (C) of this section at least annually.

(ii) Whenever a covered employee has not taken the examinations specified in paragraphs (n)(2)(i) and (n)(2)(ii)(B) and (C) of this section within six (6) months preceding the termination of employment, the employer shall provide such examinations to the employee upon termination of employment.

* * * * *

APPENDIX A TO § 1910.1018—INORGANIC ARSENIC SUBSTANCE INFORMATION SHEET

* * * * *

VI. MEDICAL EXAMINATIONS

If your exposure to arsenic is over the Action Level (5 µg/m3) -- (including all persons working in regulated areas) at least 30 days per year, or you have been exposed to arsenic for more than 10 years over the Action Level, your employer is required to provide you with a medical examination. The examination shall be every 6 months for employees over 45 years old or with more than 10 years exposure over the Action Level and annually for other covered employees. The medical examination must include a medical history; a chest X-ray (during initial examination only); skin examination and a nasal examination. The examining physician will provide a written opinion to your employer containing the results of the medical exams. You should also receive a copy of this opinion. The physician must not tell your employer any conditions he detects unrelated to occupational exposure to arsenic but must tell you those conditions.

* * * * *

APPENDIX C TO § 1910.1018—MEDICAL SURVEILLANCE GUIDELINES

I. GENERAL

* * * * *

(2) A 14" by 17" or other reasonably-sized standard film or digital posterior-anterior chest X-ray;

* * * * *

(4) Other examinations which the physician believes appropriate because of the employee's exposure to inorganic arsenic or because of required respirator use.

Periodic examinations are also to be provided to the employees listed above. The periodic examinations shall be given annually for those covered employees 45 years of age or less with fewer than 10 years employment in areas where employee exposure exceeds the action level (5 $\mu g/m^3$). Periodic examinations need not include sputum cytology or chest X-ray and only an updated medical history is required.

Periodic examinations for other covered employees shall be provided every six (6) months. These examinations shall include all tests required in the initial examination, except the chest X-ray, and the medical history need only be updated.

The examination contents are minimum requirements. Additional tests such as lateral and oblique X-rays or pulmonary function tests may be useful. For workers exposed to three arsenicals which are associated with lymphatic cancer, copper acetoarsenite, potassium arsenite, or sodium arsenite the examination should also include palpation of superficial lymph nodes and complete blood count.

* * * * *

■ 10. Amend § 1910.1027 by:
■ a. Revising paragraph (l)(4)(ii)(C);
■ b. Revising Appendix D.
The revisions read as follows:

§ 1910.1027 Cadmium.

(l) * * *
(4) * * *
(ii) * * *
(C) A 14 inch by 17 inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray (after the initial X-ray, the frequency of chest X-rays is to be determined by the examining physician);
* * * * *

APPENDIX D TO § 1910.1027—OCCUPATIONAL HEALTH HISTORY INTERVIEW WITH REFERENCE TO CADMIUM EXPOSURE

Directions

(To be read by employee and signed prior to the interview)

Please answer the questions you will be asked as completely and carefully as you can. These questions are asked of everyone who works with cadmium. You will also be asked to give blood and urine samples. The doctor will give your employer a written opinion on whether you are physically capable of working with cadmium. Legally, the doctor cannot share personal information you may tell him/her with your employer. The following information is considered strictly confidential. The results of the tests will go to you, your doctor and your employer. You will also receive an information sheet explaining the results of any biological monitoring or physical examinations performed.

If you are just being hired, the results of this interview and examination will be used to:

(1) Establish your health status and see if working with cadmium might be expected to cause unusual problems,
(2) Determine your health status today and see if there are changes over time,
(3) See if you can wear a respirator safely.

If you are not a new hire:

OSHA says that everyone who works with cadmium can have periodic medical examinations performed by a doctor. The reasons for this are:

a) If there are changes in your health, either because of cadmium or some other reason, to find them early,
b) to prevent kidney damage.

Please sign below.

I have read these directions and understand them:

_____

Employee signature

_____

Date

Thank you for answering these questions. (Suggested Format)

Name_____

Age _____

Company_____

Job_____

Type of Preplacement Exam:

[ ] Periodic

[ ] Termination

[ ] Initial

[ ] Other

Blood Pressure_____

Pulse Rate_____

1. How long have you worked at the job listed above?
   [ ] Not yet hired

   [ ] Number of months

   [ ] Number of years

2. Job Duties etc.

_____

_____

_____

3. Have you ever been told by a doctor that you had bronchitis?
   [ ] Yes

   [ ] No

   If yes, how long ago?

   [ ] Number of months

   [ ] Number of years

4. Have you ever been told by a doctor that you had emphysema?
   [ ] Yes

   [ ] No

If yes, how long ago?

[ ] Number of years

[ ] Number of months

5. Have you ever been told by a doctor that you had other lung problems?
   [ ] Yes

   [ ] No

   If yes, please describe type of lung problems and when you had these problems.

_____

_____

_____

6. In the past year, have you had a cough?
   [ ] Yes

   [ ] No

   If yes, did you cough up sputum?

   [ ] Yes

   [ ] No

   If yes, how long did the cough with sputum production last?

   [ ] Less than 3 months

   [ ] 3 months or longer

   If yes, for how many years have you had episodes of cough with sputum production lasting this long?

   [ ] Less than one

   [ ] 1

   [ ] 2

   [ ] Longer than 2

7. Have you ever smoked cigarettes?
   [ ] Yes

[ ] No

8. Do you now smoke cigarettes?
   [ ] Yes
   [ ] No

9. If you smoke or have smoked cigarettes, for how many years have you smoked, or did you smoke?
   [ ] Less than 1 year
   [ ] Number of years

   What is or was the greatest number of packs per day that you have smoked?
   [ ] Number of packs

   If you quit smoking cigarettes, how many years ago did you quit?
   [ ] Less than 1 year
   [ ] Number of years

   How many packs a day do you now smoke?
   [ ] Number of packs per day

10. Have you ever been told by a doctor that you had a kidney or urinary tract disease or disorder?
    [ ] Yes
    [ ] No

11. Have you ever had any of these disorders?

Kidney stones	[ ] Yes	[ ] No
Protein in urine	[ ] Yes	[ ] No
Blood in urine	[ ] Yes	[ ] No
Difficulty urinating	[ ] Yes	[ ] No
Other kidney/Urinary disorders	[ ] Yes	[ ] No

Please describe problems, age, treatment, and follow up for any kidney or urinary problems you have had:

_____

_____

_____

12. Have you ever been told by a doctor or other health care provider who took your blood pressure that your blood pressure was high?

[ ] Yes

[ ] No

13. Have you ever been advised to take any blood pressure medication?

[ ] Yes

[ ] No

14. Are you presently taking any blood pressure medication?

[ ] Yes

[ ] No

15. Are you presently taking any other medication?

[ ] Yes

[ ] No

16. Please list any blood pressure or other medications and describe how long you have been taking each one:

Medicine	How long Taken

17. Have you ever been told by a doctor that you have diabetes? (sugar in your blood or urine)

[ ] Yes

[ ] No

If yes, do you presently see a doctor about your diabetes?

[ ] Yes

[ ] No

If yes, how do you control your blood sugar?

[ ] Diet alone

[ ] Diet plus oral medicine

[ ] Diet plus insulin (injection)

18. Have you ever been told by a doctor that you had:

Anemia	[ ] Yes	[ ] No
A low blood count?	[ ] Yes	[ ] No

19. Do you presently feel that you tire or run out of energy sooner than normal or sooner than other people your age?

[ ] Yes

[ ] No

If yes, for how long have you felt that you tire easily?

[ ] Less than 1 year

[ ] Number of years

20. Have you given blood within the last year?

[ ] Yes

[ ] No

If yes, how many times?

[ ] Number of times

How long ago was the last time you gave blood?

[ ] Less than 1 month

[ ] Number of months

21. Within the last year have you had any injuries with heavy bleeding?

[ ] Yes

[ ] No

If yes, how long ago?

[ ] Less than 1 month

[ ] Number of months

Describe: _____

_____

_____

22. Have you recently had any surgery?

[ ] Yes

[ ] No

If yes, please describe: _____

_____

_____

23. Have you seen any blood lately in your stool or after a bowel movement?

[ ] Yes

[ ] No

24. Have you ever had a test for blood in your stool?

[ ] Yes

[ ] No

If yes, did the test show any blood in the stool?

[ ] Yes

[ ] No

What further evaluation and treatment were done? _____

_____

_____

_____

_____

The following questions pertain to the ability to wear a respirator.
Additional information for the physician can be found in The Respiratory Protective Devices Manual.

25. Have you ever been told by a doctor that you have asthma?

[ ] Yes

[ ] No

If yes, are you presently taking any medication for asthma? Mark all that apply.

[ ] Shots

[ ] Pills

[ ] Inhaler

26. Have you ever had a heart attack?

[ ] Yes

[ ] No

If yes, how long ago?

[ ] Number of years

[ ] Number of months

27. Have you ever had pains in your chest?

[ ] Yes

[ ] No

If yes, when did it usually happen?

[ ] While resting

[ ] While working

[ ] While exercising

[ ] Activity didn't matter

28. Have you ever had a thyroid problem?
[ ] Yes

[ ] No

29. Have you ever had a seizure or fits?
[ ] Yes

[ ] No

30. Have you ever had a stroke (cerebrovascular accident)?
[ ] Yes

[ ] No

31. Have you ever had a ruptured eardrum or a serious hearing problem?
[ ] Yes

[ ] No

32. Do you now have a claustrophobia, meaning fear of crowded or closed in spaces or any psychological problems that would make it hard for you to wear a respirator?
[ ] Yes

[ ] No

The following questions pertain to reproductive history.

33. Have you or your partner had a problem conceiving a child?
[ ] Yes

[ ] No

If yes, specify:

[ ] Self

[ ] Present mate

[ ] Previous mate

34. Have you or your partner consulted a physician for a fertility or other reproductive problem?

[ ] Yes

[ ] No

If yes, specify who consulted the physician:

[ ] Self

[ ] Spouse/partner

[ ] Self and partner

If yes, specify diagnosis made: _____

_____

_____

_____

_____

35. Have you or your partner ever conceived a child resulting in a miscarriage, still birth or deformed offspring?

[ ] Yes

[ ] No

If yes, specify:

[ ] Miscarriage

[ ] Still birth

[ ] Deformed offspring

If outcome was a deformed offspring, please specify type:

_____

_____

36. Was this outcome a result of a pregnancy of:

[ ] Yours with present partner

[ ] Yours with a previous partner

37. Did the timing of any abnormal pregnancy outcome coincide with present employment?

[ ] Yes

[ ] No

List dates of occurrences: _____

_____

_____

38. What is the occupation of your spouse or partner?

_____

_____

For Women Only

39. Do you have menstrual periods?

[ ] Yes

[ ] No

Have you had menstrual irregularities?

[ ] Yes

[ ] No

If yes, specify type: _____

_____

_____

If yes, what was the approximated date this problem began? _____

_____

Approximate date problem stopped? _____

_____

For Men Only

40. Have you ever been diagnosed by a physician as having prostate gland problem(s)?

[ ] Yes

[ ] No

If yes, please describe type of problem(s) and what was done to evaluate and treat the problem(s): _____

_____

_____

* * * * *

■ 11. Amend § 1910.1029 by:
■ a. Revising paragraphs (j)(2)(ii) and (j)(3);
■ b. Revising Appendix A, section VI;
■ c. Revising Appendix B, section II(A).
The revisions read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(j) * * *

(2) * * *

(ii) 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray;

* * * * *

(3) *Periodic examinations.* (i) The employer shall provide the examinations specified in paragraphs (j)(2)(i) and (j)(2)(iii) through (vi) of this section at least annually for employees covered under paragraph (j)(1)(i) of this section.

(ii) The employer must provide the examinations specified in paragraphs (j)(2)(i) and (j)(2)(iii) through (vii) of this section at least annually for employees 45 years of age or older or with five (5) or more years employment in the regulated area.

(iii) Whenever an employee who is 45 years of age or older or with five (5) or more years employment in a regulated area transfers or is transferred from employment in a regulated area, the employer must continue to provide the examinations specified in paragraphs (j)(2)(i) and (j)(2)(iii) through (vii) of this section at least annually as long as that employee is employed by the same employer or a successor employer.

* * * * *

APPENDIX A TO § 1910.1029—COKE OVEN EMISSIONS SUBSTANCE INFORMATION SHEET

* * * * *

VI. MEDICAL EXAMINATIONS

If you work in a regulated area at least 30 days per year, your employer is required to provide you with a medical examination every year. The initial medical examination must include a medical history, a chest X-ray, pulmonary function test, weight comparison, skin examination, a urinalysis, and a urine cytology exam for early detection of urinary cancer. Periodic examinations shall include all tests required in the initial examination, except that (1) the x-ray is to be performed during initial examination only and (2) the urine cytologic test is to be performed only on those employees who are 45 years or older or who have worked for 5 or more years in the regulated area. The examining physician will provide a written opinion to your employer containing the results of the medical exams. You should also receive a copy of this opinion.

* * * * *

APPENDIX B TO § 1910.1029—INDUSTRIAL HYGIENE AND MEDICAL SURVEILLANCE GUIDELINES

* * * * *

II. MEDICAL SURVEILLANCE GUIDELINES

A. *General.* The minimum requirements for the medical examination for coke oven workers are given in paragraph (j) of the standard. The initial examination is to be provided to all coke oven workers who work at least 30 days in the regulated area. The examination includes a 14" by 17" or other reasonably-sized standard film or digital posterior-anterior chest X-ray reading, pulmonary function tests (FVC and FEV 1.0), weight, urinalysis, skin examination, and a urinary cytologic examination. These tests are needed to serve as the baseline for comparing the employee's future test results. Periodic exams include all the elements of the initial exams, except that (1) the x-ray is to be performed during initial examination only and (2) the urine cytologic test is to be performed only on those employees who are 45 years or older or who have worked for 5 or more years in the regulated area. The examination contents are minimum requirements; additional tests such as lateral and oblique X-rays or additional pulmonary function tests may be performed if deemed necessary.

* * * * *

■ 12. Amend § 1910.1043 by:
■ a. Revising paragraphs (h)(2)(iii) and (h)(3)(ii);
■ b. Revising paragraph (n)(1);
■ c. Revising Appendices B–I, B–II, and B–III;
■ d. Removing and reserving Appendix C;
■ e. Revising Appendix D.

The revisions read as follows:

§ 1910.1043 Cotton Dust.

* * * * *

(h) * * *

(2) * * *

(iii) A pulmonary function measurement, including forced vital capacity (FVC) and forced expiratory volume in one second (FEV1), and determination of the FEV1/FVC ratio shall be made. FVC, FEV1, and FEV1/FVC ratio values shall be compared to appropriate race/ethnicity-specific Lower Limit of Normal (LLN) values and predicted values published in Spirometric Reference Values from a Sample of the General U.S. Population, American Journal of Respiratory and Critical Care Medicine, 159(1):179–187, January 1999 (incorporated by reference, see § 1910.6). To obtain reference values for Asian-Americans, Spirometric Reference Values FEV1 and FVC predicted and LLN values for Caucasians shall be multiplied by 0.88 to adjust for ethnic differences. These determinations shall be made for each employee before the employee enters the workplace on the first day of the work week, preceded by at least 35 hours of no exposure to cotton dust. The tests shall be repeated during the shift, no less than 4 and no more than 10 hours after the beginning of the work shift; and, in any event, no more than one hour after cessation of exposure. Such exposure shall be typical of the employee's usual workplace exposure.

* * * * *

(3) * * *

(ii) Medical surveillance as required in paragraph (h)(3)(i) of this section shall be provided every six months for all employees in the following categories:

(A) An FEV1 greater than the LLN, but with an FEV1 decrement of 5 percent or 200 ml. on a first working day;

(B) An FEV1 of less than the LLN; or

* * * * *

(n) * * *

(1) Appendices B and D of this section are incorporated as part of this section and the contents of these appendices are mandatory.

* * * * *

APPENDIX B-I

RESPIRATORY QUESTIONNAIRE

A. IDENTIFICATION DATA

PLANT _____

DAY MONTH YEAR

(figures) (last 2 digits)

NAME _____ DATE OF INTERVIEW _____

(Surname)

_____ DATE OF BIRTH _____

(First Names)

M F

ADDRESS _____ AGE ____ (8, 9) SEX _____(10)

W N IND OTHER

_____ RACE _____ _____ _____ _____ (11)

INTERVIEWER: 1 2 3 4 5 6 7 8 (12)

WORK SHIFT: 1st _____ 2nd _____ 3rd _____ (13)

STANDING HEIGHT _____ (14, 15)

WEIGHT _____ (16, 18)

PRESENT WORK AREA

If working in more than one specified work area, X area where most of the work shift is spent. If "other," but spending 25% of the work shift in one of the specified work areas, classify in that work area. If carding department employee, check area within that department where most of the work shift is spent (if in doubt, check "throughout"). For work areas such as spinning and weaving where many work rooms may be involved, be sure to check to specific work room to which the employee is assigned - if he works in more than one work room within a department classify as 7 (all) for that department.

	Work-room Number	(19) Open	(20) Pick	Area	(21) Card #1	(22) Card #2	(23) Spin	(24) Wind	(25) Twist
AT RISK (cotton & cotton blend)	1			Cards					
	2			Draw					
	3			Comb					
	4			Thru Out					
	5								
	6								
	7 (all)								
Control (synthetic & wool)	8								
Ex-Worker (cotton)	9								

Continued –

	Work-Room Number	(26) Spool	(27) Warp	(28) Slash	(29) Weave	(30) Other
AT RISK (cotton & cotton blend)	1					
	2					
	3					
	4					
	5					
	6					
	7 (all)					
Control (synthetic & wool)	8					
Ex-Worker (cotton)	9					

Use actual wording of each question. Put X in appropriate square after each question. When in doubt record "No". When no square, circle appropriate answer.

B. COUGH

(on getting up)
Do you usually cough first thing in the morning? _____

Yes _____ No _____ (31)

(Count a cough with first smoke or on "first going out of doors." Exclude clearing throat or a single cough.)

Do you usually cough during the day or at night? Yes _____ No _____ (32)

(Ignore an occasional cough.)

If `Yes' to either question (31-32):

Do you cough like this on most days for as much as three months a year? Yes _____ No _____ (33)

Do you cough on any particular day of the week? Yes _____ No _____ (34)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	
If 'Yes': Which day?	Mon	Tues	Wed	Thur	Fri	Sat	Sun	(35)

C. PHLEGM or alternative word to suit local custom.

(on getting up)

Do you usually bring up any phlegm from your chest first thing in the morning? (Count phlegm with the first smoke or on "first going out of doors." Exclude phlegm from the nose. Count swallowed phlegm.) Yes _____ No _____ (36)

Do you usually bring up any phlegm from your chest during the day or at night? (Accept twice or more.) Yes _____ No _____ (37)

If `Yes' to question (36) or (37):

Do you bring up any phlegm like this on most days for as much as three months each year? Yes _____ No _____ (38)

If `Yes' to question (33) or (38):

(cough)

How long have you had this phlegm? (1) ____ 2 years or less (39)

(Write in number of years) (2) ____ More than 2 year-9 years

(3) ____ 10-19 years

(4) ____ 20+ years

* These words are for subjects who work at night

D. CHEST ILLNESSES

In the past three years, have you had a period of (increased) *cough and phlegm lasting for 3 weeks or more?

(1) ____ No (40)

(2) ____ Yes, only one period

(3) ____ Yes, two or more periods

*For subjects who usually have phlegm

During the past 3 years have you had any chest illness which has kept you off work, indoors at home or in bed? (For as long as one week, flu?)

Yes _____ No _____ (41)

If `Yes' to (41):

Did you bring up (more) phlegm than usual in any of these illnesses?

Yes _____ No _____ (42)

If `Yes' to (42):

During the past three years have you had:

Only one such illness with increased phlegm? (1) _____ (43)

More than one such illness: (2) _____(44)

Br. Grade _____

E. TIGHTNESS

Does your chest ever feel tight or your breathing become difficult?

Yes _____ No _____ (45)

Is your chest tight or your breathing difficult on any particular day of the week? (after a week or 10 days from the mill)

Yes _____ No _____ (46)

If `Yes': Which day? (3) (4) (5) (6) (7) (8)

Mon. ^ Tues. Wed. Thur. Fri. Sat. Sun. (47)

(1) / \ (2)

Sometimes Always

If `Yes' Monday: At what time on Monday does your chest feel tight or your breathing difficult?

(1) ___ Before entering the mill (48)

(2) ___ After entering the mill

(Ask only if NO to Question (45))

In the past, has your chest ever been tight or your breathing difficult on any particular day of the week?

Yes _____ No _____ (49)

If `Yes': Which day? (3) (4) (5) (6) (7) (8)

Mon. ^ Tues. Wed. Thur. Fri. Sat. Sun. (50)

(1) / \ (2)

Sometimes Always

F. BREATHLESSNESS

If disabled from walking by any condition other than heart or lung disease put "X" here and leave questions (52-60) unasked. _____(51)

Are you ever troubled by shortness of breath, when hurrying on the level or walking up a slight hill? Yes _____ No _____ (52)

If `No', grade is 1.

If `Yes', proceed to next question.

Do you get short of breath walking with other people at an ordinary pace on the level? Yes _____ No _____ (53)

If `No', grade is 2.

If `Yes', proceed to next question.

Do you have to stop for breath when walking at your own pace on the level? Yes _____ No _____ (54)

If `No', grade is 3.

If `Yes', proceed to next question.

Are you short of breath on washing or dressing? Yes _____ No _____ (55)

If `No', grade is 4.

If `Yes' grade is 5.

Dyspnea Grd. _____ (56)

ON MONDAYS

Are you ever troubled by shortness of breath, when hurrying on the level or walking up a slight hill? Yes _____ No _____ (57)

If `No', grade is 1.

If `Yes', proceed to next question.

Do you get short of breath walking with other people at ordinary pace on the level? Yes _____ No _____ (58)

If `No', grade is 2.

If `Yes', proceed to next question.

Do you have to stop for breath when walking at your own pace on level ground? Yes _____ No _____ (59)

If `No', grade is 3.

If `Yes', proceed to next question.

Are you short of breath on washing or dressing? Yes _____ No _____ (60)

If `No', grade is 4.

If `Yes', grade is 5. B. Grd. _____ (61)

G. OTHER ILLNESSES AND ALLERGY HISTORY

Do you have a heart condition for which you are under a doctor's care?

Yes _____ No _____ (62)

Have you ever had asthma? Yes _____ No _____ (63)

If `Yes', did it begin: (1) _____ Before age 30

(2) _____ After age 30

If `Yes' before 30 did you have asthma before ever going to work in a textile mill?

Yes _____ No _____ (64)

Have you ever had hay fever or other allergies (other than above)?

Yes _____ No _____ (65)

H. TOBACCO SMOKING*

Do you smoke?

Record `Yes', if regular smoker up to one month ago (Cigarettes, cigar or pipe)

Yes _____ No _____ (66)

If `No' to (63)

Have you ever smoked? (Cigarettes, cigars, pipe. Record `No' if subject has never smoked as much as one cigarette a day, or 1 oz of tobacco a month, for as long as one year.)

Yes _____ No _____ (67)

If `Yes' to (63) or (64), what have you smoked and for how many years?

(Write in specific number of years in the appropriate square)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
Years	<5	5-9	10-14	15-19	20-24	25-29	30-34	35-39	>40	
Cigarettes										(68)
Pipe										(69)

Cigars										(70)

If cigarettes, how many packs per day? (Write in number of cigarettes)

(1) _____ Less than 1/2 pack (71)

(2) _____ 1/2 pack, but less than 1 pack

(3) _____ 1 pack, but less than 1 ½ packs

(4) _____ 1 1/2 packs or more

Number of years _____ (72, 73)

If an ex smoker (cigarettes, cigar or pipe), how long since you stopped? (Write in number of years) _____ (74)

(1) _____ 0-1 year

(2) _____ 1-4 years

(3) _____ 5-9 years

(4) _____ 10+ years

* Have you changed your smoking habits since last interview? If yes, specify what changes.

I. OCCUPATIONAL HISTORY**

Have you ever worked in:

A foundry? (As long as one year) Yes _____ No _____ (75)

Stone or mineral mining, quarry or processing? (As long as one year) Yes _____ No _____ (76)

Asbestos milling or processing? Yes _____ No _____ (77)

Other dusts, fumes or smoke? Yes _____ No _____ (78)

If yes, specify.

Type of exposure _____

Length of exposure _____

** Ask only on first interview.

At what age did you first go to work in a textile mill?

(Write in specific age in appropriate square)

(1)	(2)	(3)	(4)	(5)	(6)
<20	20-24	25-29	30-34	35-39	40+

When you first worked in a textile mill, did you work with:

(1) _____ Cotton or cotton blend (79)

(2) _____ Synthetic or wool (80)

APPENDIX B-II

Respiratory Questionnaire for Non-Textile Workers for the Cotton Industry

_____

Identification No. Interviewer Code

_____

Location Date of Interview

_____

A. IDENTIFICATION

_____

1. NAME (Last) (First) (Middle Initial)

_____

2. CURRENT ADDRESS (Number, Street, or Rural Route, City or Town, County, State, Zip Code)

_____

3. PHONE NUMBER AREA CODE NO.

(__ __ __) ___ ___ ___ - ___ ___ ___ ___

4. BIRTHDATE (Mo., Day, Yr.)

_____

5. AGE LAST BIRTHDAY

_____

6. SEX

1. _____ Male 2. _____ Female

7. ETHNIC GROUP OR ANCESTRY

1. ____ White, not of Hispanic Origin
2. ____ Black, not of Hispanic Origin
3. ____ Hispanic
4. ____ American Indian or Alaskan Native
5. ____ Asian or Pacific Islander
6. ____ Other: _____

8. STANDING HEIGHT

_____ (cm)

9. WEIGHT

_____

10. WORK SHIFT

1st _____ 2nd _____ 3rd _____

11. PRESENT WORK AREA

Please indicate primary assigned work area and percent of time spent at that site. If at other locations, please indicate and note percent of time for each.

PRIMARY WORK AREA	
SPECIFIC JOB	

12. APPROPRIATE INDUSTRY

1. _____ Garnetting
2. _____ Cottonseed Oil Mill

3. _____ Cotton Warehouse
4. _____ Utilization
5. _____ Cotton Classification
6. _____ Cotton Ginning

B. OCCUPATIONAL HISTORY TABLE

Complete the following table showing the entire work history of the individual from present to initial employment. Sporadic, part-time periods of employment, each of no significant duration, should be grouped if possible.

INDUSTRY AND LOCATION	TENURE OF EMPLOYMENT		SPECIFIC OCCUPATION	AVERAGE NO. DAYS WORKED PER WEEK	HAZARDOUS HEALTH EXPOSURE ASSOCIATED WITH WORK		
	FROM 19__ or 20__	TO 19__ or 20__			YES	NO	IF YES, DESCRIBE

C. SYMPTOMS

Use actual wording of each question. Put X in appropriate square after each question. When in doubt record "No.".

COUGH

1. Do you usually cough first thing in the morning? (on getting up)* (Count a cough with first smoke or on "first going out of doors". Exclude clearing throat or a single cough.) 1._____Yes 2._____No

2. Do you usually cough during the day or at night? (Ignore an occasional cough.)	1. ____ Yes 2. ____ No

If YES to either 1 or 2:

3. Do you cough like this on days for as much as three months a year?	1. ____ Yes 2. ____ No 3. ____ NA
4. Do you cough on any particular day of the week?	1. ____ Yes 2. _____ No

If YES:

5. Which day?	Mon. Tue. Wed. Thur. Fri. Sat. Sun. _____

PHLEGM

6. Do you usually bring up any phlegm from your chest first thing in the morning? (on getting up)* (Count phlegm with the first smoke or on "first going out of doors." Exclude phlegm from the nose. Count swallowed phlegm.	1. ____ Yes 2. ____ No
7. Do you usually bring up any phlegm from your chest during the day or at night? (Accept twice or more.)	1. ____ Yes 2. ____ No

If YES to either question 6 or 7:

8. Do you bring up phlegm like this on most days for as much as three months each year?	1. ____ Yes 2. ____ No

If YES to question 3 or 8:

9. How long have you had this phlegm?	(1) ____ 2 years or less (2) ____ More than 2 years - 9 years

(cough) (Write in number of years)

(3) ____ 10-19 years
(4) ____ 20+ years

* These words are for subjects who work at night.

CHEST ILLNESS

10. In the past three years, have you had a period of (increased) cough and phlegm lasting for 3 weeks or more?

(1) ____ No
(2) ____ Yes, only one period
(3) ____ Yes, two or more periods

For subjects who usually have phlegm:

11. During the past 3 years have you had any chest illness which has kept you off work, indoors at home or in bed? (For as long as one week, flu?)

1. ____ Yes 2. ____ No

If YES to 11:

12. Did you bring up (more) phlegm than usual in any of these illnesses?

1. ____ Yes 2. ____ No

13. Only one such illness with increased phlegm?

1. ____ Yes 2. ____ No

If YES to 12: During the past three years have you had:

14. More than one such illness:

1. ____ Yes 2. ____ No

Br. Grade _____

TIGHTNESS

15. Does your chest ever feel tight or your breathing become difficult?

1. ____ Yes 2. ____ No

16. Is your chest tight or your breathing difficult on any particular day of the week? (after a week or 10 days away from the mill) 1. ____ Yes 2. ____ No

17. If `Yes': Which day?

(3) Mon. ^ (1) / Sometimes \ (2) Always (4) Tues. (5) Wed. (6) Thur. (7) Fri. (8) Sat. Sun.

18. If YES Monday: At what time on Monday does your chest feel tight or your breathing difficult?

_____ Before entering mill

_____ After entering mill

(ASK ONLY IF NO TO QUESTION 15)

19. In the past, has your chest ever been tight or your breathing difficult on any particular day of the week? 1. ____ Yes 2. ____ No

20. If `Yes': Which day?

(3) Mon. ^ (1) / Sometimes \ (2) Always (4) Tues. (5) Wed. (6) Thur. (7) Fri. (8) Sat. Sun.

BREATHLESSNESS

21. If disabled from walking by any condition other than heart or lung disease put "X" in the space and leave questions (22-30) unasked. _____

22. Are you ever troubled by shortness of breath, when hurrying on the level or walking up a slight hill? 1. ____ Yes 2. ____ No

If NO, grade is 1. If YES, proceed to next

question.

23. Do you get short of breath walking with other people at an ordinary pace on the level? 1. ____ Yes 2. ____ No

If NO, grade is 2. If YES, proceed to next question.

24. Do you have to stop for breath when walking at your own pace on the level? 1. ____ Yes 2. ____ No

If NO, grade is 3. If YES, proceed to next question.

25. Are you short of breath on washing or dressing? 1. ____ Yes 2. ____ No

If NO, grade is 4, If YES, grade is 5.

26. Dyspnea Grd. _____

ON MONDAYS:

27. Are you ever troubled by shortness of breath, when hurrying on the level or walking up a slight hill? 1. ____ Yes 2. ____ No

If NO, grade is 1, If YES, proceed to next question.

28. Do you get short of breath walking with other people at an ordinary pace on the level? 1. ____ Yes 2. ____ No

If NO, grade is 2, If YES, proceed to next question.

29. Do you have to stop for breath when walking at your own pace on the level? 1. ____ Yes 2. ____ No

If NO, grade is 3, If YES, proceed to next question.

30. Are you short of breath on washing or dressing? 1. ____ Yes 2. ____ No

If NO, grade is 4, If YES, grade is 5.

B. Grd. _____

OTHER ILLNESSES AND ALLERGY HISTORY

32. Do you have a heart condition for which you are under a doctor's care? 1. ____ Yes 2. ____ No

33. Have you ever had asthma? 1. ____ Yes 2. ____ No

If yes, did it begin:

(1) Before age 30 _____

(2) After age 30 _____

34. If yes before 30: did you have asthma before ever going to work in a textile mill? 1. ____ Yes 2. ____ No

35. Have you ever had hay fever or other allergies (other than above)? 1. ____ Yes 2. ____ No

TOBACCO SMOKING

36. Do you smoke? 1. ____ Yes 2. ____ No
Record Yes if regular smoker up to one month ago. (Cigarettes, cigar or pipe)

If NO to (33).

37. Have you ever smoked? 1. ____ Yes 2. ____ No
(Cigarettes, cigars, pipe. Record NO if subject has never smoked as much as one cigarette a day, or 1 oz. of tobacco a month, for as long as one year.)

If YES to (33) or (34); what have you smoked for how many years?
(Write in specific number of years in the appropriate square)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
Years	<5	5-9	10-14	15-19	20-24	25-29	30-34	35-39	>40	
Cigarettes										(38)
Pipe										(39)
Cigars										(40)

41. If cigarettes, how many packs per day?
Write in number of cigarettes _____

_____ Less than 1/2 pack

_____ 1/2 pack, but less than 1 pack

_____ 1 pack, but less than 1 1/2 packs

_____ 1-1/2 packs or more

42. Number of pack years: _____

43. If an ex-smoker (Cigarettes, cigar or pipe), how long since you stopped? (Write in number of years.) _____

_____ 0-1 year
_____ 1-4 years
_____ 5-9 years
_____ 10+ years

OCCUPATIONAL HISTORY

Have you ever worked in:

44. A foundry? (As long as one year) 1. ____ Yes 2. ____ No

45. Stone or mineral mining, quarrying or processing? (As long as one year) 1. ____ Yes 2. ____ No

46. Asbestos milling or processing? (Ever) 1. ____ Yes 2. ____ No

47. Cotton or cotton blend mill? (For controls only) 1. ____ Yes 2. ____ No

48. Other dusts, fumes or smoke? If yes, specify. 1. ____ Yes 2. ____ No

Type of exposure _____

Length of exposure _____

APPENDIX B-III

ABBREVIATED RESPIRATORY QUESTIONNAIRE

A. IDENTIFICATION DATA

PLANT _____

DAY MONTH YEAR

(figures) (last 2 digits)

NAME _____ DATE OF INTERVIEW _____

(Surname)

_____ DATE OF BIRTH _____

(First Names)

M F

ADDRESS _____ AGE ____ (8, 9) SEX _____(10)

W N IND OTHER

_____ RACE _____ _____ _____ _____ (11)

INTERVIEWER: 1 2 3 4 5 6 7 8 (12)

WORK SHIFT: 1st _____ 2nd _____ 3rd _____ (13)

STANDING HEIGHT _____ (14, 15)

WEIGHT _____ (16, 18)

PRESENT WORK AREA

If working in more than one specified work area, X area where most of the work shift is spent. If "other," but spending 25% of the work shift in one of the specified work areas, classify in that work area. If carding department employee, check area within that department where most of the work shift is spent (if in doubt, check "throughout"). For work areas such as spinning and weaving where many work rooms may be involved, be sure to check to specific work room to which the employee is assigned - if he works in more than one work room within a department classify as 7 (all) for that department.

	Work-room Number	(19) Open	(20) Pick	Area	(21) Card #1	(22) #2	(23) Spin	(24) Wind	(25) Twist
AT RISK (cotton & Cotton blend)	1			Cards					
	2			Draw					
	3			Comb					
	4			Thru Out					
	5								
	6								
	7 (all)								

Control (synthetic & wool)	8								
Ex-Worker (cotton)	9								

Continued –

	Work-Room Number	(26) Spool	(27) Warp	(28) Slash	(29) Weave	(30) Other
AT RISK (cotton & cotton blend)	1					
	2					
	3					
	4					
	5					
	6					
	7 (all)					
Control (synthetic & wool)	8					
Ex-Worker (cotton)	9					

Use actual wording of each question. Put X in appropriate square after each question. When in doubt record `No'. When no square, circle appropriate answer.

B. COUGH

(on getting up)

Do you usually cough first thing in the morning? _____

Yes _____ No _____ (31)

(Count a cough with first smoke or on "first going out of doors." Exclude clearing throat or a single cough.)

Do you usually cough during the day or at night? Yes _____ No _____ (32)

(Ignore an occasional cough.)

If `Yes' to either question (31-32):

Do you cough like this on most days for as much as three months a year?

Yes _____ No _____ (33)

Do you cough on any particular day of the week? Yes _____ No _____ (34)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	
If 'Yes': Which day?	Mon	Tues	Wed	Thur	Fri	Sat	Sun	(35)

_____

C. PHLEGM or alternative word to suit local custom.

(on getting up)

Do you usually bring up any phlegm from your chest first thing in the morning? (Count phlegm with the first smoke or on "first going out of doors." Exclude phlegm from the nose. Count swallowed phlegm.)

Yes _____ No _____ (36)

Do you usually bring up any phlegm from your chest during the day or at night? (Accept twice or more.)

Yes _____ No _____ (37)

If `Yes' to question (36) or (37):

Do you bring up any phlegm like this on most days for as much as three months each year?

Yes _____ No _____ (38)

If `Yes' to question (33) or (38):

(cough)

How long have you had this phlegm?

(Write in number of years)

(1) ____ 2 years or less

(2) ____ More than 2 years-9 years

(3) ____ 10-19 years

(4) ____ 20+ years

* These words are for subjects who work at night

D. TIGHTNESS

Does your chest ever feel tight or your breathing become difficult?

Yes _____ No _____ (39)

Is your chest tight or your breathing difficult on any particular day of the week? (after a week or 10 days from the mill)

Yes _____ No _____ (40)

If `Yes': Which day? (3) (4) (5) (6) (7) (8)

Mon. ^ Tues. Wed. Thur. Fri. Sat. Sun. (41)

(1) / \ (2)

Sometimes Always

If `Yes' Monday At what time on Monday does your chest feel tight or your breathing difficult?

(1) ___ Before entering the mill (42)

(2) ___ After entering the mill

(Ask only if NO to Question (45)

In the past, has your chest ever been tight or your breathing difficult on any particular day of the week?

Yes _____ No _____ (43)

If `Yes': Which day?

(3) (4) (5) (6) (7) (8)

Mon. ^ Tues. Wed. Thur. Fri. Sat. Sun. (44)

(1) / \ (2)

Sometimes Always

E. TOBACCO SMOKING

* Have you changed your smoking habits since last interview?

If yes, specify what changes.</EXTRACT>

APPENDIX C TO §1910.1043 [Reserved]

APPENDIX D TO §1910.1043 – PULMONARY FUNCTION STANDARDS FOR COTTON DUST STANDARD

The spirometric measurements of pulmonary function shall conform to the following minimum standards, and these standards are not intended to preclude additional testing or alternate methods which can be determined to be superior.

I. APPARATUS

a. The instrument shall be accurate to within ±50 milliliters or within ±3 percent of reading, whichever is greater.

b. 1. Instruments purchased on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] should be capable of measuring vital capacity from 0 to 7 liters BTPS

2. Instruments purchased after [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] should be capable of measuring vital capacity from 0 to 8 liters BTPS.

c. The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H_2O/(liter/sec).

d. The zero time point for the purpose of timing the FEV_1 shall be determined by extrapolating the steepest portion of the volume time curve back to the maximal inspiration volume (1, 2, 3, 4) or by an equivalent method.

e. 1. Instruments purchased on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] that incorporate measurements of airflow to determine volume shall conform to the same volume

accuracy stated in (a) of this section when presented with flow rates from at least 0 to 12 liters per second.

2. Instruments purchased after [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULEIN THE FEDERAL REGISTER] that incorporate measurements of airflow to determine volume shall conform to the same volume accuracy stated in (a) of this section when presented with flow rates from at least 0 to 14 liters per second.

f. The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

g. 1. Instruments purchased on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall provide a tracing or display of either flow versus volume or volume versus time during the entire forced expiration. A tracing or display is necessary to determine whether the patient has performed the test properly. The tracing must be stored and available for recall and must be of sufficient size that hand measurements may be made within requirement of paragraph (a) of this section. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume.

2. Instruments purchased after [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall provide during testing a paper tracing or real-time display of flow versus volume and volume versus time for the entire forced expiration. Such a tracing or display is necessary to determine whether the patient has performed the test properly. Flow-volume and volume-time curves must be stored and available for recall. Real-time displays shall have a volume scale of at least 5 mm/L,

a time scale of at least 10 mm/s, and a flow scale of at least 2.5 mm/L/s, when both flow-volume and volume-time displays are visible. If hand measurements will be made, paper tracings must be of sufficient size to allow those measurements to be made within requirement of paragraph (a) of this section. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume.

h. 1. Instruments purchased on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall be capable of accumulating volume for a minimum of 10 seconds and shall not stop accumulating volume before (i) the volume change for a 0.5-second interval is less than 25 milliliters, or (2) the flow is less than 50 milliliters per second for a 0.5 second interval.

2. Instruments purchased after [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall be capable of accumulating volume for a minimum of 15 seconds and shall not stop accumulating volume before the volume change for a 1-second interval is less than 25 milliliters.

i. The forced vital capacity (FVC) and forced expiratory volume in 1 second ($FEV_{1.0}$) measurements shall comply with the accuracy requirements stated in paragraph (a) of this section. That is, they should be accurately measured to within ±50 ml or within ±3 percent of reading, whichever is greater.

j. 1. Instruments purchased on or before [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] must be capable of being calibrated in the field with respect to the FEV(1) and FVC. This calibration of the FEV(1) and FVC may be either directly or indirectly through volume and time base

measurements. The volume calibration source should provide a volume displacement of at least 2 liters and should be accurate to within + or - 30 milliliters.

2. Instruments purchased after [DATE ONE YEAR AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] must be capable of having its calibration checked in the field and be recalibrated, if necessary, if the spirometer requires the technician to do so. The volume-calibration syringe shall provide a volume displacement of at least 3 liters and shall be accurate to within ± 0.5 percent of 3 liters (15 milliliters).

II. TECHNIQUE FOR MEASUREMENT OF FORCED VITAL CAPACITY MANEUVER

a. Use of a nose clip is recommended but not required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The patient may sit, but care should be taken on repeat testing that the same position be used and, if possible, the same spirometer. Particular attention shall be given to ensure that the chin is slightly elevated with the neck slightly extended. The patient shall be instructed to make a full inspiration from a normal breathing pattern and then blow into the apparatus, without interruption, as hard, fast, and completely as possible. At least three and no more than eight forced expirations shall be carried out. During the maneuvers, the patient shall be observed for compliance with instruction. The expirations shall be checked visually for technical acceptability and repeatability from flow-volume or volume-time tracings or displays. The following efforts shall be judged technically unacceptable when the patient:

1. Has not reached full inspiration preceding the forced expiration,

2. Has not used maximal effort during the entire forced expiration,

3. Has not tried to exhale continuously for at least 6 seconds and until an obvious plateau in the volume time curve has occurred,

4. Has coughed in the first second or closed the glottis,

5. Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.),

6. Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts), and, therefore, not allowing back extrapolation of time 0 (extrapolated volume on the volume-time tracing must be less than 150 milliliters or 5 percent of the FVC, whichever is greater.)

7. Has an excessive variability between the acceptable curves. The difference between the two largest FVCs from the satisfactory tracings should not exceed 150 milliliters and the difference between the two largest FEV1s of the satisfactory tracings should not exceed 150 milliliters.

b. Periodic and routine calibration checks of the instrument for recording FVC and FEV1.0 shall be performed using a 3-liter syringe. Calibration checks to ensure that the spirometer is recording 3 liters of injected air to within ± 3.5 percent, or 2.90 to 3.10 liters, shall be conducted. Calibration checks of flow-type spirometers shall include injection of 3 liters air over a range of speeds, with injection times of 0.5 second, 3 seconds, and 6 or more seconds. Checks of volume-type spirometers shall include a single calibration check and a check to verify that the spirometer is not leaking more than 30 milliliters/minute air.

III. INTERPRETATION OF SPIROGRAM

a. The first step in evaluating a spirogram should be to determine whether or not the patient has performed the test properly or as described in II above. From the three satisfactory tracings, the forced vital capacity (FVC) and forced expiratory volume in 1 second ($FEV_{1.0}$) shall be measured and recorded. The largest observed FVC and largest observed FEV_1 shall be used in the analysis regardless of the curve(s) on which they occur.

b. [Reserved]

IV. QUALIFICATIONS OF PERSONNEL ADMINISTERING THE TEST

Technicians who perform pulmonary function testing should have the basic knowledge required to produce meaningful results. Training consisting of approximately 16 hours of formal instruction should cover the following areas.

a. Basic physiology of the forced vital-capacity maneuver and the determinants of airflow limitation, with emphasis on the relation to repeatability of results.

b. Instrumentation requirements, including calibration check procedures, sources of error, and their correction.

c. Performance of the testing including patient coaching, recognition of improperly performed maneuvers and corrective actions.

d. Data quality with emphasis on repeatability.

e. Actual use of the equipment under supervised conditions.

f. Measurement of tracings and calculations of results.

■ 13. Revise paragraphs (n)(2)(iii), and (n)(3)(i) and (ii) of § 1910.1045 to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(n) * * *

(2) * * *

(iii) 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray; and

* * * * *

(3) * * *

(i) The employer shall provide the examinations specified in paragraphs (n)(2)(i), (ii), and (iv) of this section at least annually for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examination specified in paragraphs (n)(2)(i), (ii), and (iv) of this section within 6 months preceding termination of employment, the employer shall make such examination available to the employee prior to such termination.

* * * * *

■ 14. Revise Appendix D of § 1910.1048 to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

APPENDIX D TO §1910.1048—NONMANDATORY MEDICAL DISEASE QUESTIONNAIRE

A. Identification

Plant Name: _____

Date: _____

Employee Name: _____

Job Title: _____

Birthdate: _____

Age: _____

Sex: _____

Height: _____

Weight: _____

B. Medical History

1. Have you ever been in the hospital as a patient?

   Yes__ No__

   If yes, what kind of problem were you having? _____

   _____

2. Have you ever had any kind of operation?

   Yes__ No__

   If yes, what kind? _____

   _____

3. Do you take any kind of medicine regularly?

   Yes__ No__

   If yes, what kind? _____

   _____

4. Are you allergic to any drugs, foods, or chemicals?

   Yes__ No__

   If yes, what kind of allergy is it? _____

   _____

   What causes the allergy? _____

   _____

5. Have you ever been told that you have asthma, hayfever, or sinusitis?

   Yes__ No__

6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems?

   Yes__ No__

7. Have you ever been told you had hepatitis?

   Yes__ No__

8. Have you ever been told that you had cirrhosis?

   Yes__ No__

9. Have you ever been told that you had cancer?

   Yes__ No__

10. Have you ever had arthritis or joint pain?

    Yes__ No__

11. Have you ever been told that you had high blood pressure?

    Yes__ No__

12. Have you ever had a heart attack or heart trouble?

    Yes__ No__

B-1. Medical History Update

1. Have you been in the hospital as a patient any time within the past year?

   Yes__ No__

   If so, for what condition? _____

   _____

2. Have you been under the care of a physician during the past year?

   Yes__ No__

   If so, for what condition?_____

   _____

3. Is there any change in your breathing since last year?

   Yes__ No__

   Better? _____

   Worse? _____

   No change?_____

If change, do you know why?_____

_____

4. Is your general health different this year from last year?

   Yes__ No__

   If different, in what way?_____

   _____

5. Have you in the past year or are you now taking any medication on a regular basis?

   Yes__ No__

   Name Rx_____

   Condition being treated _____

C. Occupational History

1. How long have you worked for your present employer?

   _____

2. What jobs have you held with this employer? Include job title and length of time in each job _____

   _____

   _____

   _____

3. In each of these jobs, how many hours a day were you exposed to chemicals?

   _____

4. What chemicals have you worked with most of the time?

   _____

5. Have you ever noticed any type of skin rash you feel was related to your work?

   Yes__ No__

6. Have you ever noticed that any kind of chemical makes you cough?

   Yes__ No__

   Wheeze?

   Yes__ No__

   Become short of breath or cause your chest to become tight?

   Yes__ No__

7. Are you exposed to any dust or chemicals at home?

Yes__ No__

If yes, explain: _____

_____

8. In other jobs, have you ever had exposure to:

Wood dust?

Yes__ No__

Nickel or chromium?

Yes__ No__

Silica (foundry, sand blasting)?

Yes__ No__

Arsenic or asbestos?

Yes__ No__

Organic solvents?

Yes__ No__

Urethane foams?

Yes__ No__

C-1. Occupational History Update

1. Are you working on the same job this year as you were last year?

Yes__ No__

If not, how has your job changed? _____

_____

2. What chemicals are you exposed to on your job?

_____

3. How many hours a day are you exposed to chemicals?

_____

4. Have you noticed any skin rash within the past year you feel was related to your work?

Yes__ No__

If so, explain circumstances: _____

_____

5. Have you noticed that any chemical makes you cough, be short of breath, or wheeze?

   Yes__ No__

   If so, can you identify it? _____

   _____

D. Miscellaneous

1. Do you smoke?

   Yes__ No__

   If so, how much and for how long? _____

   _____

   Pipe_____

   Cigars_____

   Cigarettes_____

2. Do you drink alcohol in any form?

   Yes__ No__

   If so, how much, how long, and how often? _____

   _____

3. Do you wear glasses or contact lenses?

   Yes__ No__

4. Do you get any physical exercise other than that required to do your job?

   Yes__ No__

   If so, explain: _____

   _____

5. Do you have any hobbies or "side jobs" that require you to use chemicals, such as furniture stripping, sand blasting, insulation or manufacture of urethane foam, furniture, etc.?

   Yes__ No__

   If so, please describe, giving type of business or hobby, chemicals used and length of exposures.

   _____

E. Symptoms Questionnaire

1. Do you ever have any shortness of breath?

   Yes__ No__

If yes, do you have to rest after climbing several flights of stairs?

Yes__ No__

If yes, if you walk on the level with people your own age, do you walk slower than they do?

Yes__ No__

If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk?

Yes__ No__

If yes, do you have to stop and rest while bathing or dressing?

Yes__ No__

2. Do you cough as much as three months out of the year?

Yes__ No__

If yes, have you had this cough for more than two years?

Yes__ No__

If yes, do you ever cough anything up from chest?

Yes__ No__

3. Do you ever have a feeling of smothering, unable to take a deep breath, or tightness in your chest?

Yes__ No__

If yes, do you notice that this on any particular day of the week?

Yes__ No__

If yes, what day or the week?

Yes__ No__

If yes, do you notice that this occurs at any particular place?

Yes__ No__

If yes, do you notice that this is worse after you have returned to work after being off for several days?

Yes__ No__

4. Have you ever noticed any wheezing in your chest?

Yes__ No__

If yes, is this only with colds or other infections?

Yes__ No__

Is this caused by exposure to any kind of dust or other material?

Yes__ No__

If yes, what kind? _____

5. Have you noticed any burning, tearing, or redness of your eyes when you are at work?

   Yes__ No__

   If so, explain circumstances: _____

   _____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work?

   Yes__ No__

   If so, explain circumstances: _____

   _____

7. Have you noticed any stuffiness or dryness of your nose?

   Yes__ No__

8. Do you ever have swelling of the eyelids or face?

   Yes__ No__

9. Have you ever been jaundiced?

   Yes__ No__

   If yes, was this accompanied by any pain?

   Yes__ No__

10. Have you ever had a tendency to bruise easily or bleed excessively?

    Yes__ No__

11. Do you have frequent headaches that are not relieved by aspirin or Tylenol?

    Yes__ No__

    If yes, do they occur at any particular time of the day or week?

    Yes__ No__

    If yes, when do they occur? _____

    _____

12. Do you have frequent episodes of nervousness or irritability?

Yes__ No__

13. Do you tend to have trouble concentrating or remembering?

Yes__ No__

14. Do you ever feel dizzy, light-headed, excessively drowsy or like you have been drugged?

Yes__ No__

15. Does your vision ever become blurred?

Yes__ No__

16. Do you have numbness or tingling of the hands or feet or other parts of your body?

Yes__ No__

17. Have you ever had chronic weakness or fatigue?

Yes__ No__

18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes?

Yes__ No__

19. Are you bothered by heartburn or indigestion?

Yes__ No__

20. Do you ever have itching, dryness, or peeling and scaling of the hands?

Yes__ No__

21. Do you ever have a burning sensation in the hands, or reddening of the skin?

Yes__ No__

22. Do you ever have cracking or bleeding of the skin on your hands?

Yes__ No__

23. Are you under a physician's care?

Yes__ No__

If yes, for what are you being treated? _____

_____

24. Do you have any physical complaints today?

Yes__ No__

If yes, explain? _____

_____

25. Do you have other health conditions not covered by these questions?

Yes__ No__

If yes, explain: _____

_____

§ 1910.1051 1,3-Butadiene.

* * * * *

APPENDIX F TO §1910.1051—MEDICAL QUESTIONNAIRES (NON-MANDATORY))

1,3-Butadiene (BD) Initial Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions are about your work, medical history, and health concerns. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date: _____

Name: _____ _____ ____

Last First MI

Job Title: _____

Company's Name: _____

Supervisor's Name: _____ Supervisor's Phone No.: ( ) ____-_____

Work History

1. Please list all jobs you have had in the past, starting with the job you have now and m oving back in time to your first job. (For more space, write on the back of this page.)

Main Job Duty	Years	Company Name City, State	Chemicals
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

2. Please describe what you do during a typical work day. Be sure to tell about you work with BD

_____

_____

3. _____

___Please check any of these chemicals that you work with now or have worked with in the past:

benzene ____

glues ____

toluene ____

inks, dyes ____

other solvents, grease cutters ____

insecticides (like DDT, lindane, etc.) ____

paints, varnishes, thinners, strippers ____

dusts ____

carbon tetrachloride ("carbon tet") ____

arsine ____

carbon disulfide ____

lead ____

cement ____

petroleum products ____

nitrites ____

4. Please check the protective clothing or equipment you use at the job you have now:

gloves ____

coveralls ____

respirator ____

dust mask ____

safety glasses, goggles ____

Please circle your answer of yes or no.

5. Does your protective clothing or equipment fit you properly?

yes no

6. Have you ever made changes in your protective clothing or equipment to make it fit better?

yes no

7. Have you been exposed to BD when you were not wearing protective clothing or equipment?

yes no

8. Where do you eat, drink and/or smoke when you are at work?

(Please check all that apply.)

Cafeteria/restaurant/snack bar ____

Break room/employee lounge ____

Smoking lounge ____

At my work station ____

Please circle your answer.

9. Have you been exposed to radiation (like x-rays or nuclear material) at the job you have now or at past jobs?

yes no

10. Do you have any hobbies that expose you to dusts or chemicals (including paints, glues, etc.)?

yes no

11. Do you have any second or side jobs?

yes no

If yes, what are your duties there? _____

_____

_____

_____

12. Were you in the military?

yes no

If yes, what did you do in the military? _____

_____

_____

_____

Family Health History

1. In the FAMILY MEMBER column, across from the disease name, write which family member, if any, had the disease.

Disease	Family Member
Cancer	
Lymphoma	
Sickle Cell Disease or Trait	
Immune Disease	
Leukemia	
Anemia	

2. Please fill in the following information about family health:

RELATIVE	ALIVE?	AGE AT DEATH?	CAUSE OF DEATH?
Father			
Mother			
Brother/Sister			
Brother/Sister			
Brother/Sister			

PERSONAL HEALTH HISTORY

Birth Date ____/____/_____ Age _____ Sex ___ Height _____ Weight _____

Please circle your answer.

1. Do you smoke any tobacco products?

yes no

2. Have you ever had any kind of surgery or operation?

yes no

If yes, what type of surgery: _____

_____

_____

3. Have you ever been in the hospital for any other reasons?

yes no

If yes, please describe the reason: _____

_____

_____

4. Do you have any on-going or current medical problems or conditions?

yes no

If yes, please describe: _____

_____

_____

5. Do you now have or have you ever had any of the following?
Please check all that apply to you.

unexplained fever	____	liver disease	____
anemia ("low blood")	____	cancer	____
HIV/AIDS	____	infertility	____
weakness	____	drinking problems	____
sickle cell	____	thyroid problems	____
miscarriage	____	night sweats	____
skin rash	____	chest pain	____
bloody stools	____	still birth	____
leukemia/lymphoma	____	eye redness	____
neck mass/swelling	____	lumps you can feel	____
wheezing	____	child with birth defect	____
yellowing of skin	____	autoimmune disease	____
bruising easily	____	overly tired	____
lupus	____	lung problems	____
weight loss	____	rheumatoid arthritis	____
kidney problems	____	mononucleosis("mono")	____
enlarged lymph nodes	____	nagging cough	____

Please circle your answer.

6. Do you have any symptoms or health problems that you think may be related to your work with BD?

yes no

If yes, please describe: _____

_____

7. Have any of your co-workers had similar symptoms or problems?

yes no don't know

If yes, please describe: _____

_____

8. Do you notice any irritation of your eyes, nose, throat, lungs or skin when working with BD?

yes no

9. Do you notice any blurred vision, coughing, drowsiness, nausea, or headache when working with BD?

yes no

10. Do you take any medications (including birth control or over-the-counter)?

yes no

If yes, please list: _____

_____

11. Are you allergic to any medication, food, or chemicals?

yes no

If yes, please list: _____

_____

12. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD?

yes no

If yes, please explain: _____

_____

13. Did you understand all the questions?

yes no

_____

Signature

1,3-Butadiene (BD) Update Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions ask about changes in your work, medical history, and health concerns since the last time you were evaluated. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date: _____

Name:_____

Last First MI

Job Title: _____

Company's Name: _____

Supervisor's Name: _____ Supervisor's Phone No.: ( ) _____-_____

Present Work History

1. Please describe any NEW duties that you have at your job:_____
   _____
   _____
   _____
   _____
   _____

2. Please list any additional job titles you have:

   _____ _____

   _____ _____

   _____ _____

Please circle your answer.

3. Are you exposed to any other chemicals in your work since the last time you were evaluated for exposure to BD?

   yes no

If yes, please list what they are: _____

_____

4. Does your personal protective equipment and clothing fit you properly?

yes no

5. Have you made changes in this equipment or clothing to make it fit better?

yes no

6. Have you been exposed to BD when you were not wearing protective equipment or clothing?

yes no

7. Are you exposed to any NEW chemicals at home or while working on hobbies?

yes no

If yes, please list what they are: _____

_____

8. Since your last BD health evaluation, have you started working any new second or side jobs?

yes no

If yes, what are your duties there? _____

_____

_____

Personal Health History

1. What is your current weight? _____ pounds

2. Have you been diagnosed with any new medical conditions or illness since your last evaluation?

   yes no

   If yes, please tell what they are: _____

   _____

3. Since your last evaluation, have you been in the hospital for any illnesses, injuries, or surgery?

   yes no

   If yes, please describe: _____

   _____

4. Do you have any of the following? Please place a check for all that apply to you.

unexplained fever	____	neck mass/swelling	____
anemia ("low blood")	____	wheezing	____
HIV/AIDS	____	chest pain	____
weakness	____	bruising easily	____
sickle cell	____	lupus	____
miscarriage	____	weight loss	____
skin rash	____	kidney problems	____
bloody rash	____	enlarged lymph nodes	____
leukemia/lymphoma	____	liver disease	____

cancer	____	child with birth defect	____
infertility	____	autoimmune disease	____
drinking problems	____	overly tired	____
thyroid problems	____	lung problems	____
night sweats	____	rheumatoid arthritis	____
still birth	____	mononucleosis "mono"	____
eye redness	____	nagging cough	____
lumps you can feel	____	yellowing of skin	____

Please circle your answer.

5. Do you have any symptoms or health problems that you think may be related to your work with BD?

yes no

If yes, please describe: _____

_____

6. Have any of your co-workers had similar symptoms or problems?

yes no don't know

If yes, please describe: _____

_____

7. Do you notice any irritation of your eyes, nose, throat, lungs, or skin when working with BD?

yes no

8. Do you notice any blurred vision, coughing, drowsiness, nausea, or headache when working with BD?

yes no

9. Have you been taking any NEW medications (including birth control or over-the-counter)?

yes no

If yes, please list:

_____ _____ _____

_____ _____ _____

10. Have you developed any NEW allergies to medications, foods, or chemicals?

yes no

If yes, please list:

_____ _____ _____

_____ _____ _____

11. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD?

yes no

If yes, please explain: _____

_____

12. Did you understand all the questions?

yes no

_____

Signature

■ 16. Revise Appendix B, section IV., of §1910.1052 to read as follows:

§ 1910.1052 Methylene chloride.

* * * * *

APPENDIX B TO SECTION 1910.1052—MEDICAL SURVEILLANCE FOR METHYLENE CHLORIDE

* * * * *

IV. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

As discussed above, MC is classified as a suspect or potential human carcinogen. It is a central nervous system (CNS) depressant and a skin, eye and respiratory tract irritant. At extremely high concentrations, MC has caused liver damage in animals. MC principally affects the CNS, where it acts as a narcotic. The observation of the symptoms characteristic of CNS depression, along with a physical examination, provides the best detection of early neurological disorders. Since exposure to MC also increases the carboxyhemoglobin level in the blood, ambient carbon monoxide levels would have an additive effect on that carboxyhemoglobin level. Based on such information, a periodic post-shift carboxyhemoglobin test as an index of the presence of carbon monoxide in the blood is recommended, but not required, for medical surveillance.

Based on the animal evidence and three epidemiologic studies previously mentioned, OSHA concludes that MC is a suspect human carcinogen. The medical surveillance program is designed to observe exposed workers on a regular basis. While the medical surveillance program cannot detect MC-induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, early detection and treatments of cancers leading to enhanced survival rates will continue to evolve.

A. Medical and Occupational History:

The medical and occupational work history plays an important role in the initial evaluation of workers exposed to MC. It is therefore extremely important for the examining physician or other licensed health care professional to evaluate the MC-exposed worker carefully and completely and to focus the examination on MC's potentially associated health hazards. The medical evaluation must include an annual detailed work and medical history with special emphasis on cardiac history and neurological symptoms.

An important goal of the medical history is to elicit information from the worker regarding potential signs or symptoms associated with increased levels of carboxyhemoglobin due to the presence of carbon monoxide in the blood. Physicians or other licensed health care professionals should ensure that the smoking history of all MC exposed employees is known. Exposure to MC may cause a significant increase in carboxyhemoglobin level in all exposed persons. However, smokers as well as workers with anemia or heart disease and those concurrently exposed to carbon monoxide are at especially high risk of toxic effects because of an already reduced oxygen carrying capacity of the blood.

A comprehensive or interim medical and work history should also include occurrence of headache, dizziness, fatigue, chest pain, shortness of breath, pain in the limbs, and irritation of the skin and eyes.

In addition, it is important for the physician or other licensed health care professional to become familiar with the operating conditions in which exposure to MC is likely to occur. The physician or other licensed health care professional also must become familiar with the signs and symptoms that may indicate that a worker is receiving otherwise unrecognized and exceptionally high exposure levels of MC.

An example of a medical and work history that would satisfy the requirement for a comprehensive or interim work history is represented by the following:

The following is a list of recommended questions and issues for the self-administered questionnaire for methylene chloride exposure.

QUESTIONNAIRE FOR METHYLENE CHLORIDE EXPOSURE

I. Demographic Information

1. Name
2. Date
3. Date of Birth
4. Age
5. Present occupation
6. Sex
7. Race

II. Occupational History

1. Have you ever worked with methylene chloride, dichloromethane, methylene dichloride, or CH(2)Cl(2) (all are different names for the same chemical)? Please list which on the occupational history form if you have not already.

2. If you have worked in any of the following industries and have not listed them on the occupational history form, please do so.

Furniture stripping
Polyurethane foam manufacturing
Chemical manufacturing or formulation
Pharmaceutical manufacturing
Any industry in which you used solvents to clean and degrease equipment or parts
Construction, especially painting and refinishing
Aerosol manufacturing
Any industry in which you used aerosol adhesives

3. If you have not listed hobbies or household projects on the occupational history form, especially furniture refinishing, spray painting, or paint stripping, please do so.

III. Medical History

A. General

1. Do you consider yourself to be in good health? If no, state reason(s).

2. Do you or have you ever had:

   a. Persistent thirst
   b. Frequent urination (three times or more at night)
   c. Dermatitis or irritated skin
   d. Non-healing wounds

3. What prescription or non-prescription medications do you take, and for what reasons?

4. Are you allergic to any medications, and what type of reaction do you have?

B. Respiratory

1. Do you have or have you ever had any chest illnesses or diseases? Explain.

2. Do you have or have you ever had any of the following:

   a. Asthma
   b. Wheezing
   c. Shortness of breath

3. Have you ever had an abnormal chest X-ray? If so, when, where, and what were the findings?

4. Have you ever had difficulty using a respirator or breathing apparatus? Explain.

5. Do any chest or lung diseases run in your family? Explain.

6. Have you ever smoked cigarettes, cigars, or a pipe? Age started:

7. Do you now smoke?

8. If you have stopped smoking completely, how old were you when you stopped?

9. On the average of the entire time you smoked, how many packs of cigarettes, cigars, or bowls of tobacco did you smoke per day?

C. Cardiovascular

1. Have you ever been diagnosed with any of the following: Which of the following apply to you now or did apply to you at some time in the past, even if the problem is controlled by medication? Please explain any yes answers (i.e., when problem was diagnosed, length of time on medication).

    a. High cholesterol or triglyceride level

    b. Hypertension (high blood pressure)

    c. Diabetes

    d. Family history of heart attack, stroke, or blocked arteries

2. Have you ever had chest pain? If so, answer the next five questions.

    a. What was the quality of the pain (i.e., crushing, stabbing, squeezing)?

    b. Did the pain go anywhere (i.e., into jaw, left arm)?

    c. What brought the pain out?

    d. How long did it last?

    e. What made the pain go away?

3. Have you ever had heart disease, a heart attack, stroke, aneurysm, or blocked arteries anywhere in your body? Explain (when, treatment).

4. Have you ever had bypass surgery for blocked arteries in your heart or anywhere else? Explain.

5. Have you ever had any other procedures done to open up a blocked artery (balloon angioplasty, carotid endarterectomy, clot-dissolving drug)?

6. Do you have or have you ever had (explain each):

    a. Heart murmur
    b. Irregular heartbeat
    c. Shortness of breath while lying flat
    d. Congestive heart failure
    e. Ankle swelling

f. Recurrent pain anywhere below the waist while walking

7. Have you ever had an electrocardiogram (EKG)? When?

8. Have you ever had an abnormal EKG? If so, when, where, and what were the findings?

9. Do any heart diseases, high blood pressure, diabetes, high cholesterol, or high triglycerides run in your family? Explain.

D. Hepatobiliary and Pancreas

1. Do you now or have you ever drunk alcoholic beverages?
Age started: _____ Age stopped: _____.

2. Average numbers per week:

a. Beers: _____, ounces in usual container:
b. Glasses of wine: _____, ounces per glass:
c. Drinks: _____, ounces in usual container:

3. Do you have or have you ever had (explain each):

a. Hepatitis (infectious, autoimmune, drug-induced, or chemical)
b. Jaundice
c. Elevated liver enzymes or elevated bilirubin
d. Liver disease or cancer

E. Central Nervous System

1. Do you or have you ever had (explain each):

a. Headache
a. Dizziness
b. Fainting
c. Loss of consciousness
d. Garbled speech
e. Lack of balance
f. Mental/psychiatric illness
g. Forgetfulness

F. Hematologic

1. Do you have, or have you ever had (explain each):

   a. Anemia
   b. Sickle cell disease or trait
   c. Glucose-6-phosphate dehydrogenase deficiency
   d. Bleeding tendency disorder

2. If not already mentioned previously, have you ever had a reaction to sulfa drugs or to drugs used to prevent or treat malaria? What was the drug? Describe the reaction.

B. Physical Examination

The complete physical examination, when coupled with the medical and occupational history, assists the physician or other licensed health care professional in detecting pre-existing conditions that might place the employee at increased risk, and establishes a baseline for future health monitoring. These examinations should include:

1. Clinical impressions of the nervous system, cardiovascular function and pulmonary function, with additional tests conducted where indicated or determined by the examining physician or other licensed health care professional to be necessary.

2. An evaluation of the advisability of the worker using a respirator, because the use of certain respirators places an additional burden on the cardiopulmonary system. It is necessary for the attending physician or other licensed health care professional to evaluate the cardiopulmonary function of these workers, in order to inform the employer in a written medical opinion of the worker's ability or fitness to work in an area requiring the use of certain types of respiratory protective equipment. The presence of facial hair or scars that might interfere with the worker's ability to wear certain types of respirators should also be noted during the examination and in the written medical opinion.

   Because of the importance of lung function to workers required to wear certain types of respirators to protect themselves from MC exposure, these workers must receive an assessment of pulmonary function before they begin to wear a negative pressure respirator and at least annually thereafter. The recommended pulmonary function tests include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV(1)), as well as calculation of the ratios of FEV(1) to FVC, and the ratios of measured FVC and measured FEV(1) to expected respective values corrected for variation due to age, sex, race, and height. Pulmonary function evaluation must be conducted by a physician or other licensed health care professional experienced in pulmonary function tests.

The following is a summary of the elements of a physical exam which would fulfill the requirements under the MC standard:

PHYSICAL EXAM

I. Skin and appendages

1. Irritated or broken skin
2. Jaundice
3. Clubbing cyanosis, edema
4. Capillary refill time
5. Pallor

II. Head

1. Facial deformities
2. Scars
3. Hair growth

III. Eyes

1. Scleral icterus
2. Corneal arcus
3. Pupillary size and response
4. Fundoscopic exam

IV. Chest

1. Standard exam

V. Heart

1. Standard exam
2. Jugular vein distension
3. Peripheral pulses

VI. Abdomen

1. Liver span

VII. Nervous System

1. Complete standard neurologic exam

VIII. Laboratory

1. Hemoglobin and hematocrit
2. Alanine aminotransferase (ALT, SGPT)
3. Post-shift carboxyhemoglobin

IX. Studies

1. Pulmonary function testing
2. Electrocardiogram

An evaluation of the oxygen carrying capacity of the blood of employees (for example by measured red blood cell volume) is considered useful, especially for workers acutely exposed to MC.

It is also recommended, but not required, that end of shift carboxyhemoglobin levels be determined periodically, and any level above 3% for non-smokers and above 10% for smokers should prompt an investigation of the worker and his workplace. This test is recommended because MC is metabolized to CO, which combines strongly with hemoglobin, resulting in a reduced capacity of the blood to transport oxygen in the body. This is of particular concern for cigarette smokers because they already have a diminished hemoglobin capacity due to the presence of CO in cigarette smoke.

C. Additional Examinations and Referrals

1. Examination by a Specialist

When a worker examination reveals unexplained symptoms or signs (i.e. in the physical examination or in the laboratory tests), follow-up medical examinations are necessary to assure that MC exposure is not adversely affecting the worker's health. When the examining physician or other licensed health care professional finds it necessary, additional tests should be included to determine the nature of the medical problem and the underlying cause. Where relevant, the worker should be sent to a specialist for further testing and treatment as deemed necessary.

The final rule requires additional investigations to be covered and it also permits physicians or other licensed health care professionals to add appropriate or necessary tests to improve the diagnosis of disease should such tests become available in the future.

2. Emergencies

The examination of workers exposed to MC in an emergency should be directed at the organ systems most likely to be affected. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical intervention. It is not possible to precisely define "severe," but the physician or other licensed health care professional's judgement should not merely rest on hospitalization. If the worker has suffered significant conjunctival, oral, or nasal irritation, respiratory distress, or discomfort, the physician or other licensed health care professional should instigate appropriate follow-up procedures. These include attention to the eyes, lungs and the neurological system. The frequency of follow-up examinations should be determined by the attending physician or other licensed health care professional. This testing permits the early identification essential to proper medical management of such workers.

D. Employer Obligations

The employer is required to provide the responsible physician or other licensed health care professional and any specialists involved in a diagnosis with the following information: a copy of the MC standard including relevant appendices, a description of the affected employee's duties as they relate to his or her exposure to MC; an estimate of the employee's exposure including duration (e.g., 15hr/wk, three 8-hour shifts/wk, full time); a description of any personal protective equipment used by the employee, including respirators; and the results of any previous medical determinations for the affected employee related to MC exposure to the extent that this information is within the employer's control.

E. Physicians' or Other Licensed Health Care Professionals' Obligations

The standard requires the employer to ensure that the physician or other licensed health care professional provides a written statement to the employee and the employer. This statement should contain the physician's or licensed health care professional's opinion as to whether the employee has any medical condition placing him or her at increased risk of impaired health from exposure to MC or use of respirators, as appropriate. The physician or other licensed health care professional should also state his or her opinion regarding any restrictions that should be placed on the employee's exposure to MC or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to MC, the physician or other licensed health care professional's opinion should also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Furthermore, the employee should be informed by the physician or other licensed health care professional about the cancer risk of MC and about risk factors for heart disease, and the potential for exacerbation of underlying heart disease by exposure to MC through its metabolism to carbon monoxide. Finally, the physician or other licensed health care professional should inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation

or treatment. This written opinion must not contain any information on specific findings or diagnosis unrelated to employee's occupational exposures.

The purpose in requiring the examining physician or other licensed health care professional to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by exposure to MC, and to assess the employee's ability to use any required protective equipment.

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 17. The authority citation for part 1915 continues to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; 29 CFR part 1911.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

Subpart A—General Provisions

■ 18. Add paragraph (d)(6) to § 1915.5 to read as follows:

§ 1915.5 Incorporation by reference.

* * * * *

(d) * * *

(6) The following material is available for purchase from the International Labour Organization (ILO), 4 route des Morillons, CH–1211 Genève 22, Switzerland; telephone: +41 (0) 22 799 6111; fax: +41 (0) 22 798 8685; Web site: *http://www.ilo.org/.*

(i) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, Occupational safety and health series; 22 (Rev.2011), IBR approved for § 1915.1001, Appendix E.

* * * * *

Subpart F—General Working Conditions

■ 19. Revise paragraph (b)(33) of § 1915.80 to read as follows:

§ 1915.80 Scope, application, definitions, and effective dates.

* * * * *

(b) * * *

(33) *Vermin.* Insects, birds, rodents and other animals that may create safety and health hazards for employees.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 20. Amend § 1915.1001 by:
■ a. Revising paragraph (m)(2)(ii)(C);
■ b. Revising Appendix D;
■ c. Revising Appendix E;
■ d. Revising Appendix I, sections III and IV(iii).

The revisions read as follows:

§ 1915.1001 Asbestos.

* * * * *

(m) * * *

(2) * * *

(ii) * * *

(C) A physical examination directed to the pulmonary and gastrointestinal systems, including a 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray to be administered at the discretion of the physician, and pulmonary function tests of forced vital capacity (FVC) and forced expiratory volume at one second (FEV(1)). Classification of all chest X-rays shall be conducted in accordance with Appendix E to this section.

* * * * *

APPENDIX D TO § 1915.1001—MEDICAL QUESTIONNAIRES; MANDATORY

This mandatory appendix contains the medical questionnaires that must be administered to all employees who are exposed to asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals above the permissible exposure limit (0.1 f/cc), and who will therefore be included in their employer's medical surveillance program. Part 1 of the appendix contains the Initial Medical Questionnaire, which must be obtained for all new hires who will be covered by the medical surveillance requirements. Part 2 includes the abbreviated Periodical Medical Questionnaire, which must be administered to all employees who are provided periodic medical examinations under the medical surveillance provisions of the standard.

Part 1
INITIAL MEDICAL QUESTIONNAIRE

1. NAME_____
2. CLOCK NUMBER_____
3. PRESENT OCCUPATION_____
4. PLANT _____
5. ADDRESS_____
6. _____
   (Zip Code)
7. TELEPHONE NUMBER_____
8. INTERVIEWER_____
9. DATE _____
10. Date of Birth _____
    Month Day Year
11. Place of Birth _____
12. Sex
    1. Male ___
    2. Female ___
13. What is your marital status?
    1. Single ___
    2. Married ___
    3. Widowed ___
    4. Separated/ Divorced ___
14. Race
    1. White ___
    2. Black ___
    3. Asian ___
    4. Hispanic ___
    5. Indian ___
    6. Other ___
15. What is the highest grade completed in school? _____
    (For example 12 years is completion of high school)

OCCUPATIONAL HISTORY

16A. Have you ever worked full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 16A:

B. Have you ever worked for a year or more in any dusty job? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

Specify job/industry _____ Total Years Worked ___

Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

C. Have you ever been exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

Specify job/industry _____ Total Years Worked ___

Was exposure: 1. Mild ____ 2. Moderate ___ 3. Severe ___

D. What has been your usual occupation or job -- the one you have worked at the longest?

1. Job occupation _____
2. Number of years employed in this occupation _____
3. Position/job title _____
4. Business, field or industry _____

(Record on lines the years in which you have worked in any of these industries, e.g. 1960-1969)

Have you ever worked:	YES	NO
E. In a mine?	_____	_____
F. In a quarry?	_____	_____
G. In a foundry?	_____	_____
H. In a pottery?	_____	_____
I. In a cotton, flax or hemp mill?....	_____	_____
J. With asbestos?	_____	_____

17. PAST MEDICAL HISTORY	YES	NO
A. Do you consider yourself to be in good health?	_____	_____
If "NO" state reason _____		
B. Have you any defect of vision?	_____	_____
If "YES" state nature of defect _____		
C. Have you any hearing defect?	_____	_____
If "YES" state nature of defect _____		
D. Are you suffering from or have you ever suffered from:	YES	NO
a. Epilepsy (or fits, seizures, convulsions)?	_____	_____
b. Rheumatic fever?	_____	_____
c. Kidney disease?	_____	_____
d. Bladder disease?	_____	_____
e. Diabetes?	_____	_____
f. Jaundice?	_____	_____

18. CHEST COLDS AND CHEST ILLNESSES

18A. If you get a cold, does it "usually" go to your chest? (Usually means more than 1/2 the time)	1. Yes ___ 3. Don't get colds	2. No ___ ___
19A. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed?	1. Yes ___	2. No ___

IF YES TO 19A:

B. Did you produce phlegm with any of these chest illnesses? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. In the last 3 years, how many such illnesses with (increased) phlegm did you have which lasted a week or more? Number of illnesses ___ No such illnesses ___

20. Did you have any lung trouble before the age of 16? 1. Yes ___ 2. No ___

21. Have you ever had any of the following?

1A. Attacks of bronchitis? 1. Yes ___ 2. No ___

IF YES TO 1A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age was your first attack? Age in Years ___ Does Not Apply ___

2A. Pneumonia (include bronchopneumonia)? 1. Yes ___ 2. No ___

IF YES TO 2A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did you first have it? Age in Years ___ Does Not Apply ___

3A. Hay Fever? 1. Yes ___ 2. No ___

IF YES TO 3A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did it start? Age in Years ___ Does Not Apply ___

22A. Have you ever had chronic bronchitis? 1. Yes ___ 2. No ___

IF YES TO 22A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

23A. Have you ever had emphysema? 1. Yes ___ 2. No ___

IF YES TO 23A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

24A. Have you ever had asthma? 1. Yes ___ 2. No ___

IF YES TO 24A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

E. If you no longer have it, at what age did it stop? Age stopped ___
Does Not Apply ___

25. Have you ever had:

A. Any other chest illness? 1. Yes ___ 2. No ___

If yes, please specify _____

B. Any chest operations? 1. Yes ___ 2. No ___

If yes, please specify _____

C. Any chest injuries? 1. Yes ___ 2. No ___

If yes, please specify _____

26A. Has a doctor ever told you that you had heart trouble? 1. Yes ___ 2. No ___

IF YES TO 26A:

B. Have you ever had treatment for heart trouble in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

27A. Has a doctor told you that you had high blood pressure? 1. Yes ___ 2. No ___

IF YES TO 27A:

B. Have you had any treatment for high blood pressure (hypertension) in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

28. When did you last have your chest X-rayed? (Year) ___ ___ ___ ___

29. Where did you last have your chest X-rayed (if known)? _____

What was the outcome? _____

FAMILY HISTORY

30. Were either of your natural parents ever told by a doctor that they had a chronic lung condition such as:	FATHER			MOTHER		
	1. Yes	2. No	3. Don't know	1. Yes	2. No	3. Don't know
A. Chronic Bronchitis?	___	___	___	___	___	___
B. Emphysema?	___	___	___	___	___	___
C. Asthma?	___	___	___	___	___	___
D. Lung cancer?	___	___	___	___	___	___
E. Other chest conditions?	___	___	___	___	___	___
F. Is parent currently alive?	___	___	___	___	___	___
G. Please Specify	___ Age if Living ___ Age at Death ___ Don't Know			___ Age if Living ___ Age at Death ___ Don't Know		
H. Please specify cause of death	_____			_____		

COUGH

31A. Do you usually have a cough? (Count a cough with first smoke or on first going out of doors. Exclude clearing of throat.) (If no, skip to question 31C.)	1. Yes ___	2. No ___
B. Do you usually cough as much as 4 to 6 times a day 4 or more days out of the week?	1. Yes ___	2. No ___
C. Do you usually cough at all on getting up or first thing in the morning?	1. Yes ___	2. No ___

D. Do you usually cough at all during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF ABOVE (31A, B, C, OR D), ANSWER THE FOLLOWING. IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO NEXT PAGE

E. Do you usually cough like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had the cough? Number of years ___ Does not apply ___

32A. Do you usually bring up phlegm from your chest? Count phlegm with the first smoke or on first going out of doors. Exclude phlegm from the nose. Count swallowed phlegm.) (If no, skip to 32C) 1. Yes ___ 2. No ___

B. Do you usually bring up phlegm like this as much as twice a day 4 or more days out of the week? 1. Yes ___ 2. No ___

C. Do you usually bring up phlegm at all on getting up or first thing in the morning? 1. Yes ___ 2. No ___

D. Do you usually bring up phlegm at all on during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF THE ABOVE (32A, B, C, OR D), ANSWER THE FOLLOWING:

IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO 33A

E. Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had trouble with phlegm? Number of years ___ Does not apply ___

EPISODES OF COUGH AND PHLEGM

33A. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year?
*(For persons who usually have cough and/or phlegm)
1. Yes ___ 2. No ___

IF YES TO 33A

B. For how long have you had at least 1 such episode per year?
Number of years ___
Does not apply ___

WHEEZING

34A. Does your chest ever sound wheezy or whistling

1. When you have a cold? 1. Yes ___ 2. No ___

2. Occasionally apart from colds? 1. Yes ___ 2. No ___

3. Most days or nights? 1. Yes ___ 2. No ___

B. For how many years has this been present?
Number of years ___
Does not apply ___

35A. Have you ever had an attack of wheezing that has made you feel short of breath? 1. Yes ___ 2. No ___

IF YES TO 35A

B. How old were you when you had your first such attack?
Age in years ___
Does not apply ___

C. Have you had 2 or more such episodes? 1. Yes ___ 2. No ___ 3. Does not apply ___

D. Have you ever required medicine or treatment for the(se) attack(s)? 1. Yes ___ 2. No ___ 3. Does not apply ___

BREATHLESSNESS

36. If disabled from walking by any condition other than heart or lung disease, please describe and proceed to question 38A. — Nature of condition(s) _____ _____

37A. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill? — 1. Yes ___ 2. No ___

IF YES TO 37A

B. Do you have to walk slower than people of your age on the level because of breathlessness? — 1. Yes ___ 2. No ___ 3. Does not apply ___

C. Do you ever have to stop for breath when walking at your own pace on the level? — 1. Yes ___ 2. No ___ 3. Does not apply ___

D. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level? — 1. Yes ___ 2. No ___ 3. Does not apply ___

E. Are you too breathless to leave the house or breathless on dressing or climbing one flight of stairs? — 1. Yes ___ 2. No ___ 3. Does not apply ___

TOBACCO SMOKING

38A. Have you ever smoked cigarettes? (No means less than 20 packs of cigarettes or 12 oz. of tobacco in a lifetime or less than 1 cigarette a day for 1 year.) — 1. Yes ___ 2. No ___

IF YES TO 38A

B. Do you now smoke cigarettes (as of one month ago) — 1. Yes ___ 2. No ___ 3. Does not apply ___

C. How old were you when you first started regular cigarette smoking?	Age in years ___ Does not apply ___
D. If you have stopped smoking cigarettes completely, how old were you when you stopped?	Age stopped ___ Check if still smoking ___ Does not apply ___
E. How many cigarettes do you smoke per day now?	Cigarettes per day ___ Does not apply ___
F. On the average of the entire time you smoked, how many cigarettes did you smoke per day?	Cigarettes per day ___ Does not apply ___
G. Do or did you inhale the cigarette smoke?	1. Does not apply ___ 2. Not at all ___ 3. Slightly ___ 4. Moderately ___ 5. Deeply ___
39A. Have you ever smoked a pipe regularly? (Yes means more than 12 oz. of tobacco in a lifetime.)	1. Yes ___ 2. No ___

IF YES TO 39A:
FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started to smoke a pipe regularly?	Age ___
2. If you have stopped smoking a pipe completely, how old were you when you stopped?	Age stopped ___ Check if still smoking pipe ___ Does not apply ___
C. On the average over the entire time you smoked a pipe, how much pipe tobacco did you smoke per week?	___ oz. per week (a standard pouch of tobacco contains 1 1/2 oz.) ___ Does not apply

D. How much pipe tobacco are you smoking now?

oz. per week ___
Not currently smoking a pipe ___

E. Do you or did you inhale the pipe smoke?

1. Never smoked ___
2. Not at all ___
3. Slightly ___
4. Moderately ___
5. Deeply ___

40A. Have you ever smoked cigars regularly?

1. Yes ___ 2. No ___

(Yes means more than 1 cigar a week for a year)

IF YES TO 40A

FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started smoking cigars regularly?

Age ___

2. If you have stopped smoking cigars completely, how old were you when you stopped smoking cigars?

Age stopped ___
Check if still ___
Does not apply ___

C. On the average over the entire time you smoked cigars, how many cigars did you smoke per week?

Cigars per week ___
Does not apply ___

D. How many cigars are you smoking per week now?

Cigars per week ___
Check if not smoking cigars currently ___

E. Do or did you inhale the cigar smoke?

1. Never smoked ___
2. Not at all ___
3. Slightly ___
4. Moderately ___
5. Deeply ___

Signature _____ Date _____

Part 2
PERIODIC MEDICAL QUESTIONNAIRE

1. NAME _____
2. CLOCK NUMBER ___ ___ ___ ___ ___ ___ ___
3. PRESENT OCCUPATION _____
4. PLANT _____
5. ADDRESS _____
6. _____
(Zip Code)
7. TELEPHONE NUMBER _____
8. INTERVIEWER _____
9. DATE _____
10. What is your marital status? 1. Single ___ 2. Married ___ 3. Widowed ___ 4. Separated/ Divorced ___

11. OCCUPATIONAL HISTORY

11A. In the past year, did you work full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 11A:

11B. In the past year, did you work in a dusty job? 1. Yes ___ 2. No ___ 3. Does not Apply ___

11C. Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11D. In the past year, were you exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

11E. Was exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11F. In the past year, what was your: 1. Job/occupation? _____ 2. Position/job title? _____

12. RECENT MEDICAL HISTORY

12A. Do you consider yourself to be in good health? Yes ___ No ___

If NO, state reason _____

12B. In the past year, have you developed:

	Yes	No
Epilepsy?	___	___
Rheumatic fever?	___	___
Kidney disease?	___	___
Bladder disease?	___	___
Diabetes?	___	___
Jaundice?	___	___
Cancer?	___	___

13. CHEST COLDS AND CHEST ILLNESSES

13A. If you get a cold, does it "usually" go to your chest? (usually means more than 1/2 the time)

1. Yes ___ 2. No ___
3. Don't get colds ___

14A. During the past year, have you had any chest illnesses that have kept you off work, indoors at home, or in bed?

1. Yes ___ 2. No ___
3. Does Not Apply ___

IF YES TO 14A:

14B. Did you produce phlegm with any of these chest illnesses?

1. Yes ___ 2. No ___
3. Does Not Apply ___

14C. In the past year, how many such illnesses with (increased) phlegm did you have which lasted a week or more?

Number of illnesses ___
No such illnesses ___

15. RESPIRATORY SYSTEM

In the past year have you had:

	Yes or No	Further Comment on Positive Answers
Asthma	_____	
Bronchitis	_____	
Hay Fever	_____	

Other Allergies	_____	
	Yes or No	Further Comment on Positive Answers
Pneumonia	_____	
Tuberculosis	_____	
Chest Surgery	_____	
Other Lung Problems	_____	
Heart Disease	_____	
Do you have:		
	Yes or No	Further Comment on Positive Answers
Frequent colds	_____	
Chronic cough	_____	
Shortness of breath when walking or climbing one flight or stairs	_____	
Do you:		
Wheeze	_____	
Cough up phlegm	_____	
Smoke cigarettes	_____	Packs per day ____ How many years ___

Date _____ Signature _____

APPENDIX E TO §1915.1001—CLASSIFICATION OF CHEST X-RAYS.

MANDATORY

(a) Chest X-rays shall be classified in accordance with the International Labour Organization (ILO) Classification of Radiographs of Pneumoconioses (revised edition 2011) (incorporated by reference, see § 1915.5), and recorded on a classification form following the format of the CDC/NIOSH (M) 2.8 form. As a minimum, the content within the bold lines of this form (items 1 through 4) shall be included. This form is not to be submitted to NIOSH.

(b) All X-rays shall be classified only by a B-reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses.

(c) Whenever classifying chest X-rays made under this section, the physician shall have immediately available for reference a complete set of the ILO Classification of Radiographs for Pneumoconioses (revised edition 2011) and the Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses (revised edition 2011).

* * * * *

Appendix I TO §1915.1001—MEDICAL SURVEILLANCE GUIDELINES FOR ASBESTOS, NON-MANDATORY

* * * * *

III. Signs and Symptoms of Exposure-Related Disease

The signs and symptoms of lung cancer or gastrointestinal cancer induced by exposure to asbestos are not unique, except that a chest X-ray of an exposed patient with lung cancer may show pleural plaques, pleural calcification, or pleural fibrosis, and may also show asbestosis (i.e., small irregular parenchymal opacities). Symptoms characteristic of mesothelioma include shortness of breath, pain in the chest or abdominal pain. Mesothelioma has a much longer average latency period compared with lung cancer (40 years versus 15-20 years), and mesothelioma is therefore more likely to be found among workers who were first exposed to asbestos at an early age. Mesothelioma is a fatal disease.

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. Symptoms include shortness of breath, coughing, fatigue, and vague feelings of sickness. When the fibrosis worsens, shortness of breath occurs even at rest. The diagnosis of asbestosis is most commonly based on a history of exposure to asbestos, the presence of characteristic radiologic abnormalities, end-inspiratory crackles (rales), and other clinical features of fibrosing lung disease. Pleural plaques and thickening may be observed on chest X-rays. Asbestosis is often a progressive disease even in the absence of continued exposure, although this appears to be a highly individualized characteristic. In severe cases, death may be caused by respiratory or cardiac failure.

IV. Surveillance and Preventive Considerations

* * * * *

(iii) A physical examination including a chest X-ray and pulmonary function test that includes measurement of the employee's forced vital capacity (FVC) and forced expiratory volume at one second (FEV(1)).

* * * * *

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart A—General

■ 21. The authority citation for subpart A continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), or 5–2007 (72 FR 31160), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 22. Amend § 1926.6 by:

■ a. Revising paragraph (u)(1) and removing and reserving (u)(2);

■ b. Redesignating paragraphs (x)(1) through (3) as paragraphs (x)(4) through (6), and adding new paragraphs (x)(1) through (3);

■ c. Revising paragraph (dd); and

■ d. Adding paragraphs (gg) and (hh).

The revisions and additions read as follows:

§ 1926.6 Incorporation by reference.

* * * * *

(u) * * *

(1) Manual on Uniform Traffic Control Devices, 2009 Edition, Part 6, May 2012, IBR approved for §§ 1926.200(g) and 1926.201(a).

* * * * *

(x) * * *

(1) ISO 27850:2013, Tractors for agriculture and forestry—Falling object protective structures—Test procedures and performance requirements, First Edition, May.01, 2013 (''ISO 27850:2013''), IBR approved for § 1926.1003(c).

(2) ISO 3471:2008, Earth-moving machinery—Roll-over protective structures—Laboratory tests and performance requirements, Fourth Edition, Aug. 8, 2008 (''ISO 3471:2008''), IBR approved for § 1926.1001(c).

(3) ISO 5700:2013, Tractors for agriculture and forestry—Roll-over protective structures—Static test method and conditions, Fifth Edition, May 1, 2013 (''ISO 5700:2013''), IBR approved for § 1926.1002(c).

* * * * *

(dd) The following material is available for purchase from the Society of Automotive Engineers (SAE), 400 Commonwealth Drive, Warrendale, PA 15096; telephone: 1–877–606–7323; fax: 724–776–0790; Web site: *http://www.sae.org/:*

(1) SAE 1970 Handbook, IBR approved for § 1926.602(b).

(2) SAE J166–1971, Trucks and Wagons, IBR approved for § 1926.602(a).

(3) SAE J167–1970, Protective Frame with Overhead Protection-Test Procedures and Performance Requirements, IBR approved for § 1926.1003(b).

(4) SAE J168–1970, Protective Enclosures-Test Procedures and Performance Requirements, IBR approved for § 1926.1002(b).

(5) SAE J185 (reaf. May 2003), Access Systems for Off-Road Machines, reaffirmed May 2003 (''SAE J185 (May 1993)''), IBR approved for § 1926.1423(c).

(6) SAE J236–1971, Self-Propelled Graders, IBR approved for § 1926.602(a).

(7) SAE J237–1971, Front End Loaders and Dozers, IBR approved for § 1926.602(a).

(8) SAE J319b–1971, Self-Propelled Scrapers, IBR approved for § 1926.602(a).

(9) SAE J320a–1971, Minimum Performance Criteria for Roll-Over Protective Structure for Rubber-Tired, Self-Propelled Scrapers, IBR approved for § 1926.1001(b).

(10) SAE J321a–1970, Fenders for Pneumatic-Tired Earthmoving Haulage Equipment, IBR approved for § 1926.602(a).

(11) SAE J333a–1970, Operator Protection for Agricultural and Light Industrial Tractors, IBR approved for § 1926.602(a).

(12) SAE J334a–1970, Protective Frame Test Procedures and Performance Requirements, IBR approved for § 1926.1002(b).

(13) SAE J386–1969, Seat Belts for Construction Equipment, IBR approved for § 1926.602(a).

(14) SAE J394–1971, Minimum Performance Criteria for Roll-Over Protective Structure for Rubber-Tired Front End Loaders and Robber-Tired Dozers, IBR approved for 1926.1001(b).

(15) SAE J395–1971, Minimum Performance Criteria for Roll-Over Protective Structure for Crawler Tractors and Crawler-Type Loaders, IBR approved for § 1926.1001(b).

(16) SAE J396–1971, Minimum Performance Criteria for Roll-Over Protective Structure for Motor Graders, IBR approved for § 1926.1001(b).

(17) SAE J397–1969, Critical Zone Characteristics and Dimensions for Operators of Construction and Industrial Machinery, IBR approved for § 1926.1001(b).

(18) SAE J743a–1964, Tractor Mounted Side Boom, 1964 (''SAE J743a–1964''), IBR approved for § 1926.1501(a).

(19) SAE J959–1966, Lifting Crane Wire-Rope Strength Factors, 1966 (''SAE J959–1966''), IBR approved for § 1926.1501(a).

(20) SAE J987 (rev. Jun. 2003), Lattice Boom Cranes—Method of Test, revised Jun. 2003 (''SAE J987 (Jun. 2003)''), IBR approved for § 1926.1433(c).

(21) SAE J1063 (rev. Nov. 1993), Cantilevered Boom Crane Structures—Method of Test, revised Nov. 1993 (''SAE J1063 (Nov. 1993)''), IBR approved for § 1926.1433(c).

* * * * *

(gg) The following material is available for purchase from the French government at *http://www.journal-officiel.gouv.fr/.*

(1) Travaux en milieu hyperbare, measures particulières de prévention (Work in hyperbaric environment, specific prevention measures). J.O. Rep. Franç. Brochure n° 1636, June 1992.

(2) [Reserved]

(hh) The following material is available for purchase from the International Labour Organization (ILO), 4 route des Morillons, CH–1211 Genève 22, Switzerland; telephone: +41 (0) 22 799 6111; fax: +41 (0) 22 798 8685; Web site: *http://www.ilo.org/.*

(1) Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2011, Occupational safety and health series; 22 (Rev. 2011), IBR approved for § 1926.1101, Appendix E.

(2) [Reserved]

Subpart D—Occupational Health and Environmental Controls

■ 23. Revise the authority citation for subpart D to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Sections 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.61 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Section 1926.62 also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

■ 24. Revise paragraph (f) of § 1926.50 to read as follows:

§ 1926.50 Medical services and first aid.

* * * * *

(f)(1) In areas where 911 emergency dispatch services are not available, the telephone numbers of the physicians, hospitals, or ambulances shall be conspicuously posted.

(2) In areas where 911 emergency dispatch services are available and an employer uses a communication system for contacting necessary emergency-medical service, the employer must:

(i) Ensure that the communication system is effective in contacting the emergency-medical service; and

(ii) When using a communication system in an area that does not automatically supply the caller's latitude and longitude information to the 911 emergency dispatcher, the employer must post in a conspicuous location at the worksite either:

(A) The latitude and longitude of the worksite; or

(B) Other location-identification information that communicates effectively to employees the location of the worksite.

Note to paragraph (f)(2)(ii) of this section: The requirement specified in paragraph (f)(2)(ii) of this section does not apply to worksites with readily available telephone land lines that have 911 emergency service that automatically identifies the location of the caller.

* * * * *

■ 25. Amend § 1926.55 by:

■ a. Revising paragraph (a);

■ b. Revising paragraph (c);

■ c. In appendix A:

■ i. Revising the heading;

■ ii. Removing the entry for ''Coke Oven Emissions'';

■ iii. Revising entries for ''Asbestos''; ''Talc (containing asbestos); use asbestos limit''; ''Tremolite, asbestiform'';

Footnote 3; and the footnote designated by a single asterisk;

■ iv. Removing Footnote 4 and the footnote designated by double asterisks.

The revisions read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

(a) *Permissible Exposure Limits.* Employers must limit an employee's exposure to any substance listed in Table A of this section in accordance with the following:

(1) *Substances with limits preceded by (C)—Ceiling Values.* An employee's exposure, as determined from breathing-zone air samples, to any substance in Table A with a permissible exposure limit preceded by (C) must at no time exceed the exposure limit specified for that substance. If instantaneous monitoring is not feasible, then the employer must assess the ceiling as a 15-minute time-weighted average exposure that the employer cannot exceed at any time during the working day.

(2) *Other substances—8-hour Time Weighted Averages.* An employee's exposure, as determined from breathing-zone air samples, to any substance in Table A with a permissible exposure limit not preceded by (C) must not exceed the limit specified for that substance measured as an 8-hour time-weighted average in any work shift.

* * * * *

(c) Paragraphs (a) and (b) of this section do not apply to the exposure of employees to airborne asbestos, tremolite, anthophyllite, or actinolite dust. Whenever any employee is exposed to airborne asbestos, tremolite, anthophyllite, or actinolite dust, the requirements of § 1926.1101 of this title shall apply.

* * * * *

TABLE A TO § 1926.55—PERMISSIBLE EXPOSURE LIMITS FOR AIRBORNE CONTAMINANTS

Substance	CAS No. [d]	ppm [a]	mg/m^3 [b]	Skin designation
* * * * *				
Asbestos; see § 1926.1101.				
* * * * *				
Talc (containing asbestos); use asbestos limit; see § 1926.1101.				
* * * * *				
Tremolite, asbestiform; see § 1926.1101.				
* * * * *				

Footnotes

* * * * *

[3] Use Asbestos Limit § 1926.1101.

* * * * *

* An ''X'' designation in the ''Skin Designation'' column indicates that the substance is a dermal hazard.

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * *

■ 26. Revise § 1926.64 to read as follows:

§ 1926.64 Process safety management of highly hazardous chemicals.

For requirements regarding the process safety management of highly hazardous chemicals as it pertains to construction work, follow the requirements in 29 CFR 1910.119 of this chapter.

Subpart E—Personal Protective and Life Saving Equipment

■ 27. The authority citation for subpart E continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.;* 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 28. Revise paragraph (c) of § 1926.95 to read as follows:

§ 1926.95 Criteria for personal protective equipment.

* * * * *

(c) *Design and selection.* Employers must ensure that all personal protective equipment:

(1) Is of safe design and construction for the work to be performed; and

(2) Is selected to ensure that it properly fits each affected employee.

* * * * *

■ 29. Revise paragraph (c) of § 1926.104 to read as follows:

§ 1926.104 Safety belts, lifelines, and lanyards.

* * * * *

(c) Lifelines used on rock-scaling operations, or in areas where the lifeline may be subjected to cutting or abrasion, shall be a minimum of 7/8-inch wire core manila rope. For all other lifeline applications, a minimum of 3/4-inch manila or equivalent, with a minimum breaking strength of 5,000 pounds, shall be used.

* * * * *

Subpart G—Signs, Signals, and Barricades

■ 30. The authority citation for subpart G continues to read as follows:

Authority: 40 U.S.C. 333; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 31. Revise paragraph (g) of § 1926.200 to read as follows:

§ 1926.200 Accident prevention signs, devices, and tags.

* * * * *

(g) *Traffic control signs and devices.* (1) At points of hazard, construction areas shall be posted with legible traffic control signs and protected by traffic control devices.

(2) The design and use of all traffic control devices, including signs, signals, markings, barricades, and other devices, for protection of construction workers shall conform to Part VI of the MUTCD, 2009 Edition, including Revision 1 dated May 2012 and Revision 2 dated May 2012, FHWA (incorporated by reference, see § 1926.6).

* * * * *

■ 32. Revise paragraph (a) of § 1926.201 to read as follows:

§ 1926.201 Signaling.

(a) *Flaggers.* Signaling by flaggers and the use of flaggers, including warning garments worn by flaggers, shall conform to Part VI of the Manual on Uniform Traffic Control Devices, 2009 Edition, including Revision 1 dated May 2012 and Revision 2 dated May 2012, FHWA (incorporated by reference, see § 1926.6).

* * * * *

§ 1926.202 [Removed]

■ 33. Remove § 1926.202.

§ 1926.203 [Removed]

■ 34. Remove § 1926.203.

Subpart H—Materials Handling, Storage, Use, and Disposal

■ 35. The authority citation for subpart H continues to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable.

Section 1926.250 also issued under 29 CFR part 1911.

■ 36. Revise paragraph (a)(2) of § 1926.250 to read as follows:

§ 1926.250 General requirements for storage.

(a) * * *

(2) Employers must:

(i) Post the maximum safe load limits of the floors within buildings and structures, in pounds per square foot, conspicuously in all storage areas, except for floors or slabs on grade, and except that employers need not post limits in detached single-family dwellings or townhouses that are under construction; and

(ii) Ensure that loads on floors do not exceed the maximum safe loads of the floors.

* * * * *

Subpart P—Excavations

■ 37. The authority citation for subpart P is revised to read as follows:

Authority: Sec. 107, Contract Worker Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), or 1–2012 (77 FR 3912), as applicable.

■ 38. Revise paragraph (j) of § 1926.651 to read as follows:

§ 1926.651 Specific excavation requirements.

* * * * *

(j) *Protection of employees from loose rock or soil.* (1) Where there is loose rock or soil on the excavation face, employers must use scaling to remove the loose material; install protective barricades at intervals as necessary on the face to stop and contain falling material; or use other means that provide equivalent protection.

(2) Protection from excavated or other materials or equipment shall be provided by placing and keeping excavated or other materials or equipment at least 2 feet (.61 m) from the edge of excavations, or by the use of retaining devices that are sufficient to prevent materials or equipment from falling or rolling into excavations, or by a combination of both if necessary.

* * * * *

Subpart S—Underground Construction, Caissons, Cofferdams, and Compressed Air

■ 39. The authority citation for subpart S continues to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83

(48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable.

■ 40. Revise paragraph (k)(10) of § 1926.800 to read as follows:

§ 1926.800 Underground construction.

* * * * *

(k) * * *

(10)(i) Internal combustion engines, except diesel-powered engines on mobile equipment, are prohibited underground.

(ii) Mobile diesel-powered equipment used underground in atmospheres other than gassy operations purchased on or before [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall

(A) Comply with paragraph (k)(10)(iii); or

(B) Have been approved by MSHA under 30 CFR part 32 (formerly Schedule 24) (1995), or be demonstrated by the employer to be fully equivalent to such MSHA-approved equipment, and be operated in accordance with that part. For purposes of this subsection, when an applicable MSHA provision uses the term ''mine,'' use the phrase ''underground construction site.'' (Each brake horsepower of a diesel engine requires at least 100 cubic feet (28.32 m^3) of air per minute for suitable operation in addition to the air requirements for personnel. Some engines may require a greater amount of air to ensure that the allowable levels of carbon monoxide, nitric oxide, and nitrogen dioxide are not exceeded.)

(iii) Mobile diesel-powered equipment used underground in atmospheres other than gassy operations purchased after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] shall comply with MSHA provisions 30 CFR 57.5067, 75.1909, 75.1910, and 75.1911(a) through (i) and shall be operated in accordance with those provisions. For purposes of this subsection, when an applicable MSHA provision uses the term ''mine,'' use the phrase ''underground construction site.'' (Each brake horsepower of a diesel engine requires at least 100 cubic feet (28.32 m^3) of air per minute for suitable operation in addition to the air requirements for personnel. Some engines may require a greater amount of air to ensure that the allowable levels of carbon monoxide, nitric oxide, and nitrogen dioxide are not exceeded.)

* * * * *

■ 41. Revise paragraph (f)(1) of § 1926.803 to read as follows:

§ 1926.803 Compressed Air.

* * * * *

(f) * * *

(1) Decompression to normal condition shall be in accordance with the 1992 French Air and Oxygen decompression tables (incorporated by reference, see § 1926.6).

* * * * *

Appendix A to Subpart S of Part 1926 [Removed]

■ 42. Remove appendix A to subpart S of part 1926.

Subpart W—Rollover Protective Structures; Overhead Protection

■ 43. The authority citation for subpart W is revised to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), or 1–2012 (77 FR 3912), as applicable.

■ 44. Amend § 1926.1000 by:

■ a. Revising the section heading;

■ b. Revising paragraphs (a) through (c).

The revisions read as follows:

§ 1926.1000 Scope.

(a) *Coverage.* This subpart applies to the following types of material handling equipment: All rubber-tired, self-propelled scrapers, rubber-tired front-end loaders, rubber-tired dozers, wheel-type agricultural and industrial tractors, crawler tractors, crawler-type loaders, and motor graders, with or without attachments, that are used in construction work. This subpart also applies to compactors and rubber-tired skid-steer equipment, with or without attachments, manufactured after *[EFFECTIVE DATE OF FINAL RULE],* that are used in construction work. This subpart does not apply to sideboom pipelaying tractors.

(b) *Equipment manufactured before [EFFECTIVE DATE OF FINAL RULE].* Material handling equipment described in paragraph (a) of this section (excluding compactors and rubber-tired skid-steer equipment) manufactured before *[EFFECTIVE DATE OF FINAL RULE],* shall be equipped with rollover protective structures that meet the minimum performance standards prescribed in § 1926.1001(b), as applicable. Agricultural and industrial tractors used in construction shall be equipped with rollover protective structures that meet the minimum performance standards prescribed in § 1926.1002(b), as applicable. When overhead protection is provided on agricultural and industrial tractors, the overhead protection shall meet the minimum performance standards prescribed in § 1926.1003(b), as applicable.

(c) *Equipment manufactured on or after [EFFECTIVE DATE OF FINAL RULE].* Material handling machinery described in paragraph (a) of this section manufactured on or after *[EFFECTIVE DATE OF FINAL RULE],* shall be equipped with rollover protective structures that meet the minimum performance standards prescribed in § 1926.1001(c). Agricultural and industrial tractors used in construction shall be equipped with rollover protective structures that meet the minimum performance standards prescribed in § 1926.1002(c). When overhead protection is provided on agricultural and industrial tractors, the overhead protection shall meet the minimum performance standards prescribed in § 1926.1003(c).

* * * * *

■ 45. Section 1926.1001 is revised to read as follows:

§ 1926.1001 Minimum performance criteria for rollover protective structures for designated scrapers, loaders, dozers, graders, crawler tractors, compactors, and rubber-tired skid steer equipment.

(a) *General.* This section prescribes minimum performance criteria for roll-over protective structures (ROPS) for rubber-tired self-propelled scrapers; rubber-tired front end loaders and rubber-tired dozers; crawler tractors and crawler-type loaders, motor graders, compactors, and rubber-tired skid steer equipment.

(b) *Equipment manufactured before [EFFECTIVE DATE OF FINAL RULE].* For equipment listed in paragraph (a) of this section (excluding compactors and rubber-tired skid steer equipment) manufactured before *[EFFECTIVE DATE OF FINAL RULE],* the protective frames shall conform to the following Society of Automotive Engineers Recommended Practices as applicable: SAE J320a, Minimum Performance Criteria for Roll-Over Protective Structure for Rubber-Tired, Self-Propelled Scrapers; SAE J394, Minimum Performance Criteria for Roll-Over Protective Structure for Rubber-Tired Front End Loaders and Rubber-Tired Dozers; SAE J395, Minimum Performance Criteria for Roll-Over Protective Structure for Crawler Tractors and Crawler-Type Loaders; SAE J396, Minimum Performance Criteria for Roll-Over Protective Structure for Motor Graders; and SAE J397–1969, Critical Zone Characteristics and Dimensions for Operators of Construction and Industrial Machinery, as applicable (each incorporated by

reference, see § 1926.6), or comply with the consensus standard (ISO 3471–2008) listed in paragraph (c) of this section.

(c) *Equipment manufactured on or after [EFFECTIVE DATE OF FINAL RULE].* For equipment listed in paragraph (a) of this section manufactured on or after *[EFFECTIVE DATE OF FINAL RULE],* the protective frames shall meet the test and performance requirements of the International Organization for Standardization (ISO) standard ISO 3471–2008 Earth-Moving Machinery—Roll-over protective structures—Laboratory tests and performance requirements (incorporated by reference, see § 1926.6).

■ 46. Amend § 1926.1002 by:

■ a. Revising paragraphs (a) through (d);

■ b. Removing paragraphs (e) through (i);

■ c. Redesignating paragraphs (j)(1) and (2) as (e)(1) and (2), respectively;

■ d. Removing paragraphs (j)(3) and (k).

The revisions read as follows:

§ 1926.1002 Protective frames (roll-over protective structures, known as ROPS) for wheel-type agricultural and industrial tractors used in construction.

(a) *General.* This section sets forth requirements for frames used to protect operators of wheel-type agricultural and industrial tractors used in construction work that will minimize the possibility of operator injury resulting from accidental upsets during normal operation. See paragraph (e) of this section for definitions of agricultural and industrial tractors.

(b) *Equipment manufactured before [EFFECTIVE DATE OF FINAL RULE].* For equipment manufactured before *[EFFECTIVE DATE OF FINAL RULE],* the protective frames shall meet the test and performance requirements of the Society of Automotive Engineers Standard J334a–1970, Protective Frame Test Procedures and Performance Requirements and J168–1970, Protective enclosures-test procedures and performance requirements, as applicable (incorporated by reference, see § 1926.6), or comply with the consensus standard (ISO 5700–2013) listed in paragraph (c) of this section.

(c) *Equipment manufactured on or after [EFFECTIVE DATE OF FINAL RULE].* For equipment manufactured on or after *[EFFECTIVE DATE OF FINAL RULE],* the protective frames shall meet the test and performance requirements of the International Organization for Standardization (ISO) standard ISO 5700–2013, Tractors for agriculture and forestry—Roll-over protective structures—static test method and acceptance conditions (incorporated by reference, see § 1926.6).

(d) For overhead protection requirements, see 29 CFR 1926.1003.

* * * * *

■ 47. Section 1926.1003 is revised to read as follows:

§ 1926.1003 Overhead protection for operators of agricultural and industrial tractors used in construction.

(a) *General.* This section sets forth requirements for overhead protection used to protect operators of wheel-type agricultural and industrial tractors used in construction work that will minimize the possibility of operator injury resulting from overhead objects such as flying or falling objection, and from the cover itself in the event of accidental upset.

(b) *Equipment manufactured before [EFFECTIVE DATE OF FINAL RULE].* When overhead protection is provided on wheel-type agricultural and industrial tractors manufactured before *[EFFECTIVE DATE OF FINAL RULE],* the overhead protection shall be designed and installed according to the requirements contained in the test and performance requirements of Society of Automotive Engineers Standard J167–1970, Protective Frame with Overhead Protection-Test Procedures and Performance Requirements, which pertains to overhead protection requirements (incorporated by reference, see § 1926.6) or comply with the consensus standard (ISO 3449–2005) listed in paragraph (c) of this section.

(c) *Equipment manufactured on or after [EFFECTIVE DATE OF FINAL RULE].* When overhead protection is provided on wheel-type agricultural and industrial tractors manufactured on or after [insert effective date of the final rule], the overhead protection shall be designed and installed according to the requirements contained in the test and performance requirements of the International Organization for Standardization (''ISO'') standard ISO 27850–2013, Tractors for agriculture and forestry—Falling object protective structures—Test procedures and performance requirements, which pertains to overhead protection requirements (incorporated by reference, see § 1926.6).

(d) *Site clearing.* In the case of machines to which 29 CFR 1926.604 (relating to site clearing) also applies, the overhead protection may be either the type of protection provided in 29 CFR 1926.604, or the type of protection provided by this section.

Appendix A to Subpart W of Part 1926 [Removed]

■ 48. Remove appendix A to subpart W of part 1926.

Subpart Z—Toxic and Hazardous Substances

■ 49. The authority citation for subpart Z continues to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

■ 50. Amend § 1926.1101 by:

■ a. Revising paragraph (m)(2)(ii)(C);

■ b. Revising Appendix D;

■ c. Revising Appendix E;

■ d. Revising Appendix I, sections III and IV(iii).

The revisions read as follows:

§ 1926.1101 Asbestos.

* * * * *

(m) * * *

(2) * * *

(ii) * * *

(C) A physical examination directed to the pulmonary and gastrointestinal systems, including a 14- by 17-inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray to be administered at the discretion of the physician, and pulmonary function tests of forced vital capacity (FVC) and forced expiratory volume at one second (FEV(1)). Classification of all chest X-rays shall be conducted in accordance with Appendix E to this section.

* * * * *

APPENDIX D TO §1926.1101—MEDICAL QUESTIONNAIRES; MANDATORY

This mandatory appendix contains the medical questionnaires that must be administered to all employees who are exposed to asbestos above permissible exposure limit, and who will therefore be included in their employer's medical surveillance program. Part 1 of the appendix contains the Initial Medical Questionnaire, which must be obtained for all new hires who will be covered by the medical surveillance requirements. Part 2 includes the abbreviated Periodical Medical Questionnaire, which must be administered to all employees who are provided periodic medical examinations under the medical surveillance provisions of the standard.

Part 1

INITIAL MEDICAL QUESTIONNAIRE

1. NAME_____
2. CLOCK NUMBER_____
3. PRESENT OCCUPATION_____
4. PLANT _____
5. ADDRESS_____
6. _____
   (Zip Code)
7. TELEPHONE NUMBER_____
8. INTERVIEWER_____
9. DATE _____
10. Date of Birth _____
    Month Day Year
11. Place of Birth _____
12. Sex
    1. Male ___
    2. Female ___
13. What is your marital status?
    1. Single ___
    2. Married ___
    3. Widowed ___
    4. Separated/ Divorced ___
14. Race
    1. White ___
    2. Black ___
    3. Asian ___
    4. Hispanic ___
    5. Indian ___
    6. Other ___
15. What is the highest grade completed in school? _____
    (For example 12 years is completion of high school)

OCCUPATIONAL HISTORY

16A. Have you ever worked full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 16A:

B. Have you ever worked for a year or more in any dusty job? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

Specify job/industry _____ Total Years Worked ___

Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

C. Have you ever been exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

Specify job/industry _____ Total Years Worked ___

Was exposure: 1. Mild ____ 2. Moderate ___ 3. Severe ___

D. What has been your usual occupation or job -- the one you have worked at the longest?

1. Job occupation _____
2. Number of years employed in this occupation _____
3. Position/job title _____
4. Business, field or industry _____

(Record on lines the years in which you have worked in any of these industries, e.g. 1960-1969)

Have you ever worked:	YES	NO
E. In a mine?	_____	_____
F. In a quarry?	_____	_____
G. In a foundry?	_____	_____
H. In a pottery?	_____	_____
I. In a cotton, flax or hemp mill?....	_____	_____
J. With asbestos?	_____	_____

17. PAST MEDICAL HISTORY

	YES	NO
A. Do you consider yourself to be in good health?	_____	_____
If "NO" state reason _____		
B. Have you any defect of vision?	_____	_____
If "YES" state nature of defect _____		
C. Have you any hearing defect?	_____	_____
If "YES" state nature of defect _____		
D. Are you suffering from or have you ever suffered from:	YES	NO
a. Epilepsy (or fits, seizures, convulsions)?	_____	_____
b. Rheumatic fever?	_____	_____
c. Kidney disease?	_____	_____
d. Bladder disease?	_____	_____
e. Diabetes?	_____	_____
f. Jaundice?	_____	_____

18. CHEST COLDS AND CHEST ILLNESSES

18A. If you get a cold, does it "usually" go to your chest? (Usually means more than 1/2 the time)	1. Yes ___	2. No ___ 3. Don't get colds ___
19A. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed?	1. Yes ___	2. No ___

IF YES TO 19A:

B. Did you produce phlegm with any of these chest illnesses? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. In the last 3 years, how many such illnesses with (increased) phlegm did you have which lasted a week or more? Number of illnesses ___ No such illnesses ___

20. Did you have any lung trouble before the age of 16? 1. Yes ___ 2. No ___

21. Have you ever had any of the following?

1A. Attacks of bronchitis? 1. Yes ___ 2. No ___

IF YES TO 1A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age was your first attack? Age in Years ___ Does Not Apply ___

2A. Pneumonia (include bronchopneumonia)? 1. Yes ___ 2. No ___

IF YES TO 2A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did you first have it? Age in Years ___ Does Not Apply ___

3A. Hay Fever? 1. Yes ___ 2. No ___

IF YES TO 3A:

B. Was it confirmed by a doctor? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

C. At what age did it start? Age in Years ___ Does Not Apply ___

22A. Have you ever had chronic bronchitis? 1. Yes ___ 2. No ___

IF YES TO 22A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

23A. Have you ever had emphysema? 1. Yes ___ 2. No ___

IF YES TO 23A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

24A. Have you ever had asthma? 1. Yes ___ 2. No ___

IF YES TO 24A:

B. Do you still have it? 1. Yes ___ 2. No ___
3. Does Not Apply ___

C. Was it confirmed by a doctor? 1. Yes ___ 2. No ___
3. Does Not Apply ___

D. At what age did it start? Age in Years ___
Does Not Apply ___

E. If you no longer have it, at what age did it stop? Age stopped ___
Does Not Apply ___

25. Have you ever had:

A. Any other chest illness? 1. Yes ___ 2. No ___

If yes, please specify _____

B. Any chest operations? 1. Yes ___ 2. No ___

If yes, please specify _____

C. Any chest injuries? 1. Yes ___ 2. No ___

If yes, please specify _____

26A. Has a doctor ever told you that you had heart trouble? 1. Yes ___ 2. No ___

IF YES TO 26A:

B. Have you ever had treatment for heart trouble in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

27A. Has a doctor told you that you had high blood pressure? 1. Yes ___ 2. No ___

IF YES TO 27A:

B. Have you had any treatment for high blood pressure (hypertension) in the past 10 years? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

28. When did you last have your chest X-rayed? (Year) ___ ___ ___ ___

29. Where did you last have your chest X-rayed (if known)? _____

What was the outcome? _____

FAMILY HISTORY

30. Were either of your natural parents ever told by a doctor that they had a chronic lung condition such as:	FATHER			MOTHER		
	1. Yes	2. No	3. Don't know	1. Yes	2. No	3. Don't know
A. Chronic Bronchitis?	___	___	___	___	___	___
B. Emphysema?	___	___	___	___	___	___
C. Asthma?	___	___	___	___	___	___
D. Lung cancer?	___	___	___	___	___	___
E. Other chest conditions?	___	___	___	___	___	___
F. Is parent currently alive?	___	___	___	___	___	___
G. Please Specify	___ Age if Living ___ Age at Death ___ Don't Know			___ Age if Living ___ Age at Death ___ Don't Know		
H. Please specify cause of death	_____			_____		

COUGH

31A. Do you usually have a cough? (Count a cough with first smoke or on first going out of doors. Exclude clearing of throat.) (If no, skip to question 31C.)	1. Yes ___	2. No ___
B. Do you usually cough as much as 4 to 6 times a day 4 or more days out of the week?	1. Yes ___	2. No ___
C. Do you usually cough at all on getting up or first thing in the morning?	1. Yes ___	2. No ___

D. Do you usually cough at all during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF ABOVE (31A, B, C, OR D), ANSWER THE FOLLOWING. IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO NEXT PAGE

E. Do you usually cough like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had the cough? Number of years ___ Does not apply ___

32A. Do you usually bring up phlegm from your chest? Count phlegm with the first smoke or on first going out of doors. Exclude phlegm from the nose. Count swallowed phlegm.) (If no, skip to 32C) 1. Yes ___ 2. No ___

B. Do you usually bring up phlegm like this as much as twice a day 4 or more days out of the week? 1. Yes ___ 2. No ___

C. Do you usually bring up phlegm at all on getting up or first thing in the morning? 1. Yes ___ 2. No ___

D. Do you usually bring up phlegm at all on during the rest of the day or at night? 1. Yes ___ 2. No ___

IF YES TO ANY OF THE ABOVE (32A, B, C, OR D), ANSWER THE FOLLOWING:

IF NO TO ALL, CHECK "DOES NOT APPLY" AND SKIP TO 33A

E. Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? 1. Yes ___ 2. No ___ 3. Does not apply ___

F. For how many years have you had trouble with phlegm? Number of years ___ Does not apply ___

EPISODES OF COUGH AND PHLEGM

33A. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year?
*(For persons who usually have cough and/or phlegm)
1. Yes ___ 2. No ___

IF YES TO 33A

B. For how long have you had at least 1 such episode per year?
Number of years ___
Does not apply ___

WHEEZING

34A. Does your chest ever sound wheezy or whistling

1. When you have a cold? 1. Yes ___ 2. No ___

2. Occasionally apart from colds? 1. Yes ___ 2. No ___

3. Most days or nights? 1. Yes ___ 2. No ___

B. For how many years has this been present?
Number of years ___
Does not apply ___

35A. Have you ever had an attack of wheezing that has made you feel short of breath? 1. Yes ___ 2. No ___

IF YES TO 35A

B. How old were you when you had your first such attack?
Age in years ___
Does not apply ___

C. Have you had 2 or more such episodes? 1. Yes ___ 2. No ___ 3. Does not apply ___

D. Have you ever required medicine or treatment for the(se) attack(s)? 1. Yes ___ 2. No ___ 3. Does not apply ___

BREATHLESSNESS

36. If disabled from walking by any condition other than heart or lung disease, please describe and proceed to question 38A.

Nature of condition(s)
_____
_____

37A. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?

1. Yes ___ 2. No ___

IF YES TO 37A

B. Do you have to walk slower than people of your age on the level because of breathlessness?

1. Yes ___ 2. No ___
3. Does not apply ___

C. Do you ever have to stop for breath when walking at your own pace on the level?

1. Yes ___ 2. No ___
3. Does not apply ___

D. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level?

1. Yes ___ 2. No ___
3. Does not apply ___

E. Are you too breathless to leave the house or breathless on dressing or climbing one flight of stairs?

1. Yes ___ 2. No ___
3. Does not apply ___

TOBACCO SMOKING

38A. Have you ever smoked cigarettes?
(No means less than 20 packs of cigarettes or 12 oz. of tobacco in a lifetime or less than 1 cigarette a day for 1 year.)

1. Yes ___ 2. No ___

IF YES TO 38A

B. Do you now smoke cigarettes (as of one month ago)	1. Yes ___ 2. No ___ 3. Does not apply ___
C. How old were you when you first started regular cigarette smoking?	Age in years ___ Does not apply ___
D. If you have stopped smoking cigarettes completely, how old were you when you stopped?	Age stopped ___ Check if still smoking ___ Does not apply ___
E. How many cigarettes do you smoke per day now?	Cigarettes per day ___ Does not apply ___
F. On the average of the entire time you smoked, how many cigarettes did you smoke per day?	Cigarettes per day ___ Does not apply ___
G. Do or did you inhale the cigarette smoke?	1. Does not apply ___ 2. Not at all ___ 3. Slightly ___ 4. Moderately ___ 5. Deeply ___
39A. Have you ever smoked a pipe regularly? (Yes means more than 12 oz. of tobacco in a lifetime.)	1. Yes ___ 2. No ___

IF YES TO 39A:
FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started to smoke a pipe regularly?	Age ___
2. If you have stopped smoking a pipe completely, how old were you when you stopped?	Age stopped ___ Check if still smoking pipe ___ Does not apply ___

C. On the average over the entire time you smoked a pipe, how much pipe tobacco did you smoke per week?	___ oz. per week (a standard pouch of tobacco contains 1 1/2 oz.) ___ Does not apply
D. How much pipe tobacco are you smoking now?	oz. per week ___ Not currently smoking a pipe ___
E. Do you or did you inhale the pipe smoke?	1. Never smoked ___ 2. Not at all ___ 3. Slightly ___ 4. Moderately ___ 5. Deeply ___

40A. Have you ever smoked cigars regularly? 1. Yes ___ 2. No ___

(Yes means more than 1 cigar a week for a year)

IF YES TO 40A

FOR PERSONS WHO HAVE EVER SMOKED A PIPE

B. 1. How old were you when you started smoking cigars regularly?	Age ___
2. If you have stopped smoking cigars completely, how old were you when you stopped smoking cigars?	Age stopped ___ Check if still ___ Does not apply ___
C. On the average over the entire time you smoked cigars, how many cigars did you smoke per week?	Cigars per week ___ Does not apply ___
D. How many cigars are you smoking per week now?	Cigars per week ___ Check if not smoking cigars currently ___

E. Do or did you inhale the cigar smoke?

1. Never smoked ___
2. Not at all ___
3. Slightly ___
4. Moderately ___
5. Deeply ___

Signature _____ Date _____

Part 2

PERIODIC MEDICAL QUESTIONNAIRE

1. NAME_____
2. CLOCK NUMBER ___ ___ ___ ___ ___ ___ ___
3. PRESENT OCCUPATION_____
4. PLANT _____
5. ADDRESS _____
6. _____
   (Zip Code)
7. TELEPHONE NUMBER _____
8. INTERVIEWER _____
9. DATE _____
10. What is your marital status? 1. Single ___ 2. Married ___ 3. Widowed ___ 4. Separated/ Divorced ___

11. OCCUPATIONAL HISTORY

11A. In the past year, did you work full time (30 hours per week or more) for 6 months or more? 1. Yes ___ 2. No ___

IF YES TO 11A:

11B. In the past year, did you work in a dusty job? 1. Yes ___ 2. No ___ 3. Does not Apply ___

11C. Was dust exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11D. In the past year, were you exposed to gas or chemical fumes in your work? 1. Yes ___ 2. No ___

11E. Was exposure: 1. Mild ___ 2. Moderate ___ 3. Severe ___

11F. In the past year,

what was your: 1. Job/occupation? _____
2. Position/job title? _____

12. RECENT MEDICAL HISTORY

12A. Do you consider yourself to be in good health? Yes ___ No ___

If NO, state reason _____

12B. In the past year, have you developed:

	Yes	No
Epilepsy?	___	___
Rheumatic fever?	___	___
Kidney disease?	___	___
Bladder disease?	___	___
Diabetes?	___	___
Jaundice?	___	___
Cancer?	___	___

13. CHEST COLDS AND CHEST ILLNESSES

13A. If you get a cold, does it "usually" go to your chest? (usually means more than 1/2 the time)

1. Yes ___ 2. No ___
3. Don't get colds ___

14A. During the past year, have you had any chest illnesses that have kept you off work, indoors at home, or in bed? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

IF YES TO 14A:

14B. Did you produce phlegm with any of these chest illnesses? 1. Yes ___ 2. No ___ 3. Does Not Apply ___

14C. In the past year, how many such illnesses with (increased) phlegm did you have which lasted a week or more? Number of illnesses ___ No such illnesses ___

15. RESPIRATORY SYSTEM

In the past year have you had:

	Yes or No	Further Comment on Positive Answers
Asthma	_____	

Bronchitis	_____
Hay Fever	_____
Other Allergies	_____

	Yes or No	Further Comment on Positive Answers
Pneumonia	_____	
Tuberculosis	_____	
Chest Surgery	_____	
Other Lung Problems	_____	
Heart Disease	_____	

Do you have:

	Yes or No	Further Comment on Positive Answers
Frequent colds	_____	
Chronic cough	_____	
Shortness of breath when walking or climbing one flight or stairs	_____	

Do you:

Wheeze	_____	
Cough up phlegm	_____	
Smoke cigarettes	_____	Packs per day ____ How many years ___

Date _____ _____ Signature _____

APPENDIX E TO §1926.1101—CLASSIFICATION OF CHEST X-RAYS—MANDATORY

(a) Chest X-rays shall be classified in accordance with the International Labour Organization (ILO) Classification of Radiographs of Pneumoconioses (revised edition 2011) (incorporated by reference, see §1926.6), and recorded on a classification form following the format of the CDC/NIOSH (M) 2.8 form. As a minimum, the content within the bold lines of this form (items 1 through 4) shall be included. This form is not to be submitted to NIOSH.

(b) All X-rays shall be classified only by a B-reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses.

(c) Whenever classifying chest X-rays made under this section, the physician shall have immediately available for reference a complete set of the ILO Classification of Radiographs for Pneumoconioses (revised edition 2011) and the Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses (revised edition 2011).

* * * * *

APPENDIX I TO §1926.1101—MEDICAL SURVEILLANCE GUIDELINES FOR ASBESTOS, NON-MANDATORY

* * * * *

III. Signs and Symptoms of Exposure-Related Disease

The signs and symptoms of lung cancer or gastrointestinal cancer induced by exposure to asbestos are not unique, except that a chest X-ray of an exposed patient with lung cancer may show pleural plaques, pleural calcification, or pleural fibrosis, and may also show asbestosis (i.e., small irregular parenchymal opacities). Symptoms characteristic of mesothelioma include shortness of breath, pain in the chest or abdominal pain. Mesothelioma has a much longer average latency period compared with lung cancer (40 years versus 15-20 years), and mesothelioma is therefore more likely to be found among workers who were first exposed to asbestos at an early age. Mesothelioma is a fatal disease.

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. Symptoms include shortness of breath, coughing, fatigue, and vague feelings of sickness. When the fibrosis worsens, shortness of breath occurs even at rest. The diagnosis of asbestosis is most commonly based on a history of exposure to asbestos, the presence of characteristic radiologic abnormalities, end-inspiratory crackles (rales), and other clinical features of fibrosing lung disease. Pleural plaques and thickening may be observed on chest X-rays. Asbestosis is often a progressive disease even in the absence of continued exposure, although this appears to be a highly individualized characteristic. In severe cases, death may be caused by respiratory or cardiac failure.

IV. Surveillance and Preventive Considerations

* * * * *

(iii) A physical examination including a chest X-ray and pulmonary function test that includes measurement of the employee's forced vital capacity (FVC) and forced expiratory volume at one second (FEV(1)).

* * * * *

■ 51. Revise paragraph (l)(4)(ii)(C) of § 1926.1127 to read as follows:

§ 1926.1127 Cadmium.

* * * * *

(l) * * *

(4) * * *

(ii) * * *

(C) A 14 inch by 17 inch or other reasonably-sized standard film or digital posterior-anterior chest X-ray (after the initial X-ray, the frequency of chest X-rays is to be determined by the examining physician);

* * * * *

§ 1926.1129 [Removed and Reserved]

■ 52. Remove and reserve § 1926.1129.

Parts 1910, 1915, and 1926 [Amended]

■ 53. In addition to the revisions and amendments set forth above, in 29 CFR parts 1910, 1915, and 1926, remove words and punctuation from the following paragraphs and appendices as follows:

Words and punctuation to remove	29 CFR		
	Part 1910	Part 1915	Part 1926
and social security number	1910.120(f)(8)(ii)(A) 1910.1001(m)(3)(ii)(A) 1910.1017(m)(1) 1910.1025(d)(5) 1910.1025(n)(3)(ii)(A) 1910.1025 App. B, Sec. XII. 1910.1026(m)(4)(ii)(A) 1910.1028(k)(2)(ii)(A) 1910.1030(h)(1)(ii)(A) 1910.1043(k)(2)(ii)(A) 1910.1044(p)(2)(ii)(a) 1910.1047(k)(3)(ii)(A) 1910.1048(o)(3)(i) 1910.1048(o)(4)(ii)(D) 1910.1050(n)(5)(ii)(A) 1910.1051(m)(4)(ii)(A) 1910.1053(k)(3)(ii)(A)	1915.1001(n)(3)(ii)(A) 1915.1026(k)(4)(ii)(A)	1926.60(o)(5)(ii)(A) 1926.62(d)(5) 1926.62(n)(3)(ii)(A) 1926.62 App. B, Sec. XII. 1926.65(f)(8)(ii)(A) 1926.1101(n)(3)(ii)(A) 1926.1126(k)(4)(ii)(A) 1926.1127(d)(2)(iv) 1926.1153(j)(3)(ii)(A)
social security numbers,	1910.1043(k)(1)(ii)(C) 1910.1048(o)(1)(vi).		
social security number,	1910.1028(k)(1)(ii)(D) 1910.1050(n)(3)(ii)(D) 1910.1052(m)(2)(ii)(F) 1910.1052(m)(2)(iii)(C).		
social security number	1910.1001(m)(1)(ii)(F) 1910.1047(k)(2)(ii)(F) 1910.1050(n)(4)(ii)(A) 1910.1051(m)(2)(ii)(F) 1910.1052(m)(3)(ii)(A).		
social security number,	1910.1018(q)(1)(ii)(D) 1910.1018(q)(2)(ii)(A) 1910.1025(n)(1)(ii)(D) 1910.1025(n)(2)(ii)(A) 1910.1026(m)(1)(ii)(F) 1910.1027(n)(1)(ii)(B) 1910.1027(n)(3)(ii)(A) 1910.1029(m)(1)(i)(a) 1910.1029(m)(2)(i)(a) 1910.1044(p)(1)(ii)(d) 1910.1045(q)(2)(ii)(D) 1910.1053(k)(1)(ii)(G)	1915.1001(n)(2)(ii)(F) 1915.1026(k)(1)(ii)(F)	1926.60(o)(4)(ii)(F) 1926.62(n)(1)(ii)(D) 1926.62(n)(2)(ii)(A) 1926.1101(n)(2)(ii)(F) 1926.1126(k)(1)(ii)(F) 1926.1127(n)(1)(ii)(B) 1926.1127(n)(3)(ii)(A) 1926.1153(j)(1)(ii)(G)

[FR Doc. 2016–19454 Filed 10–3–16; 8:45 am]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, et al.;
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489

[CMS–3260–F]

RIN 0938–AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

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

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

DATES: *Effective date:* These regulations are effective on November 28, 2016.

Implementation date: The regulations included in Phase 1 must be implemented by November 28, 2016.

The regulations included in Phase 2 must be implemented by November 28, 2017.

The regulations included in Phase 3 must be implemented by November 28, 2019.

A detailed discussion regarding the different phases of the implementation timeline can be found in Section B. II ''Implementation Date.''

FOR FURTHER INFORMATION CONTACT: LTC Regulations Team, (410) 786–6633: Sheila Blackstock, Ronisha Blackstone, Diane Corning, Lisa Parker.

SUPPLEMENTARY INFORMATION:

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAA Area Agencies on Aging
ACL Administration for Community Living
ADL Activities of Daily Living
AHCA American Health Care Association
AHLA American Health Lawyers Association
ANSI American National Standards Institute
ASPE Assistant Secretary for Planning and Evaluation
BPSD Behavioral and Psychological Symptoms of Dementia
CASPER Certification and Survey Provider Enhanced Reports
CIL Centers for Independent Living
CLIA Clinical Laboratory Improvement Amendment
CMS Centers for Medicare & Medicaid Services
CNS Clinical Nurse Specialist
CPR Cardiopulmonary Resuscitation
DoN Director of Nursing
EHR Electronic Health Records
FDA Food and Drug Administration
GAO Government Accountability Office
HACCP Hazard Analysis and Critical Control Point
HAI Healthcare-Associated Infection
HHS U.S. Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
ICN International Council of Nurses
IDT Interdisciplinary Team
IG Interpretive Guidance
IP Infection Preventionist
IPCP Infection Prevention and Control Program
LSC Life Safety Code
LTC Long-Term Care
NATCEP Nurse Aide Training Competency Evaluation Program
MAR Medication Administration Record
MDS Minimum Data Set
NA Nurse Aide
NF Nursing Facility
NP Nurse Practitioner
OIG Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator
PA Physician Assistant
PASARR Preadmission Screening and Resident Review
PIPs Performance Improvement Projects
PEU Protein-Energy under Nutrition
QA Quality Assurance
QAA Quality Assessment and Assurance
QAPI Quality Assurance and Performance Improvement
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RN Registered Nurse
SNF Skilled Nursing Facility
WHO World Health Organization

Table of Contents

This final rule is organized as follows:

I. Background

A. Executive Summary

1. Purpose

Consolidated Medicare and Medicaid requirements for participation (requirements) for long term care (LTC) facilities (42 CFR part 483, subpart B) were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, they have not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting.

Since the current requirements were developed, significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed, and has become more diverse and more clinically complex. Over the last two to three decades, extensive, evidence-based research has been conducted and has enhanced our knowledge about resident safety, health outcomes, individual choice, and quality assurance and performance improvement. In light of these changes, we recognized the need to evaluate the regulations on a comprehensive basis, from both a structural and a content perspective. Therefore, we reviewed regulations in an effort to improve the quality of life, care, and services in LTC

facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations. Specifically, we are adding new requirements where necessary, eliminating duplicative or unnecessary provisions, and reorganizing the regulations as appropriate. Many of the revisions are aimed at aligning requirements with current clinical practice standards to improve resident safety along with the quality and effectiveness of care and services delivered to residents. Additionally, we believe that these revisions will eliminate or significantly reduce those instances where the requirements are duplicative, unnecessary, and/or burdensome.

2. Summary of Provisions

Basis and Scope (§ 483.1)

• We have added the statutory authority citations for sections 1128I(b) and (c) and section 1150B of the Social Security Act (the Act) to include the compliance and ethics program, quality assurance and performance improvement (QAPI), and reporting of suspicion of a crime requirements to this section.

Definitions (§ 483.5)

• We have added the definitions for ''abuse'', ''adverse event'', ''exploitation'', ''misappropriation of resident property'', ''mistreatment'', ''neglect'', ''person-centered care'', ''resident representative'', and ''sexual abuse'' to this section.

Resident Rights (§ 483.10)

• We are retaining all existing residents' rights and updating the language and organization of the resident rights provisions to improve logical order and readability, clarify aspects of the regulation where necessary, and updating provisions to include advances such as electronic communications.

Freedom From Abuse, Neglect, and Exploitation (§ 483.12)

• We are requiring facilities to investigate and report all allegations of abusive conduct. We also are specifying that facilities cannot employ individuals who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of their property.

Admission, Transfer, and Discharge Rights (§ 483.15)

• We are requiring that a transfer or discharge be documented in the medical record and that specific information be exchanged with the receiving provider or facility when a resident is transferred.

Resident Assessments (§ 483.20)

• We are clarifying what constitutes appropriate coordination of a resident's assessment with the Preadmission Screening and Resident Review (PASARR) program under Medicaid. We are also adding references to statutory requirements that were inadvertently omitted from the regulation when we first implemented sections 1819 and 1919 of the Act.

Comprehensive Person-Centered Care Planning (§ 483.21) *New Section*

• We are requiring facilities to develop and implement a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.

• We are adding a nurse aide and a member of the food and nutrition services staff to the required members of the interdisciplinary team that develops the comprehensive care plan.

• We are requiring that facilities develop and implement a discharge planning process that focuses on the resident's discharge goals and prepares residents to be active partners in post-discharge care, in effective transitions, and in the reduction of factors leading to preventable re-admissions. We are also implementing the discharge planning requirements mandated by The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) by revising, or adding where appropriate, discharge planning requirements for LTC facilities.

Quality of Care (§ 483.24)

• We are requiring that each resident receive and the facility provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

Quality of Life (§ 483.25)

• Based on the comprehensive assessment of a resident, we are requiring facilities to ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices.

Physician Services (§ 483.30)

• We are allowing attending physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals and therapy orders to therapists.

Nursing Services (§ 483.35)

• We are adding a competency requirement for determining the sufficiency of nursing staff, based on a facility assessment, which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of individual care plans.

Behavioral Health Services (§ 483.40)

• We are adding a new section to subpart B that focuses on the requirement to provide the necessary behavioral health care and services to residents, in accordance with their comprehensive assessment and plan of care.

• We are adding ''gerontology'' to the list of possible human services fields from which a bachelor degree could provide the minimum educational requirement for a social worker.

Pharmacy Services (§ 483.45)

• We are requiring that a pharmacist review a resident's medical chart during each monthly drug regimen review.

• We are revising existing requirements regarding ''antipsychotic'' drugs to refer to ''psychotropic'' drugs and define ''psychotropic drug'' as any drug that affects brain activities associated with mental processes and behavior. We are requiring several provisions intended to reduce or eliminate the need for psychotropic drugs, if not clinically contraindicated, to safeguard the resident's health.

Laboratory, Radiology, and Other Diagnostic Services (§ 483.50) *New Section*

• We are clarifying that a physician assistant, nurse practitioner or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope-of-practice laws.

Dental Services (§ 483.55)

• We are prohibiting SNFs and NFs from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility, and we are adding a requirement that the facility have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility. We are requiring NFs to assist residents who are eligible to apply for reimbursement of dental services under the Medicaid state plan, where applicable.

• We are clarifying that with regard to a referral for lost or damaged dentures ''promptly'' means that the referral must be made within 3 business days unless there is documentation of extenuating circumstances.

Food and Nutrition Services (§ 483.60)

• We are requiring facilities to provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident. We are also requiring facilities to employ sufficient staff, including the designation of a director of food and nutrition service, with the appropriate competencies and skills sets to carry out the functions of dietary services while taking into consideration resident assessments and individual plans of care, including diagnoses and acuity, as well as the facility's resident census.

Specialized Rehabilitative Services (§ 483.65)

• We have added respiratory services to those services identified as specialized rehabilitative services.

Administration (§ 483.70)

• We have largely relocated various portions of this section into other sections of subpart B as deemed appropriate.

• We require facilities to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. Facilities are required to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.

• Binding Arbitration Agreements: We are requiring that facilities must not enter into an agreement for binding arbitration with a resident or their representative until after a dispute arises between the parties. Thus, we are prohibiting the use of pre-dispute binding arbitration agreements.

Quality Assurance and Performance Improvement (QAPI) (§ 483.75)

• We are requiring all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.

Infection Control (§ 483.80)

• We are requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP).

Compliance and Ethics Program (§ 483.85) *New Section*

• We are requiring the operating organization for each facility to have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.

Physical Environment (§ 483.90)

• We are requiring facilities that are constructed, re-constructed, or newly certified after the effective date of this regulation to accommodate no more than two residents in a bedroom. We are also requiring facilities that are constructed, or newly certified after the effective date of this regulation to have a bathroom equipped with at least a commode and sink in each room.

Training Requirements (§ 483.95) *New Section*

• We are adding a new section to subpart B that sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles.

3. Summary of Costs and Benefits

We estimate the total projected cost of this final rule will be about $831 million in the first year and $736 million per year for subsequent years. While this is a large amount in total, the average costs per facility are estimated to be about $62,900 in the first year and $55,000 per year for subsequent years. Although the overall magnitude of cost related to this regulation is economically significant, we note that these costs are significantly less than the amount of Medicare and Medicaid spending for LTC services. According to the 2015 Annual Report of the Medicare Trustees, payments for SNF services from Medicare Part A were $29.92 billion for fiscal year 2015 and payments for NF services were $50.6 billion for fiscal year 2013 (see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/2015.html*).

We are unable to quantify the benefits of the final rule; however, this final rule creates new efficiencies and flexibilities for facilities that are likely to reduce avoidable hospital readmissions, increase the rate of improvement in quality throughout facilities, and create positive business benefits for facilities.

B. Statutory and Regulatory Authority of the Requirements for Long-Term Care Facilities

In addition to specific statutory requirements set out in sections 1819 and 1919 and elsewhere in the Act, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act permit the Secretary of the Department of Health and Human Services (the Secretary) to establish any additional requirements relating to the health, safety, and well-being of SNF and NF residents, respectively, as the Secretary finds necessary.

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. LTC facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The federal participation requirements for SNFs, NFs, or dually certified facilities, are codified in the implementing regulations at 42 CFR part 483, subpart B. Sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act provide that a SNF or NF must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident. In addition, the IMPACT Act (Pub. L. 113–185) amended Title XVIII of the Act by, among other things, adding Section 1899B to the Act. Section 1899B(i) of the Act requires that certain providers, including long term care facilities, take into account, quality, resource use, and other measures to inform and assist with the discharge planning process, while also accounting for the treatment preferences and goals of care of residents.

The Affordable Care Act made a number of changes to the Medicare and Medicaid programs. For instance, in an effort to increase accountability for SNFs and NFs, section 6102 of the Affordable Care Act established a new section 1128I of the Act. In general, section 1128I(b) of the Act requires LTC facilities to have in operation an effective compliance and ethics program that is effective in preventing and

detecting criminal, civil, and administrative violations and in promoting quality of care. Section 1128I(b)(2) of the Act specifies that the Secretary, working jointly with the Inspector General of the Department of Health and Human Services (HHS), shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program. Further, section 1128I(c) of the Act adds a requirement for a quality assurance and performance improvement program (QAPI). Lastly, in an effort to promote dementia management and prevent abuse, section 6121 of the Affordable Care Act amended sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Act by requiring dementia and abuse prevention training to be included as part of training requirements for nurse aides (NAs).

C. Why revise the long-term care requirements

On July 16, 2015, we published a proposed rule entitled, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (80 FR 42168). In the proposed rule we included a robust discussion about the history the LTC requirements and how the current care and service delivery practices of LTC facilities have changed over time. We encourage readers to refer to the proposed rule for this discussion. As discussed in the proposed rule, the requirements for LTC facilities have not been comprehensively reviewed and updated since 1991. In addition, the number of individuals accessing SNF care has increased and the health concerns of individuals residing in LTC facilities have become more clinically complex. These factors demonstrated a need to comprehensively review the regulation and informed our approach for revising the regulations. The following discussion highlights our approach for revising the LTC regulations as well as some of the most significant revisions set forth in this final rule.

Facility Assessment and Competency-Based Approach

One of our goals in revising our minimum health and safety requirements for LTC facilities is to ensure that our regulations align with current clinical practice and allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services in these facilities. We have taken a competency-based approach that focuses on achieving the statutorily mandated outcome of ensuring that each resident is provided care that allows the resident to maintain or attain their highest practicable physical, mental, and psychosocial well-being. As discussed in further detail, we are requiring facilities to assess their facility capabilities and their resident population. This competency-based approach is compatible with existing state requirements and business practices, and promotes both efficiency and effectiveness in care delivery.

Current HHS Quality Initiatives

This final rule is intended to meet the spirit of current HHS quality initiatives that cut across various providers. As an effective steward of public funds, CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. This includes improving the patient experience of care, both quality and satisfaction, improving the health of populations, and reducing the per capita cost of health care. As discussed below, we are implementing several revisions consistent with these efforts.

- Reducing Avoidable Hospitalizations

One goal of the HHS Partnership for Patients Initiative is to reduce the number of individuals who experience a preventable complication requiring rehospitalization. This effort aims to improve the quality of care and services for individuals cared for in LTC facilities. In support of this initiative, CMS launched the ''Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents'' (*http://innovation.cms.gov/initiatives/rahnfr/*) in 2012. This Initiative focuses on long-stay nursing facility residents who are enrolled in the Medicare and Medicaid programs. Additional information and resources are available at *http://innovation.cms.gov/initiatives/rahnfr/index.html.*

Consistent with the HHS focus on reducing unnecessary hospitalization, this final rule strengthens the minimum health and safety standards for LTC facilities in hopes of contributing to a reduction in unnecessary hospital admissions of LTC facility residents. We discuss those changes in more detail in the discussion that follows.

- Healthcare Associated Infections

HHS is also working to reduce the incidence of healthcare associated infections (HAIs) across providers. In recognition of HAIs as an important public health and patient safety issue, HHS is sponsoring the ''National Action Plan to Prevent HAIs.'' This initiative seeks to coordinate and maximize the efficiency of prevention efforts across the federal government (*http://www.hhs.gov/ash/initiatives/hai/actionplan/*). Given the growing number of individuals receiving care in LTC settings and the presence of more complex medical care, these individuals are at an increased risk for HAIs. To advance these initiatives, this final rule implements revisions that we believe will provide more opportunities to achieve broad based improvement and contribute to reduced healthcare costs, while allowing for targeted interventions specific to each LTC facility.

- Behavioral Health

On March 29, 2012, CMS launched an initiative aimed at improving behavioral healthcare and safeguarding LTC facility residents from the use of unnecessary antipsychotic medications, the National Partnership to Improve Dementia Care in Nursing Homes. As part of the initiative, CMS has developed a national action plan that uses a multidimensional approach including public reporting, raising public awareness, regulatory oversight, and technical assistance/training and research. This plan is targeted at enhancing person-centered care for LTC facility residents, particularly those with dementia-related behaviors (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*).

Similarly, with regard to minimum health and safety standards, this final rule implements regulatory changes that may lead to a reduction in the unnecessary use of antipsychotic medication and improvements in the quality of behavioral healthcare.

- Health Information Technology

HHS also has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve health care. The Department is committed to accelerating health information exchange (HIE) through initiatives including: (1) Establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying

privacy and security requirements that enable interoperability. This strategy is described in greater detail in ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'', available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*. The use of such technology can effectively and efficiently help facilities and other providers improve internal care delivery practices, support the exchange of important information across care team members (including patients and caregivers) during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs).

- Trauma-Informed Care

HHS has also undertaken broad-based activities to support Americans that have specific needs to be considered in delivering health care and other services. Activities include raising awareness about the special care needs of trauma survivors, including a targeted effort to support the needs of Holocaust survivors living in the United States. Trauma survivors, including veterans, survivors of large-scale natural and human-caused disasters, Holocaust survivors and survivors of abuse, are among those who may be residents of long-term care facilities. For these individuals, the utilization of trauma-informed approaches is an essential part of person-centered care. Person-centered care that reflects the principles set forth in SAMSHA's ''Concept of Trauma and Guidance for a Trauma-Informed Approach,'' HHS Publication No. (SMA) 14–4884, available at *http://store.samhsa.gov/shin/content/SMA14-4884/SMA14-4884.pdf,* will help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life.

II. Provisions of the Proposed Regulation and Response to Public Comments

In response to our July 16, 2015 proposed rule (80 FR 42168), we received over 9,800 public comments. Commenters included long-term care consumers, advocacy groups for long-term care consumers, organizations representing providers of long-term care and senior service, long-term care ombudsman, state survey agencies, various health care associations, legal organizations, and many individual health care professionals. Below, we have organized our response to comments as follows: A. General Comments; B. Implementation, and C. Public Comments by Regulatory Section.

A. General Comments

Comment: Most commenters expressed overall support for the proposed revisions to the requirements. Commenters agreed that reforms to the existing requirements are necessary to ensure high quality care and quality of life in LTC facilities across the nation.

Specifically, many commenters support the change in focus towards person-centered care. One commenter stated that ''[t]he rule would require that facilities learn more about who the resident is as a person, provide greater support for resident preferences and give residents increased control and choice. This focus on person-centered care and culture change would improve both the resident's quality of life and quality of care.'' Commenters also expressed support for improved protections of resident's rights, protections against abuse and neglect, and a greater emphasis on resident and representative participation in care planning. Commenters also stated that change is necessary to reflect current standards of practice, and support our use of geriatrics-focused medical literature in developing the proposed requirements.

Response: We thank commenters for their support. Our intent in issuing the proposed requirements was to improve the quality of care and quality of life for residents of long term care facilities.

Comment: Some commenters commended CMS for the proposed revisions to the requirements, while stating that CMS should have proposed additional changes and reforms. For example, a few commenters stated that we should have explicitly required facilities to accommodate supported decision making, which is when an individual assists a resident in making his or her own decisions, rather than making decisions on their behalf. Commenters also expressed disappointment that the proposed requirements did not directly address dementia care.

Response: We thank the commenters for their responses, and believe that the flexible, person-centered nature of these requirements will support facilities in addressing each resident's goals and needs. For example, residents and their designated representatives can certainly engage in supported decision making with their care team—nothing in these requirements prohibits it. Further, we do address dementia care in the Behavioral Health sections of this final rule.

Comment: Many commenters expressed general worries that the proposed changes were too broad in scope, and that incremental changes would be easier to implement and better for LTC residents. We directly requested comments on the implementation of the revised requirements and commenters overwhelmingly indicated their preference for a phased implementation. Commenters also requested more time in which to submit comments, due to the depth and volume of the proposed revisions.

Response: We acknowledge that these requirements may be difficult to effectively implement within the standard delayed implementation period (typically 60 days for more comprehensive rulemakings). We are therefore implementing these requirements over a ''phase-in'' period. Please see section II.B. of this rule, ''Implementation,'' for a detailed discussion of the implementation timeframe. Also, in order to allow sufficient time for public review of the proposed rule, we did extend the public comment period by 30 days, instead of closing submissions after the typical 60-day public comment period. We thank the thousands of commenters who provided comments during the extended period.

Comment: Some commenters expressed disappointment that we continue to approach LTC facilities as health care institutions rather than ''homes.'' One commenter suggested we use the word ''nursing home'' instead of ''facility.''

Conversely, many commenters believe we should acknowledge that LTC facilities are no longer necessarily de facto homes, but skilled health care facilities providing more intensive care for shorter periods of time, and that the requirements should address the specific needs of shorter-stay residents, such as those who are rehabilitating after medical events before returning to their private residence. For example, these shorter stay residents (who usually stay for fewer than 30 days) are not likely interested in resident or family councils, or concerned about selecting a roommate. Commenters also expressed that short-stay individuals may not benefit from the same type of care planning as would be appropriate for longer term residents.

Response: We recognize that for many residents, a LTC facility is their home. That said, LTC facilities are specialized health care settings for individuals not capable of living independently and are not directly comparable to private residences. We do support LTC facilities in developing a home-like environment,

and note that residents are indeed recognized as residents, even if their stay is short.

We believe that the person-centered approach to care required in this rulemaking allows for flexibility in care planning and resident accommodations. A resident at the LTC facility for a short period of time may have a shorter or more focused plan of care than a long-term resident. Similarly, a short-term resident may elect not to participate in resident councils.

Comment: One commenter, who stated that their facility provides short-term rehab services following hospitalizations in addition to long-term care, expressed the belief that our proposed requirements would inhibit their ability to accept patients during evenings and weekends. They stated that this may cause ''backups'' in hospital discharges, and lead to patients being inappropriately discharged to their private home.

Response: We do not agree that our revised requirements limit admissions to long-term care facilities outside of weekday business hours. We encourage LTC facilities to work with local hospitals to ensure safe care transitions, and to exercise the flexibility allowed by the requirements to establish admissions and care planning policies appropriate for their community.

Comment: Commenters appreciated that CMS acknowledged and proposed to incorporate the full scopes of practice for non-physician practitioners related to actions that were formerly restricted to physicians. They supported these changes for being both cost effective and responsive to current standards of care.

Response: We agree and thank commenters for their support. Please note that statute restricts some positions and tasks to physicians, such as the requirement at section 1819(b)(6)(A) of the Act, which requires that the care of every resident be provided under the supervision of a physician. Where appropriate and permissible by statute, we have allowed for flexibility in who may perform certain tasks or services within their respective scopes of practice.

Comment: Some commenters stated that they saw no need for CMS to revise requirements for LTC facilities. They expressed concerns that the proposed requirements would be both excessively burdensome and confusing. A few commenters expressly identified the regulatory language of the proposed requirements as confusing. Commenters also stated their belief that the current requirements are adequate, and that changes would be detrimental to care.

Response: We thank the commenters for their input, but disagree that changes to the LTC requirements are unnecessary. Current requirements do not, in some respects, reflect advances in technology and the science of care delivery. In addition, while it is true that many facilities provide excellent care under the current requirements, data and incidents continue to show that there are LTC facilities that have room for improvement. These updated and revised requirements establish a framework for those facilities to raise their quality of care. We have reviewed and considered all comments, and in response to concerns over burden, we have revised some proposed requirements and burden estimates in this final rule. Where commenters brought up specific concerns, we address those in the relevant parts of this rule. Also, we have made clarifying revisions to several parts of the rule, in order to improve understanding.

Comment: Commenters disagreed on whether the proposed requirements align with current standards of practice. Some believe that current standards of practice may be inadequate or stated that they already met many of the newly proposed requirements. Others expressed concerns that a number of the proposed requirements are unrealistic or contrary to sound standards of practice.

Response: We recognize that standards of care are constantly evolving and have therefore tried to create meaningful, yet appropriately flexible, requirements. We thank the commenters for their input, and point out that this regulation establishes revised baseline requirements. These requirements are meant to ensure safe, professional, patient-centered care in all Medicare-and Medicaid-participating LTC facilities, while leaving room for facilities to improve and excel. We commend those facilities who strive to improve upon them and look forward to stakeholder feedback as the requirements are implemented.

Comment: A few commenters stated that they do not support the proposed reorganization of the Requirements of Participation and disagreed with the assertion that the reorganization improves the logical flow of the regulations. Commenters stated that working within the existing structure of the requirements would make it easier to implement new requirements and reduce burden on stakeholders.

Response: We thank the commenters for their input. In response to comments, we have made some changes to the order and arrangement of the requirements from the proposed rule, specifically with respect to proposed §§ 483.10, 483.11, and 483.25. In response to the concerns related to implementation, we again note that we are implementing the requirements over a phase-in period to allow for appropriate clarification and education for facilities, surveyors, and other stakeholders.

Comment: A few commenters were not supportive of the designation of these requirements of participation as ''requirements,'' rather than ''conditions of participation'' that apply to other Medicare-participating providers. Specifically, the commenters are concerned that this terminology effectively makes any violation or unmet requirement a reason for surveyors to close a facility.

Response: The term ''requirements'' reflects the statutory language at sections 1819 and 1919 of the Act. Although this rule establishes requirements for LTC facilities, and not conditions, we note that CMS and state agencies have always taken into consideration the scope and severity of violations. Except in very rare cases of serious, immediate health and safety risks to residents, facilities are always given an opportunity to address and correct deficiencies. The goal of the requirements and their enforcement is to ensure the health and safety of residents, which includes giving facilities the opportunity to improve and come into compliance with the requirements.

Comment: Some commenters expressed concerns that hands-on care would take a backseat to paperwork and documentation under the proposed requirements. Other commenters suggested that we could have gone further and established a detailed data collection program, which could be used to better identify achievement and best practices in LTC settings.

Response: It is not our intention to reduce staff time spent performing direct patient care; however, facilities must be able to demonstrate that care and services meet the requirements for participation. Unfortunately, instances of significant lapses in care continue to occur in facilities. Our requirements, including QAPI, Compliance and Ethics, and Infection Control, as well as requirements for policies and procedures, are intended to protect the health and safety of residents, prevent harm and support quality of life for residents. Establishing a detailed data collection program is outside the scope of this rule.

Comment: Some commenters stated that revisions to the requirements are meaningless without appropriate enforcement. Commenters asked that,

prior to implementation of new requirements, CMS ensure all federal and state surveyors are thoroughly trained about the substance of these new requirements as well as current professional standards of care for all professionals working in nursing centers. One commenter further suggested that surveyors be required to demonstrate competence in all relevant areas, as shown through testing and monitoring. Alternately, one commenter offered their support for ''movement from a punitive survey process to more towards a process which survey agencies and care givers work hand in hand for positive outcomes. Surveyors have a wealth of knowledge and exposure to numerous facilities. Passing on best practices to improve care giving and focusing on training the care givers would be a[n] improvement.''

Other commenters offered concerns about variability and perceived inconsistencies between surveys and surveyors. A few commenters urged CMS to provide defined consequences for noncompliance with the regulations, particularly those related to residents' rights, grievances, and abuse and neglect, including finding of Immediate Jeopardy (as appropriate) and, ultimately, sanctions, including large civil monetary penalties, temporary management, directed corrective actions, and exclusion from participation in Federal health care programs, as appropriate.

Response: We agree that surveyors must be educated and trained on the new requirements and note that such training happens on a regular basis, especially when new requirements are issued. We will consider these comments for future rulemaking. We note that surveyors are not permitted by law to act simultaneously as consultants. Specifying precise consequences for facilities out of compliance with specific requirements is outside the scope of this rulemaking.

Comment: Commenters expressed strong support for stakeholder involvement in the development of sub-regulatory materials. One commenter expressed concerns about the approach CMS has been recently taking utilizing relatively brief conference calls with numerous callers (too numerous to allow effective discussion) allegedly to engage stakeholders in development of critical implementation issues. The commenters felt that this did not constitute sufficient stakeholder engagement. One commenter observed that upon issuance of a final rule, CMS will need to develop sub-regulatory requirements, including interpretive guidelines, to provide much greater detail and guidance on the regulatory revisions. The commenter recommended that provider organizations and association representatives be involved in the development of these specific requirements and guidelines to ensure they are consistent with sound practice, pragmatic in approach, sufficiently flexible, cost-effective and representative of the current realities of providing LTC facility care to an increasingly complex and diverse resident population.

Response: We thank commenters for their input and will consider their views for possible later action.

Comment: Several commenters associated with rural LTC facilities expressed concerns that meeting the proposed requirements would be difficult in rural areas. They identified staffing as a particular hardship in rural areas, especially the proposed requirement for physician evaluation prior to non-emergency hospital transfer. Rural facilities also stated that it was already difficult to hire and retain qualified staff in all skilled positions, simply due to rural population levels. Other commenters pointed to the general labor shortage in health care across much of the country.

Response: We appreciate the commenters' input and note that we have revised the proposed requirements to allow for greater flexibility and in consideration of staffing concerns. Specifically, we are not finalizing the proposed requirement for pre-transfer evaluation by a practitioner. That said, these regulations establish what we have identified as basic staffing needs to ensure appropriate expertise and quality of care. We sympathize with those facilities that are unable to access a large labor pool, but we cannot condone substandard care. We discuss physician services and staffing requirements in greater detail in the relevant sections of this rule.

Comment: Commenters expressed concern about the overall burden of the proposed requirements, and many believe that we may have underestimated the burden on stakeholders. One commenter expressed concern about the cumulative compliance costs associated with the many changes proposed in the regulations. They believe that the additional staffing, credentialing, training, systems and contractual relationships that will be required for compliance will add to the financial stresses that LTC facilities are experiencing from ongoing Medicare and Medicaid cuts. Another commenter protested our issuance of new, burdensome requirements while at the same time ''cutting fee-for-service reimbursements'' and implementing value-based purchasing.

Response: We have revised some provisions, such as the requirement for credentialing, in response to concerns about burden. In addition, we have our burden estimates in response to comments. Please see sections V, ''Collection of Information Requirements,'' and VI, ''Regulatory Impact Analysis (RIA),'' of this rule for more details about regulatory burden estimates.

We acknowledge that the SNF value-based purchasing (VBP) program, which will take effect in FY 2019, is intended to tie SNF payments more closely to rewarding positive patient care outcomes. Under section 1888(h)(6) of the Act, the VBP incentive payments to the higher-performing SNFs are to be funded through a 2 percent reduction in the overall SNF PPS payment rates (again, effective in FY 2019); accordingly, under the terms of the VBP legislation, a SNF's successful performance in meeting the applicable quality measures can help mitigate the actual impact of the overall payment reduction. These payment changes were specifically mandated by Congress when it enacted the SNF VBP legislation in section 215 of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93). The requirements in this rulemaking share the VBP program's objective of improving the quality of care in the LTC setting. We note in addition that SNF PPS payment rates have increased steadily over recent years, due to market basket updates.

Comment: Many commenters stated concerns about inadequate Medicaid reimbursement, while others pointed out that private payer rates are continually rising to compensate for low Medicare reimbursement. Commenters worry that the current reimbursement rates are barely sufficient, in some cases already insufficient, to meet the current requirements, and that the issue will compound as facilities attempt to comply with the new requirements. Several commenters stated that falling Medicare and Medicaid reimbursement rates, relative to costs, will cause their facilities to close. Many of these commenters identified themselves as the sole LTC facilities within a geographic area, which would severely limit the options of their residents if faced with closure. One commenter suggested that, due to low Medicaid reimbursement rates, this rulemaking would disproportionately affect poor individuals who rely on Medicaid and the facilities that serve them. Another

commenter stated concerns about reduced amounts of Public Aid funding.

Response: Reimbursement rules are outside the scope of this rulemaking, and Medicaid reimbursement rates are determined by the states, with limited involvement by CMS. We do not participate in disbursement of public aid funding. We encourage commenters to address Medicaid reimbursement and public aid concerns to relevant state agencies and departments. Many commenters noted that phased implementation would be helpful in absorbing new costs. Please see Section B. ''Implementation'' for our discussion of phased-in implementation deadlines.

Comment: A number of commenters responded to our request for comments in ways that suggest misunderstandings of either current requirements or the proposed requirements. Notable misconceptions include the:

- Belief that allowing residents to choose their attending physician would be a new requirement.
- Impression that having a RN on the interdisciplinary care team would be a new requirement.
- Concerns that these requirements are entirely new, such that all existing health and safety activities at LTC facilities would need to be recreated or developed from scratch.
- Concerns that new staff would need to be hired to perform tasks already being handled by existing staff.
- Belief that a chaplain would be a mandatory member of the interdisciplinary care team.
- Belief that a complete care plan would have to be developed within a new resident's first 48 hours at the LTC facility.
- Belief that existing facilities would have to limit occupancy to two residents per room, even if that would reduce bed count.
- Impression that the new requirements are simply a duplicate of the old requirements.
- Uncertainty as to whether the LTC requirements are applicable to other healthcare settings, such as hospital ''swing-beds'' or assisted living facilities.

Some commenters also expressed concern that CMS may be unreasonably focused on regulating LTC facilities, to the point of not updating regulations and requirements for other provider types. Commenters also claimed that LTC facilities are ''the most regulated industry in America,'' and that ''the nuclear industry is less regulated'' than the LTC facility industry.

Response: We recognize that the proposed rule and this final rule are large, detailed documents, and that many individuals relied on summaries to learn about the proposed requirements. We understand that working professionals and family caregivers can be very busy, but we are concerned by some of these misinterpretations. Most of the misconceptions fell into three categories: Unfamiliarity with the old requirements, misunderstanding of the proposed requirements, or confusion about which facilities must meet the LTC requirements.

The comments displaying unfamiliarity with the existing requirements are troubling to us. The right of a LTC resident to choose his or her own attending physician is a long-standing patient right, which was established at section 1819(c)(1)(A)(i) of the Act by section 4201 of the Omnibus Budget Reconciliation Act of 1987 and at section 1919(c)(1)(A)(i) by section 4211 of the Omnibus Budget Reconciliation Act of 1987. We included the right to choose a physician in this rulemaking in order to support the statutory requirement, and remind stakeholders that it is not a new requirement and therefore should add no new regulatory burden. Similarly, the requirement that a RN serve as a member of an interdisciplinary team is not new to this rulemaking, but ''carried over'' from the old requirements to the revised requirements as an important foundational aspect of care planning. Also, we do not expect facilities to completely recreate health and safety activities. Existing effective programs may already meet the substance of the revised requirements completely, in which case no additional implementation work is necessary. We address these comments, and others, in greater detail in the relevant sections of this preamble.

For those misunderstood provisions of the proposed rule, we have attempted to clarify the relevant sections of the rule, and note that we did not propose that chaplains must be members of all interdisciplinary teams, only that their inclusion is permitted as deemed appropriate by facilities or residents. Similarly, we did not propose that a full plan of care be developed within a resident's first 48 hours, only that a baseline plan be established. The ''two persons per room'' requirement applies only to those facilities that receive approval to be constructed or reconstructed, or are newly certified after this rulemaking. Existing facilities with larger rooms are effectively grandfathered into compliance.

For those health care providers who are not sure whether these requirements apply to them, we encourage them to work with their facility's administration and governing body to determine applicability. This rulemaking applies to Medicare- and Medicaid-certified long term care facilities as defined at sections 1819 and 1919 of the Act and all facilities receiving payment under such programs. Swing-bed hospital units, for example, would need to meet specific conditions of participation for such units, as set out at 42 CFR 482.58, and which include a subset of the requirements contained 42 CFR 483. We note that CMS does not issue regulations or guidance for assisted living facilities, nor are they eligible for Medicare reimbursement. While some assisted living facilities do provide health services (such as medication supervision, nurse support, and emergency medical assistance for residents), they are not classified as health care providers or suppliers under the Act. Some states do regulate them, often as social service providers rather than health care providers. The requirements in this rulemaking may be helpful to other health care and social service settings, but only LTC facilities are required to meet them.

Comment: One commenter expressed concern about our use of the term ''state plan'' throughout the rule. The commenter felt that this is not meant to exclude those states where all Medicaid services in long term care are covered by a Section 1115 waiver and recommended we add the phrase ''or waiver'' where appropriate.

Response: We thank the commenter for their suggestion, but do not believe it is necessary to add ''or waiver.'' The commenter is correct that the use of the term ''state plan'' does not exclude those states where Medicaid-covered services in long term care facilities are provided pursuant to a CMS-approved demonstration project (often referred to as ''waivers''). Our use of the term ''state plan'' encompasses the plan and any such demonstrations.

B. Implementation Date

Comment: We received a substantial number of comments requesting that we consider delaying the implementation of the proposed requirements. Several commenters noted that the proposed rule was complex and that the comprehensive update of the regulations will be overwhelming for facilities to comply with. However, a few commenters noted that many of the proposed requirements will simply require adjustments in the current process. One commenter specifically noted that facilities should be well on their way with establishing a QAPI program and complying with the

proposed QAPI requirements. Many commenters also indicated concern regarding the financial burden associated with this regulation and suggested that a delayed implementation would allow facilities the time needed to establish compliance with the new requirements.

Commenters provided varying suggestions for a implementation timeframe. Some commenters provided suggestions specific to certain requirements. For example, one commenter recommended a 12- to 18-month implementation timeframe for pharmacy services-related requirements. Other commenters recommended that the entire regulation be implemented by phasing in requirements over a certain time period. In addition, commenters provided varying suggestions for an implementation date of the entire regulation that ranged from 1 to 10 years in the future.

Response: We appreciate the feedback from commenters. Given the comprehensive nature of the regulatory revisions, we agree that a longer period of time is necessary to implement the changes outlined in this final rule. We acknowledge that LTC facilities may find the comprehensive revision to the LTC requirements overwhelming and want to avoid any unintended consequences or unanticipated risks to both facilities and residents. We believe that allowing for a longer implementation period will allow LTC facilities the time necessary to come into compliance with the new requirements. In addition, we anticipate that additional time will be needed to develop revised interpretive guidance and survey processes, conduct surveyor training on the changes, and implement the software changes in the Quality Indicator Survey (QIS) system.

While commenters provided varying suggestions for the appropriate implementation timeframe (ranging between 1 and 10 years), overall all commenters agreed that implementation will require more than a year and the majority of commenters suggested between 3 and 5 years. After considering these proposals, we are finalizing a phased-in implementation of the requirements over a 3 year time period. We believe that a phased-in approach over 3 years will sufficiently allow for LTC facilities to achieve compliance with the revised regulations without jeopardizing resident care. We note that these final regulations will be effective 60 days following the display of this final rule in the **Federal Register**, as discussed under the ''Effective Date'' section. Over the 3 year time period following the effective date of the final rule the requirements will be implemented in three phases. We have categorized the three phases based on the complexity of the revisions and the work necessary to revise the interpretive guidance and survey process based on the revisions. The first phase of implementation will occur upon the effective date of the final rule and include those requirements that were unchanged or received minor modification. We will provide updated training to surveyors on the new regulatory language.

The second phase of implementation will have a deadline of 1 year following the effective date of the final rule and in addition to those requirements implemented in phase one, this phase will also include those brand new requirements and those provisions that required more complex revisions. The additional time for implementation will allow for complete changes in our survey processes as well as updates to the survey guidance. We will provide updated guidance to facilities, update the traditional and QIS survey process, update the survey tags in accordance with the reorganization of the regulations, and provide training to surveyors on the new tags. The third and final phase of implementation will have a deadline of 3 years from the effective date of the final rule and include all the remaining requirements that were not implemented in phases 1 and 2. We expect that this final phase will allow for the complete set of revised requirements to be incorporated into the practices of LTC facilities and sufficiently enforced through the updated survey process.

Below we provide a detailed chart specifying the specific requirements that will be implemented in phases 1, 2, and 3 of the implementation time period for this final rule. We note that some regulatory sections may have certain requirements that are implemented in varying phases. In those instances we highlight the specific requirements in a regulatory section that will be implemented in a different phase.

Implementation Timeframes

****Note:** These final regulations will be *effective* 60 days following the date of public inspection of this final rule in the **Federal Register**. **

Phase 1: Upon the *effective date* of the final rule.

Phase 2: 1 year following the *effective date* of the final rule.

Phase 3: 3 years following the *effective date* of the final rule.

Regulatory section	Implementation deadline
§ 483.1 Basis and scope	This entire section will be implemented in Phase 1.
§ 483.5 Definitions	This entire section will be implemented in Phase 1.
§ 483.10 Resident rights	The section will be implemented in Phase 1 with the following exception: • *(g)(4)(ii)–(v) Providing contact information for State and local advocacy organizations, Medicare and Medicaid eligibility information, Aging and Disability Resources Center and Medicaid Fraud Control Unit*—Implemented in Phase 2.
§ 483.12 Freedom from abuse, neglect, and exploitation	This section will be implemented in Phase 1 with the following exceptions: • *(b)(4) Coordination with QAPI Plan*—Implemented in Phase 3. • *(b)(5) Reporting crimes/1150B*—Implemented in Phase 2.
§ 483.15 Admission, transfer, and discharge rights	This section will be implemented in Phase 1 with the following exceptions: • *(c)(2) Transfer/Discharge Documentation*—Implemented in Phase 2.
§ 483.20 Resident assessment	This entire section will be implemented in Phase 1.
§ 483.21 Comprehensive person-centered care planning	This section will be implemented in Phase 1 with the following exceptions: • *(a) Baseline care plan*—Implemented in Phase 2. • *(b)(3)(iii) Trauma informed care*—Implemented in Phase 3.
§ 483.24 Quality of life	This entire section will be implemented in Phase 1.

Regulatory section	Implementation deadline
§ 483.25 Quality of care	This section will be implemented in Phase 1 with the following exception: • *(m) Trauma-informed care*—Implemented in Phase 3.
§ 483.30 Physician services	This entire section will be implemented in Phase 1.
§ 483.35 Nursing services	This section will be implemented in Phase 1 with the following exception: • *Specific usage of the Facility Assessment at § 483.70(e) in the determination of sufficient number and competencies for staff*—Implemented in Phase 2.
§ 483.40 Behavioral health services	This section will be implemented in Phase 2 with the following exceptions: • *(a)(1) As related to residents with a history of trauma and/or post-traumatic stress disorder*—Implemented in Phase 3. • *(b)(1), (b)(2), and (d) Comprehensive assessment and medically related social services*—Implemented in Phase 1.
§ 483.45 Pharmacy services	This section will be implemented in Phase 1 with the following exceptions: • *(c)(2) Medical chart review*—Implemented in Phase 2. • *(e) Psychotropic drugs*—Implemented in Phase 2.
§ 483.50 Laboratory, radiology, and other diagnostic services	This entire section will be implemented in Phase 1.
§ 483.55 Dental services	This section will be implemented in Phase 1 with the following exceptions: • *(a)(3) and (a)(5) Loss or damage of dentures and policy for referral*—Implemented in Phase 2. • *(b)(3) and (b)(4) Referral for dental services regarding loss or damaged dentures*—Implemented in Phase 2.
§ 483.60 Food and nutrition services	This section will be implemented in Phase 1 with the following exceptions: • *(a) As linked to Facility Assessment at § 483.70(e)*—Implemented in Phase 2. • *(a)(1)(iv) Dietitians hired or contracted with prior to effective date*—Built in implementation date of 5 years following effective date of the final rule. • *(a)(2)(i) Director of food & nutrition services designated to serve prior to effective*—Built in implementation date of 5 years following the effective date of the final rule. • (a)(2)(i) Dietitians designated to after the effective date—Built in implementation date of 1 year following the effective date of the final rule.
§ 483.65 Specialized rehabilitative services	This entire section will be implemented in Phase 1.
§ 483.70 Administration	This section will be implemented in Phase 1 with the following exceptions: • *(d)(3) Governing body responsibility of QAPI program*—Implemented in Phase 3. • *(e) Facility assessment*—Implemented in Phase 2.
§ 483.75 Quality assurance and performance improvement	This section will be implemented in Phase 3 with the following exceptions: • *(a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey*—Implemented in Phase 2. • *(g)(1) QAA committee*—All requirements of this section will be implemented in Phase 1 with the exception of subparagraph (iv), the addition of the ICPO, which will be implemented in Phase 3. • *(h) Disclosure of information*—Implemented in Phase 1. • *(i) Sanctions*—Implemented in Phase 1.
§ 483.80 Infection control	This section will be implemented in Phase 1 with the following exceptions: • *(a) As linked to Facility Assessment at § 483.70(e)*—Implemented in Phase 2. • *(a)(3) Antibiotic stewardship*—Implemented in Phase 2. • *(b) Infection preventionist (IP)*—Implemented in Phase 3. • *(c) IP participation on QAA committee*—Implemented in Phase 3.
§ 483.85 Compliance and ethics program	This entire section will be implemented in Phase 3.
§ 483.90 Physical environment	This section will be implemented in Phase 1 with the following exceptions: • *(f)(1) Call system from each resident's bedside*—Implemented in Phase 3. • *(h)(5) Policies regarding smoking*—Implemented in Phase 2.

Regulatory section	Implementation deadline
§ 483.95 Training requirements	This entire section will be implemented in Phase 3 with the following exceptions: • *(c) Abuse, neglect, and exploitation training*—Implemented in Phase 1. • *(g)(1) Regarding in-service training, (g)(2) dementia management & abuse prevention training, (g)(4) care of the cognitively impaired*—Implemented in Phase 1. • *(h) Training of feeding assistants*—Implemented in Phase 1.

C. Basis and Scope (§ 483.1)

We proposed to revise § 483.1 ''Basis and Scope'' to include references to sections 1819(f), 1919(f), 1128I(b) and (c), and 1150B of the Act. Sections 1819(f) and 1919(f) of the Act require that the current mandatory on-going training for NAs include dementia management and resident abuse prevention training. New section 1128I(b) of the Act requires the operating organizations for SNFs and NFs to have a compliance and ethics program and new section 1128I(c) of the Act requires the Secretary to establish and implement a QAPI program for facilities. New section 1150B of the Act establishes requirements for reporting to law enforcement suspicion of crimes occurring in federally funded LTC facilities. In addition, we proposed to spell out the term ''skilled nursing facility''.

We did not receive any comments in response to our proposals in this section. Therefore, we are finalizing our proposal without modification.

D. Definitions (§ 483.5)

Current regulations at § 483.5 provide definitions for terms commonly used in the LTC requirements. We proposed to revise some of the existing terms for clarity and define new terms that we believe are widely used within the LTC setting, and that we believe will add value to the LTC requirements while promoting resident choice and safety.

We retained the existing definitions for ''facility'' and ''distinct part''. In addition, we retained the definition of ''major modification'', which was added to the LTC regulations in the May 12, 2014 final rule, ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'' (79 FR 27106). We also proposed minor revisions to the definition of ''common area'' to recognize that some facilities have living rooms or other areas where residents gather. We proposed to expand this section to include the following definitions: ''abuse,'' ''adverse event,'' ''exploitation,'' ''misappropriation of resident property,'' ''neglect,'' ''person-centered care,'' ''resident representative,'' and ''sexual abuse''. In addition, we proposed to relocate the definitions for ''licensed health professional'' and ''nurse aide'' to this section from the ''Administration'' section at § 483.75(e)(1). In addition, we proposed to revise the definition of ''nurse aide'' in accordance with amendments to sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act made by sections 6121(a)(2) and (b)(2) of the Affordable Care Act. ''Nurse aide'' is currently defined as any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide these services without pay. ''Nurse aides'' do not include those individuals who furnish services to residents only as paid feeding assistants, as defined in § 488.301. Section 6121 of the Affordable Care Act added the following clarification to the definition of ''nurse aide'': ''Such term includes an individual who provides such services through an agency or under a contract with the facility.'' We proposed to amend the regulatory definition accordingly. We proposed to add the term ''adverse event'' to ensure clarity in our requirements relating to proposed requirements for QAPI. For purposes of this regulation, we also proposed to define the term ''resident representative'' broadly to include both an individual of the resident's choice who has access to information and participates in healthcare discussions as well as personal representative with legal standing, such as a power of attorney for healthcare, legal guardian, or health care surrogate or proxy appointed in accordance with state law to act in whole or in part on the resident's behalf. We also noted that the same-sex spouse of a resident would be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated. In addition, we proposed to add a definition of ''person-centered care'' to be defined as focusing on the resident as the locus of control and supporting the resident in making their own choices and having control over their daily lives. For purposes of these regulations, we proposed that ''abuse'' would include actions such as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. As used in this definition of ''abuse'', ''willful'' means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm. We proposed that ''abuse'' would also include the deprivation by an individual of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. The term ''sexual abuse'' would extend the meaning of ''abuse'' to include non-consensual sexual contact of any type with a resident. We proposed to define the term ''neglect'' as ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or mental illness.'' We proposed to define ''exploitation'' as ''the unfair treatment or use of a resident or the taking of a selfish or unfair advantage of a resident for personal gain, through manipulation, intimidation, threats, or coercion.''

We also proposed to add the term ''misappropriation of resident property'' and define the term as ''the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.''

Finally, we proposed to move the existing definition of ''transfer and discharge'' from § 483.12(a)(1) to § 483.5.

Comment: Several commenters supported the addition of terms to the definitions section and indicated that making the link between terms that are defined in regulation and guidance will support an increased response to elder abuse. Multiple commenters provided suggestions for additional terms to be included in the definitions sections. One commenter indicated that there is a need to define ''behavioral health'' given the addition of the regulatory section focused on behavioral health. Other commenters also suggested that

the definition of ''mistreatment'' be added to the regulations for clarity. Lastly, one commenter suggested that definitions of ''portable order for scope of treatment'' and ''staffing practices'' be added to the regulations.

Response: We agree with commenters and believe that improving the definitions section will promote resident safety and choice. For further clarity we have added discussion to the behavioral health section explaining what behavioral health is. Since behavioral health is largely discussed in the ''Behavioral Health'' section we believe it is more appropriate to add the discussion at § 483.40 rather than in the ''Definitions'' section at § 483.5.

We agree with commenters who suggested that the term ''mistreatment'' be defined in the regulation. Regulations at proposed § 483.12(a)(2)(iii) specify that facilities cannot employ or otherwise engage individuals who have had a disciplinary action taken against their professional license as a result of mistreatment. Therefore, based on public comments and the use of the term ''mistreatment'' in § 483.12, we are revising the definitions section to add the term; ''mistreatment'' which means ''to inappropriately treat or exploit a resident.'' Lastly, we do not agree that the terms ''staffing practices'' and ''portable order for scope of treatment'' should be defined because these terms are not used in the regulations.

Comment: One commenter supported moving the definition of ''transfer and discharge'' to the ''Definitions'' section, but recommended that the definition also be discussed in the ''Transitions of Care'' section (finalized as ''Admission, Transfer, and Discharge Rights'') so that readers are aware of it. The commenter also recommended that the definition of ''transfer and discharge'' be revised to include language from interpretive guidance in order to help address the failure of LTC facilities to recognize adequately a resident's transfer and discharge rights.

Response: We agree with commenters and have added a cross-reference to the definition of ''transfer and discharge'' at § 483.15(b)(1), which discusses the requirements regarding a resident's transfer and discharge rights. We note that the definition of ''transfer and discharge'' aligns with the definition that is in the state operations manual. We are unclear what information the commenter requests to have added into the definition.

Comment: Overall, commenters agreed that abuse should be defined in the regulations. Commenters provided varying suggestions aimed to improve the proposed definition. Some commenters communicated support for including the word ''willful'' in the definition of abuse. However, commenters articulated that as proposed, the definition of ''willful'' (as used in abuse) could potentially create major and unreasonable legal complications for facilities and practitioners who are forced to make difficult decisions in unclear circumstances. For example, commenters indicated that unintentional errors, such as deliberately providing medications to a resident that are later discovered to be harmful or differences of clinical opinions, such as withdrawing life-sustaining treatment, will be inappropriately categorized as abuse.

In addition, commenters suggested deleting the clause regarding the deprivation of goods and services from the definition of ''abuse''. Commenters indicated that the use of this clause is problematic and is more appropriately covered by the definition of ''neglect.'' One commenter further suggested that the sentence, ''This presumes that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish'', also be removed from the definition of abuse. The commenter communicated that definitions should not include presumptions and the phrase ''instances of abuse of all residents'' is unclear. Another commenter recommended that the definition clarify further that abuse facilitated or enabled through the use of technology refers to platforms such as social media.

Response: We appreciate the feedback from commenters regarding the definition of ''abuse''. We disagree with commenters and do not believe that the definition of ''abuse'' repeats the definition of ''neglect''. With regard to a deprivation of goods or services, we believe that ''abuse'' requires a willful act, while ''neglect'' does not. We agree with commenters that definitions should not contain presumptions and therefore have revised the language ''this presumes'' to make an explicit statement that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish.'' We do not believe that the use of the term ''willful'' should be removed from the definition of ''abuse.'' We encourage readers to refer to *Merrimack County Nursing Home,* DAB CR2352 (December 5, 2011) (ALJ Decision) and *Honey Grove Nursing Center,* DAB CR3039 (May 8, 2014) (ALJ Decision), which discusses actions that were deliberate, not inadvertent or accidental or with the intent to inflict injury or harm. We agree that abuse enabled through the use of technology would include the use of social media, as well as the use of cameras or the Internet. Following the publication of the final rule, we will release updated interpretive guidance that will aid facilities in implementing these regulations and provide further clarification for this regulation. The interpretive guidance is the most appropriate place to further clarify and provide examples regarding abuse that is facilitated through the use of technology.

Comment: One commenter indicated that an ''adverse event'' is adverse whether or not it is anticipated and suggested that the concept of anticipation be removed from the proposed definition, as it may be misleading. Another commenter recommended that the definition of ''adverse event'' be expanded to include events noted in the February 2014 OIG report entitled, ''Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries'' (OEI–06–11–00370), such as preventable harm due to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. The commenter indicates that the focus of the definition should be placed on a facility's systematic analysis and action rather than only on one-time events.

Response: We appreciate the commenters' feedback. When considering the proposed definition of ''adverse events'' we reviewed the February 2014 Office of the Inspector General (OIG) report referenced by commenters. We believe that increasing the level of specificity in the definition could potentially preclude recognition of additional adverse events. As proposed, the definition encompasses events that harm the patient, that are a result of substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. In addition, we proposed the definition of ''adverse event'' that is currently defined in regulations for transplant centers. As written, the definition does not exclude anticipated events, but rather states ''adverse events'' are ''usually unanticipated.''

Comment: Several commenters supported the clarification added to the definition of ''composite distinct part'' which prohibits the use of a composite distinct part designation as a means to segregate residents by payment status or on any other basis other than care needs.

Response: We appreciate the support from commenters and believe that the

clarification will help to avoid creating inequitable care situations.

Comment: Many commenters supported our proposal to add a definition of ''exploitation'' to the regulations. A few commenters provided suggestions to improve the proposed definition. One commenter indicated that the use of the term ''selfish'' in the definition of ''exploitation'' is misplaced and unnecessary. Another commenter disagreed with the use of the term ''manipulation'' in the definition because manipulation is difficult to identify and pinpoint. The commenter indicated that the definition of ''exploitation'' should not create unanticipated consequences and recommended substituting the use of the term ''manipulation'' with ''deception''.

Response: We appreciate the commenters' feedback and believe that further revisions are needed to improve clarity. We agree that the term ''selfish'' may possibly be hard to identify and evaluate. However, we prefer to use the term ''manipulation'' rather than ''deception,'' as recommended by commenters. We believe that the term ''manipulation'' is generally understood and appropriately indicates when power is being used in an unacceptable manner. Overall, in response to comments we have revised the definition of ''exploitation'' to ''taking advantage of a resident for personal gain by using manipulation, intimidation, threats, or coercion.''

Comment: A few commenters suggested that the definition of ''licensed health professional'' be expanded to include pharmacists, respiratory therapists, dietitians, and psychologists.

Response: The statute at section 1819(b)(5)(G) of the Act defines ''licensed health professional'' as ''a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; registered respiratory therapist or certified respiratory therapy technician.'' Therefore, in an effort to conform our definition to the statute, we have added respiratory therapists to the regulatory definition of ''licensed health professional.'' We have not added ''pharmacists, dietitians, and psychologists,'' since they are not included in the statutory definition.

Comment: Several commenters supported including the definition of ''misappropriation of property'' in the ''Definitions'' section. One commenter recommended replacing the term ''deliberate'' with ''willful'' for consistency throughout the definitions, since ''willful'' is used in the definition of ''abuse''. Another commenter requested that the definition of ''misappropriation of property'' be revised to add language to ensure that the facility remains responsible for replacing or reimbursing for items that are lost or stolen.

Response: We appreciate the commenters' feedback, but disagree with the suggestions. The term ''willful'' is defined specifically, since it is an element of the definition of ''abuse.'' We believe that the term ''deliberate'' is correctly used in the definition of ''misappropriation of property''. In addition, it is not appropriate to add language regarding facility responsibilities to the definition of ''misappropriation of property''. The definition was added to clarify what constitutes as the misappropriation of a resident's property. Regulations at § 483.12(c) discuss the requirements that must be met in response to allegations of the misappropriation of resident property. While our regulations do not require replacement or reimbursement, facilities have the flexibility to establish their own policies related to internal remedies for replacement or reimbursement of resident property.

Comment: Multiple commenters supported the addition of the definition of ''neglect''. One commenter indicated that mental disorder is not a condition that can be attributed to neglect. The commenter recommended modifying the definition of ''neglect'' to explicitly state that neglect could lead to increased psychiatric or behavioral symptoms. Another commenter recommended the definition of ''neglect'' be revised to remove the statement that an individual suspected of neglect must have acted willfully.

Response: We agree that the wording in the definition of ''neglect'' can be improved and have revised the definition to clarify that the facility and its employees are neglectful when a reasonable person would conclude that a deprivation of the omitted goods and services would cause, among other things, emotional distress (rather than mental disorder). As proposed, the definition of ''neglect'' does not include the term ''willful''. We have revised the definition of ''neglect'' to read, ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''

Comment: One commenter indicated that ''nursing aide'' is an obsolete term and the correct terminology is ''nursing assistant''.

Response: We appreciate the commenter's feedback, however we are maintaining the use of the term ''nursing aide'' since that is the term used in the statute.

Comment: Several commenters supported promoting individual choices and individualized care and agreed that adding a definition of ''person-centered care'' is necessary. Commenters suggested additional terms to replace ''person-centered care''. A few commenters provided suggestions to improve the definition. One commenter indicated that the proposed definition only addresses resident choice and is too narrow. The commenter notes that the concept of ''focusing on the resident as the locus of control'' is vague and unsurveyable. Furthermore the commenter suggests that the definition should specify the actions that facilitate individualized care and not just focus on the resident as the locus of control.

Another commenter recommended that the definition of ''person-centered care'' be modified to include that the relationship between residents and providers is a collaborative partnership.

Response: The term ''person-centered care'' is recognized in the long-term care community. However, we understand that some facilities and health care professionals may use alternative terms and wording to describe a similar care model. We have used the term ''person-centered care'', but facilities have the flexibility to use any term they choose internally as long as the principles described in the regulation are met. Facilities should implement the principle of ''person-centered care'' by developing internal guidelines that promote resident choice and control over their individual care. The definition of ''person-centered care'' has been added to the regulation to assist in meeting these requirements and to provide some guidance regarding our intent and expectations. We note that the interpretive guidance for this regulation will also provide more detailed information and best practices for implementing person-centered care.

Comment: Many commenters believe that as proposed the definition of ''resident representative'' may create potential problems and supersede state law, regulations, or case law regarding a resident's surrogate decision makers. The commenters indicated that allowing for both a representative of the resident's choice as well as a representative with legal standing might create issues in instances where these

two individuals disagree. They note that the regulation is not clear as to who supersedes and these types of decisions should not be made by the facility.

Other commenters recommended that the definition of ''resident representative'' be revised to appropriately capture the many relationships that individuals may have with the resident. Commenters indicated that the definition should clearly identify the rights that such individuals have acting on behalf of or advocating with the resident. Commenters also noted that it is important to clarify that residents are not obligated to choose or designate anyone as a representative. Commenters recommended the use of terms, such as ''resident enabler'' and ''resident supporter'' to more appropriately incorporate the concept of supported decision-making. One commenter recommended that our definition be revised to align with the definition in the State Long-Term Care Ombudsman Program regulations found at 45 CFR 1327.1 (recently relocated to 45 CFR 1324.1; see the final rule, ''Administration for Community Living Regulatory Consolidation'' (81 FR 35644, June 3, 2016).

One commenter affirmed the need to highlight the equal treatment of same-sex spouses, while another commenter suggested that the discussion regarding the selection of a same-sex spouse as a representative be removed from the definition. The commenter notes that same-sex spouses are now covered under state law and it is unnecessary to specify one particular group in this definition while omitting others.

Response: We appreciate the feedback from commenters and agree that the definition of ''resident representative'' can be improved. Our intent behind proposing the definition of ''resident representative'' was to recognize that a resident has the right to designate an individual or individuals who can support them in their decision-making. We did not intend to expand the scope of authority of any representative or to supersede state law, regulations, or case law regarding a resident's surrogate decision makers. As one commenter noted, a definition of ''resident representative'' can be found in existing HHS regulations. The regulations at 45 CFR 1324.1 define a ''resident representative'' as ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by state or federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications ; (3) Legal Representative, as used in 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''

We believe that this definition matches our intent behind defining ''resident representative'' in the LTC regulations and to align with existing HHS regulation, we are revising the definition of ''resident representative'' to match the definition found at 45 CFR 1324.1. Generally speaking, the authority of an individual vested with decision-making power under state law would exceed that of an individual without formal legal recognition.

Comment: One commenter recommended that the definition of ''sexual abuse'' be modified in an effort to avoid categorizing accidental touching, which may occur while moving or cleaning a resident, as abuse. Another commenter recommended that the definition of ''sexual abuse'' be modified to include the use of technology to sexually abuse a resident.

Response: We understand that accidental touching is possible; however the term ''sexual abuse'' has been added to the regulations in an effort to prevent harmful acts. It was not added to prevent or complicate care, but to ensure that residents are protected especially in vulnerable situations. For acts such as bathing a resident or assisting a resident with using the restroom, it is the facility's responsibility to have procedures and guidelines in place for what is acceptable and appropriate for providing assistance. We believe that the use of technology to harm a resident is covered by the definition of ''abuse'' which speaks specifically to abusive situations facilitated through technology.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications. We have—

- Revised the definition of ''abuse'' to read, ''the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means that the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.''
- Revised the definition of ''exploitation'' to read, ''taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.''
- Revised the definition of ''licensed health professional'' by adding ''registered respiratory therapist or certified respiratory therapy technician.''
- Added a definition of ''mistreatment'' and defined it as ''inappropriate treatment or exploitation of a resident.''
- Revised the definition of ''neglect'' to read, ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''
- Revised the definition of ''resident representative'' to read (in accordance with 45 CFR 1324.1), ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (3) Legal representative, as used in section 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''

E. Resident Rights (§ 483.10)

Current regulations at § 483.10 address a number of resident rights and facility requirements, including those establishing a resident's right to exercise his or her rights, including rights associated with a dignified existence, self-determination, planning and implementing care, access to information, privacy and confidentiality. Resident rights are also addressed in existing § 483.15. Based on a review of these regulations, we proposed to retain all existing residents' rights, but update the language and organization of the resident rights provisions to improve logical order and readability, to clarify aspects of the regulation that warranted it, and to update provisions to include technological advances such as electronic communications. In order to achieve these objectives, we proposed to revise existing § 483.10 to include only those provisions specifying resident rights, including a number of provisions that are currently included in § 483.15. We further proposed to add a new § 483.11, to focus on the responsibilities of the facility, including relevant provisions currently included in § 483.10 and § 483.15. As with § 483.10, we proposed multiple re-designations and revisions to improve logical order and readability, clarify aspects of the regulation that warranted it, and reflect technological advances such as electronic communications. Under our proposal, some existing provisions would have components in both § 483.10 and § 483.11. We discuss below our proposed revisions to those provisions retained in or moved to § 483.10 and note that regulatory citations have been updated throughout to reflect the proposed new structure.

We proposed to revise § 483.10 to focus specifically on resident rights. In proposed § 483.10(a)(2), we clarified the resident's right to be supported in his or her exercise of rights under this subpart. In proposed § 483.10(a)(3), we clarified the resident's right to designate a representative to exercise only those rights delegated by the resident, and the resident's retention of rights not delegated, including the right to revoke a delegation.

In § 483.10(a)(4) we proposed to clarify that a resident who was adjudged incompetent under the laws of a state would retain the right to exercise those rights not addressed by a court order, that the resident representative can only exercise the rights that devolve to them as a result of the court order, that the resident's wishes and preferences should continue to be considered, and that the resident should continue to be involved in the care planning process to the extent practicable, as the resident is at the center of the care team. Lastly, in our December 12, 2014 proposed rule ''Medicare and Medicaid Programs; Revisions to Certain Patient's Rights Conditions of Participation and Conditions for Coverage'' (79 FR 73873), we proposed at § 483.10(a)(4) to require that the same-sex spouse of a resident be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated. We proposed to re-designate this requirement from § 483.10(a)(4) (as set out in the December 2014 proposed rule at 79 FR 73811) to § 483.10(a)(5).

In proposed § 483.10(b), we included resident rights related to planning and implementing care. We proposed to re-designate and revise current § 483.10(b)(3), § 483.10(b)(4) and § 483.10(b)(8), relating to the resident's right to be informed of his or her total health status, including medical conditions; the right to be informed in advance of the risks and benefits of proposed care, including treatment and treatment alternatives or treatment options so that the resident can choose the alternative or option he or she prefers; the right to request, refuse and/or discontinue treatment, including participating in or refusing to participate in experimental research; and the right to formulate advance directives. We proposed to add new requirements in § 483.10(b)(5) to specify that the resident has the right to participate in the care planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care. We further specified in § 483.10(b)(5)(iv) that the resident has the right to receive the services and items included in the plan of care. We also proposed to re-designate and revise existing § 483.10(d)(2) to specify that the resident has the right, in advance, to be informed of and to participate in, his or her care and treatment, including the right to be informed, in advance, of the care to be furnished and the disciplines that will furnish care. In addition, we proposed to specify the resident's right to participate in the development of his or her comprehensive care plan. We also proposed at § 483.10(b)(6) to include the resident's right to self-administer medication if the interdisciplinary team has determined that doing so would be clinically appropriate. Finally, we proposed to add a new section at § 483.10(b)(7) to specify that these rights cannot be construed as a right to receive medical care that is not medically necessary or appropriate.

We proposed to require that the facility ensure that the attending physician is appropriately licensed and credentialed to provide care and meet the requirements of applicable regulations. In proposed § 483.10(c), we added new paragraphs § 483.10(c)(1), (2) and (3) to specify that the physician chosen by the resident must be licensed to practice medicine, and must meet professional credentialing requirements of the facility.

In § 483.10(d), we proposed to re-designate a number of provisions relating to resident respect and dignity, based on existing § 483.13(a) and § 483.15. We further proposed to add a new § 483.10(d)(5) to specify that a resident has the right to share a room with his or her roommate of choice, when both residents live in the same facility, both residents consent to the arrangement, and the facility can reasonably accommodate the arrangement. We noted that married couples, whether opposite or same sex, are addressed by § 483.10(d)(5). Our proposed provision provided for a rooming arrangement that could include a same-sex couple, siblings, other relatives, long-term friends or any other combination as long as the requirements above are met.

In proposed § 483.10(e), we proposed to revise a number of provisions relating to resident self-determination. We proposed to revise § 483.10(e)(3) to ensure not only that specified individuals and/or organizations have access to the resident, but also to ensure that the resident can receive his or her visitors of choice at the time of his or her choosing. We proposed to revise § 483.10(e)(4) and (5), clarifying that it is the resident's right to participate in family groups and have his or her family members or resident representatives participate in family groups in the facility.

In § 483.10(f), we proposed to re-designate and revise a number of provisions relating to resident access to information. We proposed to specify in § 483.10(f)(2) that the resident has the right to receive notices verbally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands. We also proposed to add a new § 483.10(f)(2)(i) to reference required notices and a new § 483.10(f)(2)(iv) to ensure residents are aware of and can contact an Aging and Disability Resource Center or other ''No Wrong Door'' program.

Federal requirements and expectations related to the privacy and confidentiality of patient records, in particular regulations governing protected health information, changed substantially with the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequent issuance of the HIPAA Privacy and Security Rules (see 45 CFR part 160 and subparts A, C, and E of part 164), the Health Information Technology for Economic and Clinical Health (HITECH) Act and the issuance of the HIPAA Breach Notification Rule and HIPAA Final Rule (45 CFR part 160 and subpart D of part 164; 78 FR 5566, January 25,2013). For simplicity, we hereinafter collectively refer to these laws and their implementing regulations as ''HIPAA.'' We note that administration and enforcement of the privacy, security, and breach-related portions of the HIPAA regulatory scheme are delegated to the HHS Office for Civil Rights (OCR) and more detailed information related to these regulations can be accessed through the OCR Web site at *http://www.hhs.gov/ocr/privacy*.

We proposed to retain the requirements of current § 483.10(b)(2)(i) and (ii), subject to the clarifying revisions described below, at new § 483.10(f)(3). In doing so, we recognized that the HIPAA rules establish a federal floor of privacy and security protections and individual rights with respect to protected health information held by covered entities (and their business associates), and the rights granted in the proposed regulation do not conflict in any way with the HIPAA regulations. In addition, to the extent that HIPAA provides additional rights to individuals (that is, residents, in the long-term care context) beyond what is provided in this proposal, covered entities and business associates must comply with the requirements in HIPAA to ensure individuals are afforded these additional rights. Therefore, we proposed revisions to clarify the relationship between the requirements of 45 CFR 164.524 and the revised version of § 483.10(f)(3)(i) and (ii). We proposed to specify in paragraph (f)(3) that the resident has the right to access medical records pertaining to him or herself and to further specify in proposed (f)(3)(i) that the resident, upon oral or written request, has the right to receive requested medical records in the form and format requested by the resident, if it is readily producible in such form and format (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual. This is consistent with the requirements of 45 CFR 164.524(c)(2). Finally, we proposed to specify in paragraph (f)(3)(ii) that the facility could impose a reasonable, cost-based fee for providing copies of the medical records, provided that the fee included only the cost of labor for copying the health information requested by the individual, whether in paper or electronic form; the supplies for creating the paper copy or electronic media if the individual requested that the electronic copy be provided on portable media; and postage, when the individual requested that the copy be mailed. This is consistent with 45 CFR 164.524(c)(4). We noted in the proposed rule that this proposal does not address the creation or provision of summary reports, which could be provided in accordance with applicable law. More detailed information about the HIPAA right to access at 45 CFR 164.524 can be found at *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/*.

In § 483.10(g)(1) we proposed to revise a number of provisions related to resident privacy and confidentiality to update the language to accommodate electronic communications. We proposed to retain existing § 483.10(c)(1) at proposed § 483.10(g)(2), reiterate the residents' right to a secure and confidential medical record at proposed § 483.10 (g)(3) and, in proposed § 483.10(g)(4), we retained the provisions of existing § 483.10(e)(2) and (3).

In § 483.10(h), we proposed to re-designate and revise a number of provisions relating to resident communications. Specifically, we proposed a new § 483.10(h) Communications, with § 483.10(h)(1) revised to include Teletypewriter (TTY) and Telecommunications Device for the Deaf (TDD) services and cellular telephones; and a new § 483.10(h)(2) to provide reasonable access and privacy for electronic communications such as email or internet-based interpersonal video communications.

In § 483.10(i), we proposed to revise the language to state that the resident has a right to a safe, clean, comfortable, home-like environment, and a right to receive treatment safely. In § 483.10(j), we proposed to revise language relating to resident grievances to add that a resident could not be deterred from voicing a grievance for fear of reprisal or discrimination.

Comment: A number of commenters expressed concern about the way in which CMS proposed to restructure the section on Resident Rights, and particularly the fact that there was not complete parity between residents' rights and facility responsibilities. One commenter stated that, since residents, their families and advocates look at the residents' rights language to know what residents' rights are (and they may be given copies of the federal rights), it is important that the statement of residents' rights be thorough, comprehensive, and accurate. The commenter recommended that CMS add rights currently found under Facility Responsibilities but not under Resident Rights to the Resident Rights section. Another commenter stated that the list of residents' rights should be complete and comprehensive and should not require review of other requirements of participation (RoPs) in order to identify all residents' rights.

One commenter stated that they were concerned with the likely disruption of administrative and judicial decisions over the past 25 years interpreting the current regulations. Administrative Law Judges and state and federal court judges could view changes in regulatory language as signaling changes in administrative interpretation of the Nursing Home Reform Law. They will view prior long-standing interpretations of similar current regulations as no longer legally binding as they interpret new regulatory language, following the legal principle that an agency intends a new interpretation when it changes the language of a regulation. They believed that an agency does not change regulatory language unless it wants to make a change in the prior interpretation of that language.

The commenter further objected to the reorganization of existing RoPs because the commenter felt it would inevitably involve unnecessarily long (but avoidable) delay. The commenter stated that CMS would need to draft the final standards in response to public comments, give facilities time to understand and implement the new Requirements, create a new survey protocol, and train state and federal surveyors in the new protocol, at the very least. As these multiple changes are made, effective enforcement of RoPs, already weak, will be further postponed.

The commenter noted that, to maintain the same regulatory standards within the definition of substandard quality of care requires CMS to combine subsections of multiple RoPs. The commenter recommended that, instead of reorganizing the regulations, as CMS proposes, CMS should retain the current regulatory structure as much as possible and to make all revisions within that existing, familiar structure. Keeping the current structure will save time and

effort on the part of CMS, surveyors, advocates, and providers alike, time and effort that would be better spent on addressing RoPs that actually reflect substantive change and improvement.

Response: We considered commenters' concerns regarding proposed § 483.10 and § 483.11. Rather than increase duplication by adding language to both sections, we have combined these two sections for a comprehensive section that includes in a single location both statements of resident rights and, co-located, the attendant facility responsibilities to support those rights. We believe this addresses commenters' concerns and meets the commenter's suggestion that the statement of resident rights be thorough, comprehensive and accurate. This reorganization, to the extent that the regulatory language is unchanged, does not reflect any intent by CMS to change prior interpretations of regulatory language. Rather, our intent, as stated in the preamble to the proposed rule, is to improve the logical order, readability, and clarity of the regulations. We continue to believe that it is helpful to ensure that regulatory section titles reflect the content of the section. Thus, we have included provisions that state ''the resident has a right to . . .'', in general, in a regulatory section titled ''Residents Rights,'' we have included provisions about prohibiting and preventing abuse, neglect and exploitation in a section titled ''Freedom from Abuse, Neglect, and Exploitation,'' and we have withdrawn our proposal to rename ''Admission, Discharge, and Transfer Rights'' to retain the title that most clearly relays the content of the section to the non-expert reader. We further clearly expressed in the preamble to the proposed rule that we do not intend in this update to diminish resident rights or protections. Rather, we want to ensure that those rights and protections encompass advancements, such as in the area of telecommunications, that were not envisioned when the original regulations were written.

With regard to concerns that this revision will delay enforcement of the requirements and that keeping the current structure would save time and effort in updating facilities, surveyors, advocates, providers, and, we would add, current and future residents, we disagree that this effort is unnecessary or poorly focused. The commenter contends that enforcement of the current requirements is already weak. The efforts that we will undertake as a result of this rule to update and improve interpretive guidance, to train surveyors, and to outreach to the affected community of providers, residents, and caregivers will lead to stakeholders' improved understanding of our higher expectations, could result in improved efficiencies, and improve the effectiveness of our survey process. This final rule will be effective 60 days after its publication, maintaining existing protections for residents, with delayed implementation deadlines for certain sections, where there are new expectations and requirements that require additional time for providers to implement. Please see our discussion of implementation in section II.B. of this preamble for additional detail.

We received a significant number of specific comments on both proposed sections § 483.10 and § 483.11. As we will finalize these sections as a single section, we respond to all specific comments on both proposed sections, following our description of our proposals regarding facility responsibilities, below.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We finalize a consolidated section § 483.10, which contains provisions proposed in § 483.10 and § 483.11. Specific revisions are addressed in the following section.

F. Facility Responsibilities (§ 483.11)

We proposed a new § 483.11 ''Facility Responsibilities,'' in which we combined many of the regulations addressing facility responsibilities which are currently dispersed throughout the existing provisions regarding resident rights and quality of life.

Consistent with § 483.10 and based on existing requirements, the introductory language for proposed § 483.11 would have established that the facility would have to treat its residents with respect and dignity and provide care and services for its residents in a manner and in an environment that promotes maintenance or enhancement of the resident's quality of life, and would be required to protect and promote the resident's rights, as specified in § 483.10. Further, the facility would be required to recognize each resident's individuality and provide services in a person-centered manner. We proposed to establish sections similar to those proposed in § 483.10. The proposed sections are ''Exercise of Rights,'' ''Planning and Implementing Care,'' ''Attending Physician,'' ''Self-Determination,'' ''Information and Communication,'' ''Privacy and Confidentiality,'' ''Safe Environment,'' and Grievances.''

In a new section proposed at § 483.11(a), ''Exercise of Rights,'' we proposed a requirement that the facility would have to promote and protect the rights of the resident. These are not new requirements, and are already set out in our regulations as residents' rights. In order to ensure clarity, we restated clearly in this provision that it would be the responsibility of the facility to recognize and effectuate those rights. Proposed § 483.11(a)(1) provided that the facility ensure that the resident could exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility. We proposed to re-designate current § 483.12(c)(1) as new § 483.11(a)(2) and move to this section the requirement that the facility provide equal access to quality care regardless of diagnosis, severity of condition, or payment source and establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services for all residents, regardless of source of payment. In proposed § 483.11(a)(3) and (4), we specified that the facility would have to treat the decisions of a resident representative as the decisions of the resident to the extent required by a court, or as delegated by the resident, with the condition that the facility could not extend greater authority to the resident representative than would be permitted under applicable law. In addition, we proposed to add a new § 483.11(a)(5) to clarify for facilities that if facility staff believed that a resident representative was making decisions or taking actions that are not in the best interest of the resident, the facility would have to comply with any state reporting requirements that might apply.

In proposed § 483.11(b), ''Facility responsibilities'' would include ensuring that the resident was informed of, and participated in, his or her treatment to the extent practicable, consistent with § 483.10(b). The resident could participate in care planning, making informed decisions, and self-administering drugs when appropriate. We also proposed new requirements in § 483.11(b)(1) to require that the facility ensured that the care planning process facilitated the inclusion of the resident or resident representative, included an assessment of the resident's strengths and needs, and incorporated the resident's personal and cultural preferences in developing goals of care. We proposed to re-designate § 483.10(b)(9) as § 483.11(c)(1) and revise it to add other primary care providers to ensure that the resident would know the name, specialty and

means of contacting the professionals officially responsible for his or her care, whether that provider was a physician, nurse practitioner, physician assistant, or clinical nurse specialist. We further proposed to add a new § 483.11(c)(2), consistent with our proposed § 483.10(c)(1), (2) and (3), to clarify that the facility would have a responsibility to ensure that the resident's attending physician had appropriate professional credentials and met the requirements of this subpart. If the physician was not appropriately credentialed or was unwilling or unable to meet the requirements of this subpart, the facility could seek an alternate physician after informing and discussing this matter with the resident. In order to ensure that the resident could seek out a suitable alternative, we proposed to add a new § 483.11(c)(3) to specify that if the resident subsequently found a new physician who met the necessary requirements, the facility would be required to honor that selection.

We proposed a new § 483.11(d) to address the facility's responsibilities related to resident self-determination. We proposed to re-designate § 483.10(j), regarding access to the resident, as § 483.11(d)(1), and revised it to include visitors as specified in our ''Resident Rights'' provision, including immediate access to the resident by the resident representative, and to update the languages and references for the Office of the State long term care ombudsman and the protection and advocacy system. In addition, we proposed to add a new § 483.11(d)(2) to require that the facility have written policies and procedures regarding visitation rights of residents. We proposed to re-designate § 483.15(c)(5) as § 483.11(d)(3)(ii) and revised it to clarify that the facility-designated staff person who participates in a resident or family group must be approved by the resident or family group and the facility. In the proposed rule, we clarified that this provision does not require a facility to implement every recommendation of a resident or family group, but that the facility should be able to provide the rationale for their response. We proposed a new § 483.11(d)(4), to incorporate requirements currently specified in § 483.10(h) and specify that the facility is responsible for ensuring that a resident is not required to perform services for the facility.

We proposed a new § 483.11(d)(5), to incorporate requirements from § 483.10(c) that focus on the facility's responsibility related to the protection of resident funds. Specifically, we proposed in § 483.11(d)(5)(ii) to reflect the different dollar threshold requirements of sections 1819(c)(6)(B)(i) and 1919(c)(6)(B)(i) of the Act and establish the statutory requirement for deposit of resident funds in excess of $100 in an interest-bearing account for Medicare and other non-Medicaid SNF residents, consistent with section 1819(c)(6)(B)(i) of the Act, and funds in excess of $50 for Medicaid beneficiaries, consistent with section 1919(c)(6)(B)(i) of the Act. We proposed in § 483.11(d)(5)(v) to include the return of funds to residents upon discharge or eviction, in accordance with state law in addition to the already existing regulatory requirement for conveyance to the estate upon death.

We proposed to add a new § 483.11(d)(6)(i)(G) to indicate that the facility may not charge the resident for hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan, whether provided directly by the SNF, NF or by a hospice provider under agreement with the SNF or NF.

We proposed in § 483.11(d)(6)(ii), re-designated from § 483.10(c)(8)(ii), to add to the limitations on charges to residents' funds. We proposed to add new § 483.11(d)(6)(ii)(L)(*1*) and (*2*) to clarify that the facility may not charge for special food and meals ordered for a resident by a physician, physician assistant, nurse practitioner, clinical nurse specialist, dietitian or other clinically qualified nutrition professional and to cross-reference to provisions regarding the expectation that the foods and meals a facility generally prepares should be developed taking into consideration residents' needs and individual preferences in addition to the overall cultural and religious make-up of the facility's population. We proposed a clarification in proposed § 483.11(d)(6)(iii) by adding the term ''non-covered'' before ''item or service,'' as this provision would only apply to non-covered items or services.

We proposed to establish a new § 483.11(e) to incorporate multiple provisions related to information and communication. With the exception of medical records, we proposed in § 483.11(e)(1) to specify that the facility is responsible for ensuring that information provided to the resident is provided in a form and manner that the resident can access and understand, including in a language that the resident can understand.

We proposed in § 483.11(e)(2) to revise facility requirements currently in § 483.10(b)(2)(i) through (ii), consistent with our proposal at § 483.10(f)(3). We proposed in paragraph (e)(2)(i) to require that facilities provide residents with access to their medical records in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if it is not readily producible in such form and format, in a readable hard copy form or other form and format as may be agreed to by the facility and the individual. This proposal included the existing requirement that access be provided upon oral or written request, redesignated from § 483.10(b)(2)(i), and that this access be provided within 24 hours, excluding weekends and holidays, as required by sections 1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act. We proposed at § 483.11(e)(2)(i) to require that the facility allow the resident, after receipt of his or her medical records for inspection, to purchase a copy of the medical records or any portion thereof upon request and with 2 working days advance notice to the facility. We further proposed at § 483.11(e)(2)(iii) to revise the standard for the fee a facility may charge for the requested information from a community standard to a cost-based standard under which the fee includes only the cost of labor for copying the requested health information, whether in paper or electronic form; the supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media, postage when the individual requested the copy be mailed. This is consistent with the requirements of 45 CFR 164.524(c)(4).

We proposed to add a new § 483.11(e)(3), incorporating and re-designating part of existing § 483.10(g)(1), with revisions required by section 6103(c) of the Affordable Care Act, which added new sections 1819(d)(1)(C) and 1919(d)(1)(V) of the Act. Those provisions require that individuals have access to surveys of the facility conducted by federal or state surveyors and any plan of correction in effect with respect to the facility for the preceding 3 years. We note that this provision does not require a specific format, but consistent with proposed § 483.11(e)(1), it must be in a form and manner accessible to and understandable by the resident.

We proposed to add a new § 483.11(e)(4)(i) and (ii) to require the facility to post, in a form and manner easily accessible and understandable to residents, resident representatives and support persons, information that would allow individuals to contact pertinent client advocacy groups, including the State Survey Agency, the state licensure

office, the State Long-Term Care Ombudsman Program, the Protection and Advocacy Network, and the Medicaid Fraud Control Unit. We also proposed to require that the facility post a statement that a resident may file a complaint with the State Survey Agency. The facility is already required at existing § 483.10(b)(7) to provide this information in the written description of legal rights provided to the resident. The provision would be re-designated at proposed § 483.11(e)(12).

We proposed to add a new paragraph § 483.11(e)(7)(i) to specify that when a facility notifies a physician of a change in a resident's status, the facility must ensure that certain pertinent information is available and is provided to the physician upon request.

We proposed to revise the language of § 483.10(b)(11)(i) and re-designate it as new § 483.11(e)(7)(i) to provide that the facility would be required to notify the resident representatives, rather than the current requirement that the facility notify ''. . . the resident's legal representative or an interested family member . . .'' The proposed language allows a guardian or other legal representative as well as any other individuals the resident identifies, including family members, other relatives, close personal friends, or any other persons identified by the resident, to receive the required notifications and thus remain informed of important information about the resident.

We proposed to re-designate § 483.10(b)(1), which addresses the facility requirement to provide a notice of rights and services, as § 483.11(e)(9)(i) through (iii). We proposed one minor revision for clarity in § 483.11(e)(9)(ii) to state ''the State-developed notice of Medicaid rights, if any'' instead of the current language ''notice (if any) of the State developed under 1919(e) of the Act''.

We proposed to revise § 483.10(b)(5)(i) and (ii) and re-designate them as § 483.11(e)(10). The revised provision specifies that the facility must inform each resident, in writing, at the time of admission to a Medicaid-participating nursing facility and when the resident becomes eligible for Medicaid—(1) of the items and services that are included in nursing facility services under the state plan and for which the resident may not be charged; (2) of those items for which the resident may be charged, and the amount of charges for those services; and (3) inform Medicaid-eligible residents when changes are made to the items and services in paragraph (e)(11)(i) of this section.

We proposed to revise and re-designate § 483.10(b)(6) as new § 483.11(e)(11). In addition, we proposed to add new paragraphs (i) through (v) to require the facility to provide notice to residents when changes are made to the items and services covered by Medicare and/or Medicaid or to the amount that the facility charges for items and services.

To improve clarity, we proposed to re-designate § 483.10(b)(7) as new § 483.11(e)(12) and revise current paragraph (b)(7)(iii) to require that the facility provide the resident with ''a list of names, addresses (mailing and email), and telephone numbers of all pertinent state regulatory and informational agencies, resident advocacy groups such as the State Survey Agency, the state licensure office, the State Long-Term Care Ombudsman Program, the protection and advocacy agency, adult protective services, the state or local contact agencies for information about returning to the community and the Medicaid Fraud Control Unit.'' Additionally, we proposed to revise current paragraph (b)(7)(iv) to require that the facility include in the written description of legal rights ''a statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of LTC requirements, including but not limited to resident abuse, neglect, misappropriation of resident property in the facility, non-compliance with the advance directives requirements, and requests for information regarding returning to the community.''

We proposed a new § 483.11(e)(13) that establishes that the facility must protect and facilitate a resident's right to communicate with individuals and entities both inside and external to the facility, including at § 483.11(e)(13)(ii) reasonable access to the internet, to the extent it is available to the facility. Section 483.11(e)(13)((i) replaces § 483.10(k) and § 483.11(e)(13)((iii) revises and replaces § 483.10(i)(2) with regard to reasonable access to a telephone, including TTY and TDD services, and to stationery, postage, writing implements and the ability to send mail, respectively.

We proposed a new § 483.11(f) to include provisions related to privacy and confidentiality. Proposed § 483.11(f)(1) requires that the facility respect the resident's right to personal privacy. Proposed (f)(1)(ii) incorporates the definition of personal privacy currently set out at § 483.10(e)(1). We proposed to replace the requirements of existing § 483.10(e)(2) with new § 483.11(f)(2) which requires the facility to comply with the requirements of proposed § 483.10(g)(3). We proposed to re-designate existing § 483.10(j)(3) as § 483.11(f)(3) and revise it to require that the facility allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with state law. This is consistent with the requirements of section 712(b)(1) of the Older Americans Act.

We propose a new § 483.11(g) that would include provisions related to a safe environment. Specifically, we propose to re-designate § 483.15(h)(1) through (7) as § 483.11(g)(1) through (7) and revise paragraph (g)(1) to include paragraphs (g)(1)(i) specifying that the facility must ensure an environment where care and services can be delivered safely, and (g)(1)(ii) specifying that the facility must ensure that the physical layout of the facility maximizes independence and does not pose a safety risk.

We proposed a new § 483.11(h) Grievances, to incorporate the facility responsibilities expressed in existing § 483.10(f) and also require that facilities ensure that residents know how to file grievances. The proposed provision also requires that the facility establish a grievance policy to ensure the prompt resolution of grievances, and identify a Grievance Officer. Additionally, the facility is required to provide a copy of this policy upon request, as well as make information about filing grievances available to residents. Furthermore, the facility would be required to take a number of actions in response to a grievance, including:

1. Preventing further violations of resident rights during an investigation,

2. Immediately reporting allegations of neglect, abuse (including injuries of unknown source), and/or misappropriation of resident property, by anyone furnishing services on behalf of the facility, to the administrator of the facility and as required by state law,

3. Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concerns, a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued,

4. Taking appropriate corrective action in accordance with state law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction confirms a violation of any of these residents' rights within its area of responsibility; and

5. Maintain evidence demonstrating the resolution of complaints and grievances for at least 3 years.

Finally, we proposed a new § 483.11(i) which requires that a facility not prevent or discourage a resident from communicating with Federal, State, or local officials, including but not limited to Federal and State surveyors, other Federal or State health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and of the protection and advocacy system.

General

Comment: Many commenters supported specific aspects or the overall intent of our proposed revisions to resident rights and facility responsibilities, and provided wording suggestions or relocations, identified specific improvements, or raised concerns about specific provisions. Some commenters recommended we retain the existing language for a number of sections.

Response: We appreciate commenters support. We have considered each wording suggestion, suggested improvement and area of concern. We did not accept some wording changes or relocations that did not affect the meaning of or add substantial clarity to the regulatory requirement, or that were more appropriate to sub-regulatory guidance. Although we considered them, we do not specifically address all of those suggestions below. We also considered retaining existing language where suggested but do not specifically address each suggestion below. We discuss our response to comments on restructuring in section C. Resident Rights (§ 483.10) of this preamble and address other specific concerns and suggestions for change in the subsequent sections.

Comment: Some commenters suggested we use the term ''oral'' instead of ''verbal'' in a number of places.

Response: While both terms are accurate, we agree we should be consistent. Therefore, we have replaced the term ''verbal'' with ''oral'' throughout the regulation.

Comment: One commenter stated, with regard to resident rights as enumerated at § 483.10, that the proposed rule encourages a culture change towards a more resident-focused approach towards long term care. They note that improving quality of life and quality of care, allowing choices in daily living, and assisting individuals to make informed health care decisions are all major goals of culture change and person-centered care. They further state that involving individuals in choices about food and dining such as food selections, dining locations, and meal times can help them maintain a sense of dignity, control, and autonomy and they applaud CMS for proposing to revise its regulations in accordance with this resident-focused philosophy.

Response: We thank the commenter for their support. Person-centered care was one over-arching principle of our proposal. In addition, we believe that principles of quality of life and quality of care are also over-arching principles that apply to all the requirements for long-term care facilities. Many of the items the commenter mentions speak directly to each of these principles.

Comment: Some commenters stated that these requirements involve costly measures for nursing facilities. One commenter stated this would require them to employ translators, procure translation technology, or overhaul facility communications.

Response: Facilities should already have access to these services. Facilities are currently required to have the ability to communicate effectively, verbally and in writing, with residents. For example, facilities must inform residents in a language they can understand of their total health status and to provide notice of rights and services both orally and in writing in a language the resident understands.

Resident's Rights

Comment: Some commenters expressed concern that proposed revisions would diminish resident rights.

Response: We have maintained existing resident rights and protections, and have made revisions to ensure that those rights and protections encompass advancements, such as in the area of telecommunications, that were not envisioned when the original regulations were written.

Comment: One commenter recommended strengthening the wording of § 483.10(b)(5)(ii) to include asking residents their goals first. The commenter stated that the best and most respectful practice relative to establishing goals with residents starts with inquiry of the resident as to their preferred goals.

Response: This provision establishes the resident's right to participate in the care planning process. Section 483.21 addresses comprehensive person-centered care planning and is responsive to the commenter's concern. Please see our discussion of § 483.21(b), comprehensive care plans.

Comment: One commenter strongly support the new language that reads: ''A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life, recognizing each resident's individuality.'' Several commenters suggested that ''facility'' be changed to ''home or nursing home.''

Response: We thank the commenters for their support and their suggestion. We have retained the term ''facility'' throughout the regulation in keeping with the statutory language that serves as the basis for these regulations.

Exercise of Rights

Comment: A few commenters recommended that CMS explicitly include the right to vote and to require facilities to have policies and procedures to support voting. One commenter suggests that such policies and procedures include:

- A process for informing new residents about voting registration or change of address procedures;
- assistance in registering as needed and desired by the resident;
- procedures for informing residents of elections, including date, time, and location of voting places and community resources available to provide assistance;
- assistance with transportation to polling places;
- processes for reaching out to election officials to develop a plan for officials to come to the facility to register residents and conduct voting to the maximum extent election officials have the ability to do this;
- the designation of staff charged with assisting with voting; and
- training of designated staff in how to help a resident who requires assistance to vote where election officials are unable to provide that service to the extent needed.

The commenters contend that currently, residency in a LTC facility poses an enormous obstacle to exercising voting rights.

Response: The regulations, as proposed, state that the resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States, that the facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility, and that the resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart. Furthermore, facility staff

must be trained with regard to these rights and the facility responsibilities with regard to these rights, and residents must be informed of their rights. These requirements certainly include the right to vote. The suggested policies and procedures represent best practices, but we are concerned that some of the suggestions, such as requiring that facilities train designated staff to help a resident who requires assistance to vote where election officials are unable to provide that service, are overly prescriptive and burdensome. We would defer additional specificity with regard to this section to interpretive guidance.

Comment: A number of commenters expressed concern about the role of the resident's representative. One commenter urged CMS to encourage an appropriately expansive view of the representative's role while ensuring respect for the resident's right to self-determination. One commenter strongly supports proposed requirements that clarify that representatives can only exercise the rights delegated to them. Another commenter recommended that nursing facilities be required to have clearly defined procedures regarding resident representatives. The commenter recognized that a resident may not be prepared to designate a representative at the time of admission due to other pressing issues and suggests that nursing facilities should periodically remind residents that they have the option to select one or more representatives. Some commenters were concerned that nursing facility staff may not become aware of the resident's selection of a representative and recommended that CMS require nursing facilities to establish a mechanism for formally recording the designation of a representative and informing staff of the resident's selection and scope of delegation of responsibilities. Commenters also recommended that nursing facilities have a process for the residents to designate what they want to happen in the event that a resident is adjudged to be incompetent under the state law.

Some commenters stated that they disagreed that a resident has ''the right to revoke delegation'' of a court-appointed guardian when they have been deemed incompetent by a court. Similarly, if the practitioner in their professional opinion has determined the resident's medical condition impairs their decision-making capacity such that a resident's representative appointed by advanced directive or durable power of attorney needs to make decisions, a resident cannot revoke that representative. Some commenters expressed that the resident representative should be making decisions in the best interest of the resident or consistent with the resident's specified wishes and that the facility should try to resolve discrepancies and, if unresolvable, seek to legally remove the assigned representative.

Some commenters objected to allowing residents to have more than one representative. One commenter expressed concern that having a resident representative in addition to one appointed by the court or by the resident's own authorization through advance directives or a durable power of attorney will slow notifications and increase the likelihood of disagreements which may delay health-care decisions and necessary care. The commenter recommended that the definition of resident representative be modified to apply only when the resident does not have either a court-appointed guardian or an already designated health care proxy such as a durable power of attorney for health care or person specified in a living will to avoid having multiple resident representatives that will delay decision-making while differences are reconciled and requiring multiple notifications of numerous parties.

With regard to residents who have been adjudged incompetent, some commenters agreed that residents should retain as many rights as possible and their preferences be elicited and honored whenever possible. Once commenter felt that our proposed language will likely add confusion and is not internally consistent. The commenter stated that the court order for scope of decisions is not always clearly defined and the distinction between medical care decisions in the context of frail elderly in LTC facilities and personal decisions regarding quality of life often is not clear, resulting in confusion about who is the appropriate decision maker. The commenter is concerned that multiple decision makers will make this situation worse.

One commenter recommended that the definition of ''resident representative'' be modified to apply only when the resident has neither a court-appointed guardian nor a designated healthcare proxy through advance directives nor an identified durable power of attorney.

Response: We believe we have taken a comprehensive view of the role of resident representatives and the right of residents to choose whomever they want to assist them in making healthcare and other decisions both while the resident retains decision-making capacity and in the event a resident should not have or would lose after admission this capacity. See our discussion above, regarding the definition of ''resident representative.'' The term is not intended to create a new role, but instead is a general term intended to encompass several terms used to describe an individual who a resident or court provides with authority, in accordance with federal or state law, to participate in health care discussions or to make decisions on behalf of a resident. Nothing in this paragraph requires that a resident appoint or have a resident representative. We agree that a resident who is adjudicated incompetent cannot revoke a court's delegation of authority to a representative, which is why § 483.10(b)(3)(ii) defers to state law. In addition, residents adjudged incompetent by a court of competent jurisdiction are separately addressed in § 483.10(b)(7). With regard to limiting the rights of residents to have more than one representative, we decline to do so and defer to state law, to the extent that state law does or does not address this concern. While we acknowledge that multiple representatives could create complexity in decision making, we do not believe it is necessary or appropriate for us to limit the resident's ability to do so when state law would allow this. With regard to medical determinations of incapacity, we again defer to state law. Physicians can and do make determinations regarding an individual's decision-making capacity. We are aware that, at least in some states, if a patient disputes a determination of incapacity, a surrogate's decision-making cannot be substituted for the patient's until a court decides the matter. For certain situations, more than one physician's determination that a patient lacks decision-making capacity is required. With regard to the comprehensive nature of court decisions, we agree that generally such a decision would be in regard to an individual's ability to make all decisions. However, should a court's determination be more limited, we believe it is important that a resident be allowed to exercise his or her rights and to not have the facility extend the court's decision in deferring to a court-appointed representative. With regard to our reference to a court's order, generally, a court's determination would be formalized through a court order. However, for clarity in the event that a court's determination does not result in an order, we have modified our language to refer to the court's determination. We note that, in

§ 483.10(b)(4), we require that the facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law. This requirement presumes that a facility knows when a resident has a representative and the nature of the representative's appointment. We will not, at this time, be prescriptive regarding what a facility must do to fulfill this obligation, however, we would expect a facility to have process in place in order to ensure that they meet this requirement.

Comment: One commenter requested that CMS explicitly incorporate the concept of negotiated risk into proposed § 483.10(a)(2), which states that the resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility, and to be supported by the facility in exercising his or her rights.

Response: The rights of the resident to be informed about and agree to, refuse, and/or discontinue treatments are established under planning and implementing care, § 483.10(c), and further addressed section § 483.21, ''Care Planning.'' We defer any additional discussion to sub-regulatory guidance.

Comment: Another commenter recommended that we amend language at proposed § 483.10(a)(4) (iii) to read: ''The resident's wishes and preferences must be considered in the exercise of rights by the court-appointed representative'' rather than ''the resident's wishes and preferences must be considered in the exercise of rights by the representative.''

Response: A resident representative, whether court-appointed or not, should take the resident's wishes and preferences into consideration in the exercise of delegated authority. However, CMS has no authority to compel any action on the part of representatives, regardless of status.

Comment: One commenter suggested that the intent of proposed § 483.10(a)(4)(i) was unclear.

Response: Our intent is to ensure that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it. While guardianships are often general in nature, giving all decision making authority to a guardian, in some case a guardianship may be limited. A limited guardian has the authority to make decisions only in specific areas, such as financial or residential. Typically, a court's findings of fact and orders or the guardian's letters of appointment will identify these areas. Facilities are expected to be aware of when a guardianship is limited and not automatically defer all decisions to a guardian. We are finalizing this provision at § 483.10(b)(7)(i) and have revised it to state that, in the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

Comment: One commenter stated that in proposed § 483.10(a)(5), the first sentence in this section covers everyone who is covered under state law. Therefore, it is superfluous to single out a specific group later on in the paragraph.

Response: The provision in question states that ''In the case of a resident who has not been adjudged incompetent by the state court, the resident has the right to designate a representative, in accordance with state law and any legal surrogate so designated may exercise the resident's rights to the extent provided by state law. The same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.'' We originally included this language to account for State law that did not recognize the validity of same sex marriages. Although all states must now, pursuant to the Supreme Court's decision in *Obergefell* v. *Hodges* (576 U.S. ____, 135 S.Ct. 2584 (2015)) both issue same-sex marriage licenses and recognize the validity of such licenses issued in other states, in order to emphasize the importance of this provision, we are finalizing it as proposed.

Comment: One commenter asked if proposed § 483.11(a)(3) and (4) overrides a state statute that permits a NF provider to refuse to comply with health care agents' directives where they question the agent's ''good faith'' and to have the issue resolved by a court or agency as needed. The comments asked if the NF provider had to comply with a resident representative's decision until and unless the NF obtains court authority pursuant to § 483.11(a)(5).

Response: Proposed § 483.11(a)(3) and(4) are finalized as § 483.10(b)(4) and (5). Both provisions state that the requirement is ''in accordance with applicable law,'' which would include applicable state law. Proposed § 483.11(a)(5), finalized at § 483.10(b)(6), requires the facility to report, when a resident representative is making decisions or taking actions that the facility believes are not in the best interests of the resident as required by state law. Our regulations defer to state laws rather than preempt them.

Comment: One commenter was concerned that proposed § 483.11(a)(5) is confusing and could lead to underreporting of suspicion of crimes.

Response: We agree our language could be confusing and have modified it to state: ''[i]f the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law'', finalizing it at § 483.10(b)(6).

Comment: One commenter suggested that the order of proposed § 483.11(d)(3)(iii)(A) (limiting the requirement to act on residents' of families' requests and grievances) and (B) (requiring that facilities demonstrate that they have responded to such requests and grievances) should be reversed to emphasize that while a facility must have a response for every grievance or recommendation from a resident or family group, not every request has to be adopted as recommended.

Response: We agree that the suggested modification better conveys the information and have the provision accordingly, finalizing it at § 483.10(f)(5)(iv)(A)&(B).

Comment: One commenter requested that we clarify that proposed § 483.11(d)(5)(v) precludes a facility from taking resident funds for past due balances before the facility conveys any personal funds to a resident or resident representative.

Response: Proposed § 483.11(d)(6), which we finalize at § 483.10(f)(11), addresses those items and services for which a facility may or may not impose a charge against the resident's personal funds.

Comment: CMS begins the newly-named ''Facility Responsibilities'' section by expanding on existing requirements that facilities must treat residents with respect and dignity, and provide care and services that maintain or enhance the resident's quality of life and protect the resident's rights. The commenter supported the new ''Exercise of Rights'' § 483.11(a), including proposed § 483.11(a)(2)'s requirement that facilities provide ''equal access to quality care regardless of diagnosis, severity of condition, or payment source and establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services for all residents regardless of source of payment.'' The commenter encouraged CMS to provide greater clarity on proposed § 483.11(a)(3) and (4) over the

expectations of facilities deferring to resident representatives for decisions that exceed the scope of a court order, resident delegation, or other applicable law. Similarly, proposed § 483.11(a)(5)'s language of expectations for facilities complying with state requirements in the case of a resident representative making decisions not in the best interest of the resident seems rather vague and may provide potential for abuse.

Response: We thank the commenter for their support. Please see our previous response with regard to resident representatives. As we discussed in the preamble, we understand that there is a potential for abuse in the relationship between a resident and his or her resident representative, such as a guardian, and we want to ensure that facilities recognize their role in identifying and reporting such concerns in accordance with applicable state law. We would defer more detailed discussion to interpretive guidance.

Comment: Some commenters were concerned about the requirement that ''[t]he facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source.'' One commenter felt that this suggests that every facility must provide care for every individual regardless of the facility's care expertise or the ability to care for every condition any individual might have. For example, a person may require the use of a ventilator yet not every facility has the ability to provide care for such patients. Similarly, a facility that provides care for frail elders is unlikely to have the expertise to care for a child who requires facility care. The commenter suggested we delete ''diagnosis.'' One commenter pointed out that facilities, like clinics, may specialize in providing services to residents with specific conditions. Another commenter, while supporting the expectation to provide quality care (that is, safe, effective, person-centered, equitable, efficient, and timely) to everyone, recommends deleting ''equal access to,'' stating that terms such as ''equal access'' can easily be misconstrued as requiring the same amount of care or comparable treatments regardless of need or condition.

Response: We note that the phrase ''equal access to quality care'' is statutory language, specifically identified as a requirement relating to residents' rights in both sections 1819(c)(4) and 1919(c)(4) of the Act, and refers to the issue of possible discrimination in treatment based on the source of payment. We therefore are retaining the language as proposed in § 483.11(a)(2), finalizing it at § 483.10(a)(2).

This provision is not intended to require that every facility have every possible capability and unlimited capacity. However, a facility cannot choose, deliberately or inadvertently, to provide higher quality care to some residents over other residents in the facility based on diagnosis, severity of condition, or payment source. For example, if two residents require the same care, one resident cannot receive a lesser quality because the payer is Medicaid rather than Medicare. The amount and type of care is based on the resident's needs and goals, as evidenced by the care plan.

These provisions are also not intended to facilitate selective admissions or transfers. We considered, but did not include, admissions when we reviewed the existing requirement that requires a facility to establish and maintain identical policies and practices regarding transfer and discharge. Facilities are expected, as required by our provision for a facility assessment, to know their own capabilities and capacities when making admissions decisions. This expectation would apply to the second example provided by the commenter. Once an individual is a resident of the facility, the facility is obligated to provide equal access to quality of care, as stated in this provision. Thus, a facility that admits a pediatric resident is expected to provide quality care to that resident, based on that resident's needs. If a resident's condition changes such that a facility does not have the ability and is unable make accommodations to provide the care that a resident requires, that is an acceptable reason for discharge or transfer under § 483.15, as it is permissible to discharge or transfer a resident when it is necessary for the resident's welfare and the resident's needs cannot be met in the facility. This provision would apply in the instance where a resident's condition declines such that a ventilator is required in a facility that does not have the expertise or equipment to provide care to a ventilator dependent resident. However, the facility will have to include in its documentation the specific resident needs that it cannot meet, facility attempts to meet the resident needs, and the service(s) available at the receiving facility that will meet the resident's needs.

Comment: Some commenters were concerned that we do not include admission in the statement regarding equal access to quality of care and are concerned that this can result in discrimination in violation of Title VI of the Civil Rights Act of 1964. Another suggested that we expressly prohibit all forms of discrimination against residents.

Response: Nothing in these regulations allows facilities to violate other statutes or regulations. Furthermore, facilities are expressly required by § 483.70(b) to operate in compliance with all applicable Federal, State, and local laws, regulations, and codes. This includes, for example, the Americans with Disabilities Act and section 504 of the Rehabilitation Act. In addition, § 483.70(c) explicitly requires compliance with other HHS regulations. This would include but not be limited to those regulations pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); non-discrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). These provisions cover all phases of patient care, including, but not limited to, admissions.

Planning and Implementing Care

Comment: One commenter supported proposed changes to ensure that the resident is informed of, and participates in, his or her treatment, and that the resident participates in care planning. However, the commenter urged CMS to include stronger language with regard to including the resident or the resident's representative. The commenter strongly suggested that CMS include specific language that would require nursing facilities to provide reasonable advance notice to resident representatives of the care planning meeting, establish alternative means of participating (for example, via telephone or video conferencing), offer a reasonable choice of dates and times, and document the same. This would help facilitate the participation of resident representatives in care planning.

Response: We thank the commenter for their support of our proposal at § 483.11(b), which we are finalizing at § 483.10(c), and for their comments regarding care planning. We refer readers to our discussion of § 483.21 for further discussion of care planning.

Comment: Some commenters suggested that we add that residents have a right to a copy of the care plan.

Response: We appreciate the comments that were submitted on this

issue. While we agree that a resident should be able to review their own comprehensive care plan, we also understand that the comprehensive care plan is a clinically oriented document that is frequently reviewed and updated based on the needs of the resident. Therefore, in an effort to further promote a resident's right to be informed, while balancing the burden imposed on facilities, we have revised § 483.21(a)(3) to require facilities to provide residents and their resident representatives with a summary of their baseline care plan. This summary must include, but is not limited to, the initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary. Note that this summary is subject to the provisions at § 483.10(g)(3) and must be provided in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Furthermore, we note that § 483.10(c)(2)(v) gives the resident the right to see the care plan, along with the right to sign it after significant changes. The intent is to ensure that the resident, to the extent practicable and consistent with the resident's choices, demonstrates his or her participation in and review of his or her care planning and that participation is evident to care-givers, surveyors, and other interested parties. We believe that the combination of these resident rights, with the responsibility of the facility to provide a summary of the baseline care plan and include the resident as a member of the interdisciplinary care team, will actively engage residents in their care planning process.

Lastly, we would encourage a facility to provide a copy of the full comprehensive care plan upon request; with the understanding that care plans are dynamic documents that may change frequently. We believe that the comprehensive care plan should serve as an important tool for delivering patient-centered care and encourage facilities to explore ways to allow residents, families, and other representatives to access the care plan on a routine basis as appropriate, for instance, using technology solutions that enable real-time access for authorized users and dynamic updating by members of the care team. In addition, as finalized, residents have a right to review and obtain a copy of their medical record, or any portion thereof under § 483.10(g)(2)(ii). The care plan is included in the medical records. Sections 1819(b)(6)(C) and 1919(b)(6)(C) of the Act state that clinical records on all residents include the plans of care and the residents' assessments. We discuss our use of the term ''medical record'' in our discussion of § 483.70(i). As noted in that discussion, we regard the terms ''medical record'' and ''clinical record'' as synonymous.

Comment: Some commenters expressed concern about proposed requirements to inform the resident in advance of changes to the care plan and the right to see and sign the care plan after the changes are made. Commenters stated that the care plan is an evolving document and suggested that care could be delayed to wait on getting a signature, placing residents at risk for fall, skin breakdown, weight loss, and other undesirable outcomes.

Response: The right of the resident to be informed, in advance, about care and treatment and of changes in care and treatment that may affect the resident's well-being is not new. It is important that the resident receives information necessary to make a health care decision, including information about his or her medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives. Care necessary to prevent an adverse event or outcome should not be delayed just to obtain a signature on a care plan. However, we expect that residents will be involved, to the extent possible and as desired by the resident, in care planning. This includes seeing the care plan initially and after changes are made. Allowing the resident to sign the care plan after changes are made documents the resident's involvement. Furthermore, it supports both staff and resident perceptions that the resident is a vital member of the care planning team. We understand that care plans are evolving documents and would not expect that facilities would ask residents to sign care plans on a daily basis, and, therefore, have modified § 483.10(c)(2)(v), as finalized, to state that the resident has the right to sign the care plan after significant changes.

Comment: Some commenters suggested that CMS specifically include language related to informed consent. Others felt that language in proposed § 483.10(b)(2)(iii) needed further definition. One commenter appreciated CMS' proposed language recognizing the residents' right to be informed in advance of the risks and benefits of proposed care and treatment, especially with respect to the use of antipsychotic drugs often without first obtaining informed consent. The commenter believed that nursing facilities should be required to document that the attending physician discussed the benefits, risks, and alternatives of a drug with the resident and/or the resident's representative and that the doctor obtain informed consent prior to administering the drug(s). Some commenters suggested that this language was too restrictive and could delay care. One commenter suggested we revise the regulatory language to say ''the right to be informed, to the extent practicable, in advance of changes to the plan of care.'' Another commenter stated that advising the resident of the risks and benefits of proposed care, treatment and treatment alternatives or options are the responsibilities of the practitioner, not the facility, and recommends we revise the language accordingly. The commenter also stated that the resident should be informed of his or her right to refuse the medication and of alternative behavioral interventions, and this should be documented, as well. With respect to a resident's right to refuse a particular treatment or medication, the commenter was concerned that language stating that ''nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate'', as currently worded, could be used by nursing facility physicians and staff to deny a resident's/representative's request for alternative behavioral interventions on the basis that a physician or nursing facility nurse believes that a drug regimen is a better or more appropriate treatment. The commenter suggested that, in order to protect the resident's right to self-autonomy, CMS should clarify the definition of ''medically unnecessary or inappropriate'' in this context to make it clear that such decisions should be evidence-based. Another commenter suggested that CMS clarify the meaning of ''clinically appropriate.''

Response: Antipsychotic medications are addressed in § 483.45. Please see our discussion of comments related to that section. Although the requirements do not use the term ''informed consent,'' and informed consent laws may vary from state to state, the elements of informed consent are generally contained in the statements of resident rights. Proposed § 483.10(b)(3) establishes the resident's right to be informed in advance of the risks and

benefits of proposed care, of treatment and treatment alternative or treatment options, and to choose the alternative or option that the resident prefers. We note that the right to be informed in advance about care and treatment is not a new right and the facilities are already required to meet this requirement. Proposed § 483.10(b)(4) establishes the resident's right to request, refuse, or discontinue treatment. We agree that it is the responsibility of the practitioner to discuss the risks and benefits of proposed care, treatment and treatment alternatives or options with a resident or their representative and have modified the provision accordingly, now at § 483.10(c)(5). In addition, the practitioner is responsible for documenting this discussion in the medical record. The facility has a role in supporting the resident's rights, for example, by ensuring a resident or resident representative knows how to contact a provider. As one commenter noted, facilities can help residents facilitate existing informed consent rights, but may not abridge or abrogate them. With regard to clarifying the definition of medically unnecessary or inappropriate, we believe that there is a clear distinction between an alternative that a provider may not prefer and a treatment or service that is medically unnecessary or inappropriate. We defer additional discussion/examples of ''medically unnecessary'' as well as ''clinically appropriate'' to interpretive guidance.

Comment: Some commenters stated that they were pleased to see that the proposed regulations support the resident's right to participate in care planning. One commenter suggests we require that CMS require the planning process to identify staffing practices that maximize staff's delivery of person-centered care and the prevention of adverse events.

Response: We considered these suggestions, but are not incorporating them at this time. Staffing provisions address the need to ensure that nursing and other staff have the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e). Adverse events, including monitoring and prevention, are addressed by QAPI.

Comment: One commenter was concerned that the use of some terms is unclear. The commenter stated that the use of the term ''roles'' in proposed § 483.10(b)(5)(i) was confusing and should be replaced with a word that is clearer as to the intent. Other commenters asked if this meant that the resident could choose which nurse/therapist/aide would participate in the care plan meeting or if the meeting could not proceed if that individual was unable to participate. One commenter was concerned that the meaning of the phrase ''and the disciplines that will furnish care'' in proposed § 483.10(b)(2) was unclear and suggested ''The right to be informed, in advance, of the care to be furnished and the professions/practitioners/departments that will furnish care.'' The commenter offered other specific language alternatives.

Response: We reviewed these sections. We believe the term ''roles'' is appropriate. A resident may not be able to identify a specific person they want included in the planning process, or a specific individual may be unable to participate, but that should not prevent the resident from including a role, such as an individual to provide spiritual, nutritional, or behavioral health input. With regard to the term ''disciplines,'' to improve clarity, we have revised it to read ''type of care giver or professional'' that will furnish care.

Comment: Some commenters were concerned about adequate resident involvement in the care planning process. One commenter stated that ''often the resident or their representative is not aware of the right to participate in the development and implementation of his or her person-centered plan of care.'' The commenter was concerned that, although proposed § 483.10(b)(5)(i) allows the resident to request the right to participate in the planning process, if the resident isn't aware of the right, they are unable to implement it. The commenter recommended that CMS add language requiring the facility to ask the resident or resident representative at least quarterly if they choose to participate in the planning process, and to inform the resident of the date and time of the meeting. Another commenter suggested setting a minimum number of care planning meetings per year, such as monthly or quarterly, that the facility must invite the resident or representative to attend.

Response: We believe that our proposed requirements adequately address resident involvement in the care planning process. Regulations at § 483.21(b)(2)(ii)(E) require that to the extent possible the resident and/or their representative(s) must participate on the IDT that develops the resident's care plan. In addition, regulations at § 483.21(b)(2)(ii)(E) require that the facility provide an explanation in the resident's medical record if the participation of the resident and their representative is determined not practicable for the development of the resident's care plan. We encourage readers to refer to section H, ''Comprehensive Person-Centered Care Planning'' (§ 483.21) for a detailed discussion regarding the care planning requirements.

Comment: Some commenters applauded CMS's inclusion of advance directives in several provisions of the proposed rule and recommended that CMS incorporate other advance care planning tools in all provisions relating to advance directives. Commenters specifically recommended CMS incorporate recognition of Physician Orders for Life Sustaining Treatment (POLST) in several sections of the regulation, including defining ''Portable Order for Scope of Treatment.'' Commenters further suggested adding such orders as required documentation in the resident's medical record, if applicable and with the resident's consent, including such orders in both the baseline and comprehensive care plan, when applicable, and a review and update of such orders as part of the discharge planning process. One commenter recommended that CMS encourage repeated conversations related to advance care planning throughout a resident's stay.

Response: We thank the commenters for their support for the inclusion of advance directives. We note that advance directives are currently included in the requirements for participation and our proposed revisions were primarily to improve clarity and readability. We also thank the commenters for their suggestions but decline to add additional regulatory requirements regarding portable orders for scope of treatment at this time. We recognize that these tools serve a function beyond advance directives. Several of our requirements are also intended to facilitate shared, informed decision making and communication between health care professionals and residents with serious, progressive illness or frailty. These requirements apply both to the resident's care within a facility and to communication with other providers when a resident is transferred or discharge. We would expect that the issues that are addressed by portable orders for scope of treatment would be raised in the context of advanced directives as well in ongoing

discussions related to care planning and keeping in mind residents' goals of care and treatment preferences. To the extent applicable, such concerns should also be reflected in resident's discharge plan and discharge summary. All physician orders are documented in a residents' care plans. We note that a few states have developed POLST programs, a few states do not have such a program, and many states are in the process of developing such programs. Consistent with state law, it would be appropriate for facilities to inform residents about portable orders for scope of treatment, as those tools are referenced and recognized within the state. We note that current requirements already require a facility to provide written information to residents that includes a description of the facilities policies to implement advance directives and applicable state law.

Comment: One commenter was concerned with regard to Advance Directives that providing information is inadequate unless the facility explains what the information means, and suggested that CMS add language to require that an explanation to the resident or resident representative about what the various advance directives mean, including different code statuses, and that it can be changed if desired in the future.

Response: Facilities are required to provide written advance directive information in accordance with 42 CFR part 489, subpart I. In addition, residents have a right to be informed of their total health status; the right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care; of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers; and the right to request, refuse, and/or discontinue treatment. We also proposed and are finalizing provisions related to resident and resident representative participation in the care planning process, which includes discussion of resident goals of care and preferences. We would expect that the discussions resulting from these rights would include discussions tailored to the resident's specific situation, including, as appropriate, discussions around the types of care that would be covered by advance directives.

Comment: Some commenters supported CMS's proposal to strengthen resident rights related to care planning, but believed the proposed rule does not go far enough in creating truly person-centered planning and saw no reason why the person-centered planning process in nursing facilities should not be more consistent with the process mandated for Medicaid-funded home and community-based services. Some commenters recommended changes that would give more control to residents and permit residents to play a greater role in directing their own care. One commenter recommended specific revisions to the proposed regulatory language, including incorporating the term 'informed consent' and emphasizing the resident's right to direct the care-planning process.

Response: Our proposed regulatory language establishes that each resident has the right to be fully informed, in language that he or she can understand, of his or her total health status, and to make many types of decisions regarding his or her care. We believe that the rights set out in this section comprise the essential elements of informed consent, and are phrased in language that residents and their representatives can easily understand.

As we noted in the preamble to the proposed rule, our proposals support the guidance issued by HHS for implementing person-centered planning and self-direction in home and community-based services programs, as set forth in section 2402(a) of the Affordable Care Act. We agree that the principles in that guidance regarding dignity and self-direction apply equally to individuals who reside in a nursing facility. Although nursing facilities are expressly not considered home and community based settings (42 CFR 441.301(b)(1)(ii)), we have incorporated many requirements that are supportive of the principles reflected in the process mandated for Medicaid-funded home and community-based services. We refer readers to our discussion of § 483.21 regarding comprehensive person-centered care planning.

Choice of Attending Physician

Comment: Many commenters were concerned about facilities' requirement or ability to establish credentialing requirements for physicians. Commenters supported the right of residents to choose their own attending physicians and to require facilities to protect and promote that right. One commenter specifically supported changes designed to ensure that residents are the driving force in their care, so they can make choices that preserve their dignity, reflect their preferences, and support their independence. Nevertheless, the commenter was concerned by the lack of clarity around what is meant by the ''professional credentialing requirements of the facility,'' which is not otherwise defined in existing regulations. The commenter was concerned that leaving this level of flexibility to facilities could allow facilities inclined to not accept residents' choices with a potentially fairly easy way to undermine this right, and urges CMS to make clear that credentialing requirements cannot be used for the purpose of denying a resident's right to choose their own physician without good cause and/or right of appeal. The commenter requested clarification about how this right would be maintained when residents are in facilities that have closed medical staff models or facilities that employ their own physicians. The commenter also noted that credentialing itself does nothing to ensure adequate performance or competent care so they urge CMS to ensure that quality programs incorporate physician performance indicators and measures.

Another commenter urged CMS to confirm that this requirement applies to the attending physician only and not to a covering physician since that list can be extremely long and may change frequently. To the extent that CMS would apply this requirement to covering physicians, this would likely result in the unintended consequences of significant on-call coverage problems as well as potentially discouraging physicians from caring for SNF residents at a time when the agency is striving for greater and more frequent physician involvement in SNF care.

The commenter also pointed out that verification of professional credentialing requirements can take time which may result in a resident's physician being unable to serve as the attending physician upon admission. Thus, the resident would be under the care of another ''credentialed'' attending physician until their physician completes the facility's credentialing process. This switching of physicians is not a best practice and may result in resident's experiencing adverse events, as such attending physician may not be familiar with the resident. The commenter recommended amending § 483.10(c) to read: ''Choice of attending physician. The resident has the right to choose his or her attending physician. (1) The facility must develop its own credentialing process that does not require primary source verification, which is typically conducted by state licensure entities or the process for conveying hospital admitting privileges or managed care certification. (2) The physician must be licensed to practice, and (3) The physician must meet the professional credentialing requirements of the facility within a timely manner

following the resident's admission to the facility.''

Yet another commenter recommended additional wording in order to support the role of the medical director in ensuring practitioner accountability for improved performance. The commenter stated that credentialing refers only to background, education, training, licensing, etc. Just requiring credentialing is not enough to ensure adequate physician performance (for example, timely visits and competent care). Addressing the challenges of medical care requires holding people accountable for their performance and practice, not just their credentials. The commenter suggested that we modify the requirement to read: ''(c) Choice of attending physician. The resident has the right to choose his or her attending physician. (1) The physician must be licensed to practice, and (2) The physician must meet the professional credentialing, practice, and performance requirements of the facility.''

Other commenters recommended that CMS delete the credentialing requirement entirely. The commenters stated that CMS proposes, without explanation, to limit residents' free choice of physician to physicians who meet their facilities' credentialing requirements and that the commenters do not see a need for such a requirement. Further, one commenter is concerned that the proposal does not provide any standards for credentialing. The commenter stated that the public policy concerns about physicians have always been the lack of appropriate medical care in LTC facilities and how few physicians actually provide care to residents and that the new credentialing requirement would not improve the medical care of residents and could further reduce the number of qualified physicians providing care to residents. One commenter stated that, if the intent of the requirement is to improve the care provided by attending physicians, CMS should pull stakeholders together to determine how that could best be done and assess whether credentialing would accomplish that goal. If the intent is to remove a physician of the resident's choosing who is failing to fulfill a given requirement (for example, frequency of physician visits, unnecessary drugs), the current interpretive guidelines that outline such a process could be retained (''the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment''). The commenter further states that the proposed requirement is contrary to federal law at section 1819(c)(1)(A)(i) of the Act, which gives residents an unfettered right to choose their physician. The commenter stated that they oppose the proposed requirement as it is written and recommends it be deleted.

Response: Based on commenter concerns, we have withdrawn the proposed requirement related to physician credentialing. We are finalizing the requirements that the physician must be licensed to practice and must meet applicable regulatory requirements as well as the requirement that, in the event that it becomes necessary for a facility to seek alternate physician participation, the facility must discuss this with the resident and honor the resident's selection of a new attending physician.

Comment: Some commenters suggested that the resident's right to select his or her attending physician was a new right and stated that this could be burdensome and problematic.

Response: The right of a resident to choose his or her attending physician is not new. It is in current regulations and is a statutory requirement at both sections 1819(c)(1)(A)(i) and 1919(c)(1)(A)(i) of the Act. All facilities should already be in compliance with this requirement. We proposed requirements to ensure that physicians chosen by resident complied with requirements for licensing and credentialing. As a result of public comments, we are withdrawing our proposal regarding credentialing. Please see our previous response on this issue.

Comment: One commenter stated that the requirement to honor a resident's preference regarding a physician must be related to the physician's responsibility to practice appropriately and provide quality care and that the failure to hold physicians to this standard has major adverse consequences for long-term and post-acute care residents/patients. The commenter suggests adding the word ''relevant'' to emphasize that the choice needs to consider the physician's performance and practice as well as other factors.

Response: We have revised these requirements to state that the physician must be licensed to practice and must meet applicable regulatory requirements as well as a requirement that, in the event that it becomes necessary for a facility to seek alternate physician participation, the facility must discuss this with the resident and honor the resident's selection of a new attending physician. We do not agree that the requested revision is necessary and defer additional specificity to sub-regulatory guidance.

Comment: A commenter is concerned that proposed revisions relating to choice of physician in proposed § 483.10(c)(2) and (3) and proposed § 483.11(c)(2) conflict.

Response: We have withdrawn proposed § 483.10(c)(2) and have co-located the provisions related to choice of physician in § 483.10(d).

Respect and Dignity

Comment: A few commenters are concerned that the proposed rules require facilities to allow residents to use their personal belongings, but do not impose any obligations on facilities to assure the security of residents' property from loss or theft. These commenters recommend that CMS add additional requirements relating to the protection of residents' belongings. Others stated that CMS should specify that the use of person possession must meet fire code.

Response: Our proposed rule requires that a facility provide to a resident a safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible. A safe, home-like environment includes the security of the residents' personal belongings. Therefore, in response to commenters' suggestions, we have added language at proposed paragraph (j), safe environment, finalized at § 483.10(i) stating that the facility shall exercise reasonable care for the protection of the resident's property from loss or theft. We defer additional detail to interpretive guidance. We agree that the use of personal possessions must comply with fire safety. We note that we require that such use must not infringe upon the safety of other residents. Furthermore, facilities are required to comply with requirements related to Life Safety Code, which are located at § 483.90(a).

Comment: Commenters both supported and opposed our proposed changes to visitation requirements. One commenter strongly supports the language requiring that the ''facility'' provide immediate access to a resident by immediate family member and other relatives of the resident, and by others who are visiting with the consent of the resident, subject to the resident's right to deny or withdraw consent at any time. The commenter noted that this was included in the 2009 interpretive guidelines but having it in the regulations makes it an even stronger requirement. One commenter strongly supports changes to expand the rights of residents related to self-determination, to enable immediate access to the resident by the resident representative,

and the requirement that facilities must have written policies and procedures regarding visitation rights of residents. The commenter further supports providing residents with more flexibility around when they receive visitors and who may visit. Some commenters support proposed visitation provisions that enable residents to receive visitors of the resident's choosing, at the time of the resident's choosing, stating that this is an essential element of self-determination and, since the facility is the resident's home, residents should have the same 24-hour access to visitors as those who live in the community. Some commenters felt that residents don't want visitors late at night and prefer that the doors are locked. These commenters felt that our proposal unreasonably imposed visitors upon residents.

Many commenters expressed safety concerns with regard to open visitation. Some commenters stated that having unexpected visitors entering the facility at any time of day or night is unreasonable, disruptive, and potentially dangerous, but suggested that pre-arranged visits during ''off-hours'' could be accommodated and felt that, in order for a facility to provide a safe and secure environment for all patients and residents, there must be reasonable parameters applied to this visiting provision. One commenter suggested establishing specific time frames. Another commenter stated that their facility used a security code to ensure that staff knows when a visitor is in the facility. Some commenters stated that it is important that residents, visitors and staff understand that visitation privileges does not include a visitor living in the facility. Another concern is visitors who are extremely boisterous, confrontational, under the influence of drugs or alcohol. One commenter stated that a center must have the ability to protect staff and residents from this disruptive behavior. Other commenters noted that the rights of other facility residents must considered in an ''open visitation'' policy. One commenter highlighted important distinctions between hospitals and LTC facilities that should be considered, including concerns that LTC facilities do not employ distinct security personnel, or, if they do employ security personnel, they are typically not present around the clock. The commenter stated that it is more common for a LTC facility to have a receptionist at the main entrance who welcomes and guides visitors and that reception staff are present until early evening hours. The commenter stated that around the clock visitation would require increased staffing, at a minimum, which did not seem to be included in CMS' estimate of costs per facility for implementation of these rules. Commenters noted that, currently, facilities accommodate visitors at any time when a request is made or the clinical situation of the resident is such that the presence of visitors is essential. This provides everyone involved with the time to prepare and to accommodate everyone's needs. Mandatory ''open visitation'' in what is both a home and a health care facility means there will be more unanticipated visitors, and this could lead to facility resources being diverted to quickly arrange for an appropriate visiting environment for all involved, as opposed to attending to other needs. The commenter urges CMS to clarify this section of the proposed rule to ensure that facilities maintain the ability to limit visitations if those limitations are based on clinical or safety considerations that are outlined in the facility's policies and procedures and shared with each resident.

One commenter expressed concern about facilities establishing their own policies and procedures for visitation. For example, the commenter suggested that rather than allowing a facility to make its own decisions about restricting visits in the event of an infectious disease, the commenter suggested instead that the facility should follow CDC guidelines, which are evidence-based. The commenter also expressed a concern about permitting 24-hour visitation, stating that 24-hour visitation is already allowed but questions about 24-hour visitation still arise and many facilities still post signs indicating only specific hours for visitation. The commenter recommends that the regulations clarify this point.

Some commenters felt that the regulatory language impermissibly limited visits to residents from CMS, the State Survey Agency, family members and was concerned that CMS proposed to redefine access and visitation rights, currently at § 483.10(j), as a subcategory under ''self-determination,'' both for residents' rights (§ 483.10) and facility responsibilities (§ 483.11), with some language only included in proposed § 483.11. Some commenters object to the proposed language that would make visits from other visitors subject to reasonable ''clinical and safety restrictions'' and allow the facility to create written policies and procedures restricting resident access to visitors for clinical or safety reasons. One commenter stated that these requirements would gut resident visitation rights by giving facilities complete latitude to create whatever policies they want. Other commenters were concerned that proposed language erodes resident visitation rights by placing restrictions on visits that go beyond what is permitted under the Nursing Home Reform Law. Some commenters recommended that CMS delete proposed § 483.11(d)(2) in its entirety as inconsistent with the requirements of the Nursing Home Reform Law.

One commenter notes that relatives are not ''subject to reasonable clinical and safety restrictions'' in the way ''others who are visiting with a resident'' are and recommended that CMS delete all references to ''clinically necessary or reasonable restriction or limitation or safety restriction or limitation'' and that the facility policies and procedures clearly state that residents have the right to 24-hour visitation by anyone they choose. Another commenter stated that sometimes the facility needs to protect the resident against certain visitors.

Response: As noted above, several commenters suggested that our proposed provisions related to visitation were in conflict with statutory requirements. We have reviewed and revised this section to eliminate any confusion. Sections 1819 and 1919 of the Act establish specific requirements regarding access and visitation for residents of long term care facilities. Specifically, the statute requires that a facility permit immediate access to any resident by any representative of the Secretary, by any representative of the state, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician; (B) permit immediate access to a resident, subject to the resident's right to deny or withdraw consent at any time, by immediate family or other relatives of the resident; (C) permit immediate access to a resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, by others who are visiting with the consent of the resident; (D) permit reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and (E) permit representatives of the State ombudsman (described in paragraph (2)(B)(iii)(II)), with the permission of the resident (or the resident's legal representative) and consistent with state law, to examine a resident's clinical records. Our regulations are intended to be fully compliant with these statutory requirements. We have revised the

language related to the resident's right to receive visitors to clarify that restrictions on visitation apply only to those categories of visitors where such restriction is permitted by statute. As noted earlier, in order to be responsive to public comments, we have revised § 483.10 and § 483.11 into a single regulatory section, so that all of the provisions relating to visitation are now located at § 483.10(f).

We note that, in the proposed rule, in addition to the statutorily mandated individuals (any representative of the Secretary, by any representative of the state, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician) we expanded the individuals who must be provided immediate access to the resident to include the resident's representative as well as any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106–402, codified at 42 U.S.C. 15001 *et seq.*), and any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (Pub. L. 99–319, codified at 42 U.S.C. 10801 *et seq.*) as we believe that immediate access to a resident by these entities is important to the health and safety of a resident.

With respect to statutory language regarding reasonable restrictions and reasonable access, we proposed to add the caveat that those restrictions or limitations on access must be based on clinical or safety concerns. Furthermore, such restrictions and the rationale for such restrictions must be included in a facility policy on visitation that is consistent with the regulatory requirements. We believe limiting the bases for restrictions to reasons of health (that is, clinical concerns) and safety as well as requiring that the facility have their procedures and restrictions, including rationale, included in written procedures are useful in identifying and preventing inappropriate restrictions on visitation. We note that these limitations apply only to ''others who are visiting with the consent of the resident,'' based on the statute's language regarding ''reasonable restrictions'' and to ''any entity or individual that provides health, social, legal, or other services to the resident,'' based on the statute's language requiring ''reasonable access.'' As noted above, we believe that ''reasonable restrictions'' as well as ''reasonable access'' should only be limited based on clinical or safety concerns, such as those commenters identified. Commenters identified a number of safety restrictions that may be imposed by facilities. These restrictions protect the security of all the facility's residents, and include requirements such as keeping the facility locked at night; visitors making prior arrangements for late night access, denying access or providing limited and supervised access to a visitor if that individual has been found to be abusing, exploiting, or coercing a resident; denying access to a visitor who has been found to have been committing criminal acts such as theft; or denying access to visitors who are inebriated and disruptive. In addition, we agree that clinical restrictions in order to prevent the spread of communicable disease are appropriate.

With regard to ''imposing'' visitors upon residents, we have, consistent with the statute, included language that defers to a resident's choice when allowing visitors. Generally, residents do not have to have visitors unless they choose to have visitors.

Comment: One commenter objects to the word ''visitation'' as it can be defined as ''an official or formal visit, a disaster or difficulty regarded as a divine punishment. . .'' and recommends changing it to ''visit'' or ''visiting,'' which is not the same thing as ''visitation.''

Response: We appreciate the commenter's suggestion; however decline to make this change. We acknowledge that there are multiple definitions of the term ''visitation,'' including, perhaps most simply, as ''the act of visiting,'' which is applicable to the context in which we use it. Further, the term ''visitation'' is in the statute, specifically at sections 1819(c)(3) and 1919(c)(3) of the Act, to establish the specific right upon which this regulatory right is premised and in other regulations addressing similar subject matter, such as the hospital and critical access hospital conditions of participation.

Comment: Some commenters expressed concerns about provisions relating to resident and family groups. One commenter suggested that we expand those who have a right to participate to include ''friends of the resident who have his or her permission''. Another commenter recommended that it be clarified that it is also the right of family members or resident representatives themselves as well as other persons interested in the welfare of the resident or residents to participate in family groups. The commenter supports the intent of the proposed language that requires nursing facilities to provide a resident or family group, if one exists with private space, but believes that the facility should be prohibited from impeding and should be required to facilitate the formation or continued existence of such groups. The commenter believes that nursing facilities should be required to, with the approval of the groups, take reasonable steps to notify, through conspicuous postings, and other means, residents and family members of the groups and of upcoming meetings in a timely manner. The commenter supports our clarification that the designated staff person who participates in a resident or family group must be approved by the resident or family group and by the facility, but suggests CMS be clear that the designated staff person does not necessarily have to be the same person for both the resident group and the family group. The commenter also suggested CMS clarify that resident and family groups can convene without a facility staff member present and may convene off-site. Commenters support the proposal that the grievances and recommendations of the groups must be addressed, and if not implemented, the rationale for this must be provided to the group but recommend that we require a written response to the group within a specific timeframe.

Response: CMS fully supports family and caregiver engagement. However, we believe that the right of family members to participate in a family group is a result of and subordinate to the resident's right in this instance. We can envision circumstances where a resident would not want and it would not be appropriate to allow a family member, such as an estranged spouse or an abusive relative, to participate in a family group as a result of a residents' presence in a facility. Therefore, we have retained this language as written. We proposed to expand this right to include resident representatives in order to ensure that individuals of the resident's choosing, whether a familial relation or not, can also participate in these groups. We believe this supports the resident's ability to choose who they consider 'family.' We also provide that visitors may attend at the groups' request. We decline to give ''friends'' or ''other persons interested in the welfare of the resident or residents'' a right to participate independently of an invitation from the group, as this additional participation should be determined by the group rather than imposed upon it. Other provisions require that facilities make residents aware of contact information for State

and local advocacy organizations, such as the State Long-Term Care Ombudsman program, and the Aging and Disability Resource Center or other program in the No Wrong Door System, should residents wish to invite such entities to a resident- or family group. In addition, nothing precludes an individual interested in the welfare of the resident or residents from requesting such an invitation. With regard to group meetings outside of the facility, nothing in these requirements precludes a resident or family group from meeting outside the facility and the resident has a right to interact with members of the community and participate in community activities both inside and outside the facility. We agree that facilities should take reasonable steps to ensure that residents and family members are aware of upcoming group meetings and have revised accordingly, finalizing this provision at § 483.10(f)(5)(i).

We defer to sub-regulatory guidance further discussion of the designated staff person(s) assigned to provide resident or family groups with assistance and response. We note that we already state that staff or visitors may attend group meetings at the group's invitation.

We require that facilities must respond to a grievance voiced by a resident or family group with a response and a corresponding rationale. We expect that such response would generally be a written response, but might also take another form. For example, if a resident group requests a specific action and the facility can show that the action has been taken, there may be no need for a written response. We have clarified that the facility response must be timely, but decline at this time to specify a time frame, given the potential variation in such grievances and recommendations.

We require the facility to provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay, both orally and in writing in a language that the resident understands. This includes all of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. We further require notification if those rights change. These rights include the right of the resident to organize and participate in resident groups.

Comment: One commenter recommended that CMS explicitly prohibit the facility from taking any action that would discourage the formation and/or activities of resident and family groups, and that CMS require the facility to (1) provide the resident or family group access to a bulletin board or other public notice space for their exclusive use to communicate with other residents, friends, and family, and (2) provide, at the group's request, a roster of the group members, including name and contact information, excluding information of those member who have declined such inclusion in writing.

Response: We appreciate the commenter's suggestion, but are concerned that these requirements are overly prescriptive. Furthermore, we believe that the underlying concerns can be addressed either by individuals through the grievance process or by the resident and family groups' facility representative and complaints/recommendations made by the group to the facility.

Comment: One commenter stated that both residents and families need to be able to freely raise and discuss issues in their respective groups and the presence of one or more residents at a family group would likely prevent at least some family members from speaking out candidly or at all. The commenter stated that this undermines the purpose of such a group and suggests revisions to these provisions to address participation across groups.

Response: The requirements as written provide for both resident groups and family groups. We have clarified that staff, visitors, or other guests may attend the resident group or family group at the respective group's invitation. We understand the commenter's concern and believe that family groups can determine how to best manage this issue. We would not prohibit residents from participating in family groups. We defer additional discussion to sub-regulatory guidance.

Comment: Some commenters were concerned about the protection of resident personal funds and recommend additional requirements. One commenter supported CMS efforts to pull provisions related to the protection of residents' funds together into one place for clarity, to update those requirements and to add limitations on the kinds of things for which facilities may charge residents. Suggestions to strengthen these requirements included requiring that facilities periodically review accounts of resident funds for suspicious withdrawals, requiring administrators to take training in protecting resident accounts, and providing the residents or resident representative monthly accounting statements so that any changes are noticed as quickly as possible. Another commenter expressed concern that the proposed rules under residents' rights as they relate to protection of resident funds are extremely limited, and the other specific current rights at § 483.10(c) are shifted solely to the proposed § 483.11(d)(5). The commenter stated that residents' rights provisions need to include sufficient detail to ensure that residents and their families and representatives know what the rights are. The commenter suggested that we restore all of the language at current § 483.10(c) to proposed § 483.10(e)(9) and restore an independent title ''Protection of resident funds'', stating that resident funds should not be a subcategory of the term ''self-determination.''

Response: We thank the commenters. As addressed earlier in this section, we have consolidated proposed § 483.10 and § 483.11, which addresses commenter concerns about residents rights containing sufficient detail to ensure that resident know both their rights and the facility's responsibility to support those rights. We maintain that it is appropriate to retain all of this information in the section relating to the resident's right to manage his or her financial affairs, and therefore have not restored an independent title of ''protection of resident funds.'' Under current requirements, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, including establishing and maintaining a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf and providing the individual financial record through a quarterly statement as well as on request. Current interpretive guidance establishes that ''hold, safeguard, manage and account for'' means that the facility must act as fiduciary of the resident's funds, report at least quarterly on the status of these funds in a clear and understandable manner, and includes money that an individual gives to the facility for the sake of providing a resident with a non-covered service. We have revised paragraph § 483.10(f)(10)(i), as finalized, to state that the facility must act as a fiduciary of a resident's funds. According to Cornell University Law School, a fiduciary duty is a legal duty to act solely in another party's interests. Parties owing this duty are called fiduciaries. The individuals to whom they owe a duty are called principals. Fiduciaries may not profit from their relationship with their principals unless they have the principals' express

informed consent. They also have a duty to avoid any conflicts of interest between themselves and their principals or between their principals and the fiduciaries' other clients. A fiduciary duty is the strictest duty of care recognized by the U.S. legal system. (see *https://www.law.cornell.edu/wex/fiduciary_duty*)

Although current sub-regulatory guidance already identifies the facilities responsibility for resident accounts as a fiduciary responsibility, we would strengthen this expectation by spelling it out in regulation. We believe that this addresses the commenters concern but allows for some flexibility in implementation. We defer additional specificity to sub-regulatory guidance.

Comment: One commenter recommended stricter oversight of resident funds, including the use of auditors with an accounting background.

Response: We have strengthened the requirements related to resident funds, as discussed in the previous response. Establishing requirements that facilities hire independent auditors to audit resident accounts is outside the scope of the current rulemaking, but we will keep this suggestion in mind for future occasions.

Comment: Several commenters supported revisions to a resident's choice of roommate. One commenter strongly supported new language that states: ''The right to share a room with her or his roommate of choice when practicable, when both residents live in the same home and both residents consent to the arrangement,'' which could include same sex or opposite sex couples or individuals choosing to share a room.

Response: We thank the commenter for their support. We agree that choice of roommate is significant to a resident's quality of life and an important aspect of treating a resident with respect and dignity.

Comment: Some commenters objected to our proposed provision regarding choice of roommate. One commenter expressed concern that the right of one resident to have a roommate of choice could violate the rights of an existing roommate. Other commenters suggested that this meant that a resident who didn't want a roommate would have to be provided a private room.

Response: Section 483.10(e)(5) states that the resident has the right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement. It does not require the provision of a private room. Furthermore, we have included the phrase ''when practicable'', as we realize that such arrangements may not always be possible, or may require some delay in order to accommodate. For example, such a move may require waiting until a room is available for both residents who want to be roommates to move into. We would not expect a facility to accommodate such a request when doing so would violate the rights of another resident.

Comment: Some commenters recommended that we strengthen language related to involuntary changes in room or roommate. One requested that we better define notice. Another suggested that we qualify a resident's right to refuse a transfer to not apply when the resident's medical needs can't be met. Another commenter stated that the impact of moving residents against their will is well documented, and can lead to both psychosocial and physical harm and suggests that, given the potential risk of any move that is not the resident's choice, such moves should only be permitted for certain reasons and written notice should be provided within a set timeframe. The commenter noted that several states, including Connecticut, Colorado, Texas and Indiana, require written notice when the facility is proposing to move a resident. The commenter further stated that facilities should be required to prepare a resident for a transfer in the same way as required for a transferred or discharged. The commenter suggested that involuntary changes in room only be allowed if the transfer is necessary for medical reasons as determined by the attending physician; or the transfer is necessary for the welfare of the resident or other residents, and the resident must be given notice, including the name, address, and telephone number of the local and state long term care ombudsman and, if applicable, the mailing address and telephone number of the agency responsible for the protection and advocacy at least 5 business days before relocation. In addition, the commenter suggested that the facility be required to develop a relocation plan to orient and prepare the resident for the move, including taking the resident to see his or her new room and unit and meeting staff who will be assigned to him or her.

Response: We agree that, absent extenuating circumstances, many of the commenters' suggestions make sense. Involuntary transfers should not be undertaken solely for the convenience of the staff. However, there are circumstances, generally involving safety, where advance notice and preparation may not be appropriate. Examples could include when one roommate is diagnosed with a communicable illness or when a move is necessary for the safety of either resident in a room, even if one of the roommates disagrees. We have revised § 483.10(e)(6), to require written notice, including the reason for the change, and paragraph (e)(7), to give the resident the right to refuse a transfer that is made solely for the convenience of the staff. We will consider requirements for a specific timeframe and preparation for a room change for inclusion in future rule-making.

Comment: One commenter requested that we clarify our use of the term ''eviction'' as opposed to ''discharge''.

Response: The term ''eviction'' is used to reflect an involuntary discharge from a place of residence. To ''evict'' is to make a person leave a place (*http://www.merriam-webster.com/dictionary/evict*). Not all residents consider the LTC facility his or her place of residence, but for those who do, an involuntary discharge is equivalent to an eviction.

Self-Determination

Comment: Some commenters were pleased to see that the proposed regulations include the resident's right to choose schedules. One commenter suggested we require that these choices are communicated to staff who are assigned using staffing practices that maximize staff's ability to fulfill the resident's choices and that we further state that residents must be able to choose from a range of activities that correspond to their interests. Other commenters expressed concern that they would be unable to accommodate every request every time and would be penalized as a result. Some commenters pointed out that these rights must be balanced with other residents' rights.

Response: While we considered these suggestions, we will defer to interpretive guidance for more detailed discussion of how a facility can meet the requirement that residents have the right to choose activities and schedules.

Comment: One commenter stated that, with regard to proposed § 483.10(e)(2), not all patients/residents are realistically able to participate in activities outside the facility. The commenter suggests that we amend this paragraph to by adding ''as appropriate based on the resident's functional capability.'' Other commenters suggest that residents should have free access both inside and outside of the facility.

Response: Some residents may not, realistically, be able to participate in activities outside the facility. However, many may be able to do so, particularly

with family or other assistance or planning. The facility has a responsibility to promote and facilitate resident self-determination, rather than act as a hindrance or barrier. At the same time, we recognize that there may be safety and security concerns with unfettered access to outside spaces and in and out of the facility. These competing interests must be balanced, taking into consideration the needs and preferences of residents in the facility.

Comment: One commenter stated that, with regard to proposed § 483.10(e)(5), not all facilities have family groups and in those centers that provide care for post-acute, short-stay patients, it is seldom that these individuals and their families have interest in participating in a family group. The commenter suggests we add the qualifier ''if any.''

Response: There is no requirement for a facility to have a resident or family group if the residents or their representatives do not want one. However, if interest does exist, the facility should support the formation of such a group, as required by this section. Adding ''if available'' may imply that if such a group does not already exist, the right to participate does not exist. This is not accurate.

Comment: One commenter is concerned that, as written, proposed § 483.10(e) could be interpreted to require that a facility contract with any and all hospice providers, therapists/therapy companies, etc. and conflicts with the proposed § 483.10(c) Choice of attending physician. The commenter recommends amending the provision by adding ''consistent with § 483.10(c) and other relevant contracting requirements''

Response: We considered the commenters concern and added ''and other applicable provisions of this Part'' to the provision.

Comment: Some commenters were concerned that the residents' right to choose health care and providers of health care services consistent with their interests, assessments, and plan of care would require facilities contract with, utilize, or arrange for a health care subcontractor that had not previously been contracted with or approved by the facility. They were concerned that such entities might be on the OIG's list of excluded individuals or entities, might have failed background checks, or might be operating outside of their legally permissible scope of service. They also suggested that such entities might not be not properly licensed or insured, might not meet the quality standards of the facility, or could potentially create an unsafe situation for the resident. The commenters further contend that the facility must be able to control the expenses related to who provides services due to bundled payments.

Response: Facilities cannot subcontract to health care entities that are on the OIG's list of excluded individuals or entities, and should not contract for any services with entities otherwise unsuitable for providing services. However, residents should not be required to accept services from providers to which they object, or entities that impose unreasonable charges on the resident's personal funds. We would expect facilities to work with residents to reach agreements.

Comment: One organization stated that they support CMS's proposal ''to clarify that the facility may not charge for special food and meals ordered for a resident by a physician, physician assistant, nurse practitioner, clinical nurse specialist, dietitian or other clinically qualified nutrition professional.'' The commenter noted that client satisfaction is critical and expressed support for the resident-centered concept of care. The commenter further stated that many of their members believe it is their duty to provide residents with everything they need during their stay and that members report that client satisfaction improves oral intake, nutritional status, quality of life and well-being and is likely to result in fewer hospitalizations. They suggested that comparable and reasonable substitutions, as determined by the registered dietitian, should be permitted. The commenter sought confirmation that the special food and meals purchased for a resident must be in alignment with a required specific diet order as a therapeutic diet in order for the items not to be charged to the resident. In addition, they request guidance as to whether facilities could require residents or their families to provide their own special supplements or functional foods if the facilities did not have them in their formularies.

Response: Facilities are required to provide the services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care. If a special diet is included in a resident's plan of care, the facility is obligated to provide it. For situations in which special foods are requested without being part of the plan of care, we defer the matter to sub-regulatory guidance.

Comment: Some commenters objected to the requirement that facilities convey the resident's funds and a final accounting of those funds to the resident or the resident's estate, within 30 days of death, eviction, or discharge. Commenters stated that this time frame is too short, that third-party payers do not pay the facility in a timely manner and that an accurate accounting is likely to take longer. Other commenters felt that the resident's funds should be returned more quickly.

Response: The existing requirement for the final accounting and return of funds is already 30 days in the event of death, and no changes were proposed to this standard in the proposed rule. We are therefore retaining this standard as proposed.

Information and Communication

Comment: One commenter stated that, since all facilities must convey their MDS data electronically, all facilities have Internet access and proposed language related to facility access and expense is not needed and could be used to deny residents electronic access. The commenter finds limits placed on resident access to electronic communication problematic. Other commenters objected to the burden of requiring an expanded electronic footprint.

Response: We disagree that our requirement that facilities convey MDS data electronically means, consequently, that all facilities will have Internet access that can be made available to residents. Some facilities may utilize a vendor to submit MDS data and may not have onsite Internet access. Other facilities may have Internet access, but that access might not include capacity sufficient to accommodate expanded user access. We did not propose to require facilities to expand their Internet access. We are finalizing proposed § 483.11(e)(13) at § 483.10(g)(7).

Comment: Some commenters stated that, with regard to proposed § 483.10(h)(2), it is important that whatever Internet research is being done by residents is legal. For example, access to sites that promote child pornography or other illegal activities must be limited. Furthermore, providing absolute privacy for each resident wanting to use email and video communication may require advance planning. For example, if a facility has one room with several computer terminals available for residents' use, privacy may require a resident to schedule private use in advance, during which time no other resident may use a terminal in that room. The commenter suggested we revise the provision to read ''The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and

for Internet research. All such activities are limited to legal Web sites/activities as determined by state and federal laws. If absolute privacy is required, the facility may require advance scheduling of a computer to assure such privacy.'' Some commenters asked if the facility was required to ensure that communications were secure.

Response: We agree that use of the Internet, or any form of communication, including the U.S. Postal service, must be in compliance with other legal limitations and restrictions relating to those devices or systems. We have added language to that effect at finalized § 483.10(g)(9)(iii). We acknowledge that for devices provided for the community, advance planning may be required. Further, one resident's use of video communications must not infringe upon the rights of other residents. These were considerations when we used the term ''reasonable access.''

Comment: Several commenters were concerned that our proposal limits the type of information that residents can access, including their records. One commenter stated that CMS provides no rationale for restricting residents' access solely to medical records other than to conform the requirements to 45 CFR 164.524(c)(4) and stated that such justification is not sufficient. Some commenters recommended that CMS retain the current language. One commenter supported the expansion of accessibility to information by the resident (proposed § 483.11(e)), including the language stating ''that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.'' The commenter supported the requirement that facilities provide residents with access to medical records in the form and format requested by the individual if they are readily producible, and if not, then in written form or in another form as agreed to by the individual and the facility. This requirement builds on the existing requirements that such information be made available within 24 hours, and upon oral and written request. Reflecting the reality that many nursing facility residents cannot access records electronically, the commenter appreciated that the proposed rule leaves the decision to the resident as to whether to access records electronically or in another ''readily producible'' format. One commenter suggested that retrieving electronic information in a format that is user friendly is actually more difficult than non-electronic information. Another commenter was concerned that our proposal mandated that facilities be able to provide an electronic copy of the medical record. One commenter suggested that access to a person's own medical record should not be contingent on weekday staffing and recommends striking the parenthetical statement, ''excluding weekends and holidays,'' as well as the requirement for inspection prior to purchase of the medical record. One commenter believed that CMS should clarify that a resident is entitled to his or her complete set of medical records, and proposed that the definition of ''medical records'' include all records concerning the resident during the period of time the resident was in the nursing facility's care. Without clarification, the commenter was concerned that nursing facilities may self-define what records it considers to be ''medical records'' for the purposes of responding to resident requests to the exclusion of records related to outside consultations, financial records, and other records that may be kept outside of the facility medical records. Allowing nursing facilities this degree of flexibility may undermine the resident's right to access his or her own records and allow a nursing facility to conceal any deficient care provided to the resident.

Some commenters were concerned that 2 working days advance notice may not be adequate time depending upon the size of the records. One commenter stated that this should be 30 days, consistent with HIPAA. Other commenters suggested that there should be a definition of ''working day.'' These commenters suggested we amend proposed § 483.10(f) (3)(ii) to read: ''After receipt of his or her medical records for inspection, to purchase, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 to 5 working days (working days defined as between 8 a.m. and 6 p.m., Monday through Friday) advance notice to the facility. Some commenters recommended that residents have access to their records 24 hours a day, 7 days a week so that they can review records with family members at any time, including weekends and holidays.

Response: We thank those commenters who supported our proposals. We agree that flexibility, contingent upon the resident's ability to access and understand the information, is important. It is not our intent to reduce a resident's access to information. Although sections 1819(c)(1)(iv) and 1919(c)(1)(iv) of the Act only require access to current clinical records, we agree that it is important that LTC facility residents also have access to certain other records about themselves that may be held by a long-term care facility, such as their financial or social records. We have reviewed our proposals and expanded the language which we are finalizing at § 483.10(g)(2) and at § 483.10(h) to include both personal and medical records. We acknowledged in the proposed rule that we were proposing changes related to facilities providing access to and copies of medical records in order to ensure consistency with HIPAA. Federal requirements and expectations related to the privacy and confidentiality of patient records, especially with regard to protected health information, changed substantially with the enactment of HIPAA. Thus, aligning with other statutory requirements that apply to long-term care facilities was one aspect of updating the requirements for long-term care facilities.

With regard to medical records, the resident has access to the medical record itself and the right to access a copy of that record, not a version of the medical record that has been revised to ensure the resident's understanding. Summaries of medical records are addressed by the privacy regulations at 45 CFR 164.524. We retain the access limitations related to weekends and holidays based on statutory requirements in section 1819(c)(1)(A)(iv) of the Act. We disagree that 48 hours is not sufficient time to provide a copy of the resident's record. This is a long-standing standard and we did not propose to change the time frame. Further, for those facilities using electronic records, the electronic record may simplify the effort needed to print or create an electronic copy of the record, depending on the specific software system used by the facility. We do not mandate that facilities be able to provide an electronic copy of the medical record, unless the records are maintained in an electronic format and are readily producible in that format. We also agree that, while residents or their representatives may wish to do so, they should not be required to inspect a record prior to purchasing it. Therefore, we have removed this requirement at finalized § 483.10(g)(2)(ii).

With regard to our use of the term ''medical record'', please see our discussion of § 483.70(i). As noted in that discussion, we regard the terms ''medical record'' and ''clinical record'' as synonymous. Section 1819(b)(6)(C) of the Act states that clinical records on all residents include the plans of care and

the residents' assessments. We further note that for ''covered entities'' as defined at 45 CFR 160.103, individuals have a right to access protected health information in a ''designated record set.'' A ''designated record set'' is defined at 45 CFR 164.501 as a group of records maintained by or for a covered entity that comprises the medical records and billing records about individuals maintained by or for a covered health care provider; enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals. The term ''record'' means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity. Thus, individuals have a right to a broad array of health information about themselves maintained by or for covered entities, including: Medical records; billing and payment records; insurance information; clinical laboratory test results; medical images, such as X-rays; wellness and disease management program files; and clinical case notes; among other information used to make decisions about individuals. In responding to a request for access, a covered entity is not, however, required to create new information, such as explanatory materials or analyses that does not already exist in the designated record set. A ''designated record set'' under HIPAA is not synonymous with ''personal and medical records'' under these requirements. However, as noted earlier, to the extent that HIPAA provides additional rights to individuals (that is, residents, in the long-term care context) beyond what is provided in this final rule, covered entities and business associates must comply with the requirements in HIPAA to ensure individuals are afforded these additional rights. As noted in a separate response under this section, we expect that most, if not all, long-term care facilities are covered entities who must comply with HIPAA.

Comment: Some commenters thought that we were requiring facilities to provide electronic copies of medical records and expressed concern that this would require the purchase of new equipment and new staff to manage the task.

Response: Proposed § 483.10(f)(3)(i) specified that the resident would have a right to receive medical records in the form and format requested if the requested records are readily producible in such form and format. We are not requiring facilities to provide records in an electronic format if the record is not maintained or readily producible in an electronic format. We are finalizing this provision at § 483.10(g)(2)(i).

Comment: Several commenters object to our proposed standards for the fees that facilities may charge for these records. Some oppose the proposal to move from a community standard to a cost-based standard under which the fee may include the cost of labor for copying the requested health information, the supplies for creating the paper copy or electronic media, and postage, which could be abused and could inappropriately and unfairly impede a resident's access to his or her own health records. The commenter recommends, at a minimum, a limit on fees that can be charged, and to ensure that said fee includes any labor charges (research fees, clerical fees, handling fees or related costs). One commenter recommends the establishment of a ''hardship exemption'' for low-income residents, allowing them to receive copies of their records at no charge, perhaps upon providing an affidavit of inability to pay or otherwise demonstrating an inability to pay fees. Another commenter stated that there are a large number of residents who use Medicaid who are required to contribute most of their income to their care and are left with a small personal needs allowance, a minimum of $25 per month, who cannot afford these larger amounts to get copies of their records. The commenter suggests we restore the existing regulatory language and include parallel language as a resident's right. Commenters are concerned that the costs CMS proposes to allow, specifically labor costs, in this section create an opportunity for a nursing facility to create a financial burden and barrier to a resident's right to receive a copy of their own medical record. Some commenters recommend that facilities provide a copy of the medical record on an annual basis at no charge to the resident, and otherwise, costs should be limited to supplies and postage.

Response: We thank the commenters for their concern. Prior to development of the proposed rule, we received input regarding the definition of ''community standard'' and concern about exorbitant charges for medical records. Commenters to the proposed rule have suggested the community standard be set at the amount charged by a local library, Post Office, or commercial copy center, or a set fee. We considered these options. However, the cost that providers who are subject to HIPAA (''covered entities'') may charge for medical records is established by the HIPAA Privacy Rule at 45 CFR 164.524(c)(4). Our proposal is consistent with that standard, which states that a facility may charge a reasonable, cost-based fee that can include only cost of copying, including supplies and labor, and postage, if the patient requests that the copy be mailed. The fee may not include costs associated with reviewing the request, searching for and retrieving the requested records, and segregating or otherwise preparing the record that is responsive to the request for copying. Given that long-term care facilities are generally likely to be subject to HIPAA and we require in § 483.70 that facilities comply with other HHS regulations, we believe that our policy here should be consistent with the HIPAA Privacy rule at 45 CFR 164.524(c)(4). Therefore, we will finalize our proposal at § 483.10(g)(2)(ii) without change. We again refer readers to recently released HHS guidance on individuals' right under HIPAA to access their health information *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html*).

Comment: One commenter stated that they are pleased that CMS is proposing to require facilities to make reports related to surveys, certifications, complaint investigations, and plans of correction available for individuals to review, and to post a notice of this information's availability. Other information the commenter recommends be made available to residents includes:

- Results from independent resident/family caregiver experience surveys (resident and family)—such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Nursing Home Surveys;
- Whether or not the facility provides special care services and if so, the kinds of services provided;
- Policies of the facility. For example, whether it has family groups, allows pets, etc.; and
- Information available in other languages, as appropriate.

CMS may wish to consider, where appropriate, whether the existing standards that apply to medical records—that they be made available within 24 hours and upon oral and written request should be extended to the other types of information that are required to be made available under proposed § 483.11(e).

Response: We thank the commenter for their support. We considered but are not, at this time, expanding the information which must be provided to every resident. We note that facilities are required at finalized § 483.10(g)(16)

to provide a notice of rights and services to the resident prior to or upon admission and are generally required at finalized § 483.10(g)(3) to ensure that information is provided in a form and manner that a resident can understand. As a result of comments concerned that our proposal limited the information about themselves that residents have access to, we have expanded our provisions relating to medical records to include personal records, to the extent applicable.

Comment: One commenter requested that we clarify in the regulations that ''readily accessible'' means not having to ask a staff person for access in order to review survey reports or plans of correction. Another commenter stated that it was unreasonable to require the availability of 3 years of reports.

Response: Section 1919(c)(8) of the Act requires that a nursing facility must post in a place readily accessible to residents, and family members and legal representatives of residents, the results of the most recent survey of the facility. This requirement is not premised upon a request. In contrast, section 1819(c)(1)(A)(ix) of the Act imposes this same requirement premised upon a ''reasonable request.'' We note that we generally deem all requests to be reasonable unless the requestor demands unreasonable deadlines or more information than is contained in the document. We have revised § 483.10(g)(11) to reflect the stricter standard imposed by the statutory language in section 1919(c)(8) of the Act, which does not require a request. With regard to 3 years of survey, certification, complaint investigation reports, both sections 1819(d) and 1919(d) of the Act states that these must be available ''upon request.'' We have revised this language, with the addition of availability of any plan of correction in effect with respect to the facility, as we proposed, to better reflect the statutory requirements, including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

Comment: One commenter stated that providing every survey, certification, and complaint report available ''in a form understandable by residents'' is excessive and incomprehensively burdensome.

Response: We understand that these reports are in specific formats and may be lengthy, and that an unaltered copy of the report is the expected document. Therefore, in finalized § 483.10(g)(11) we have eliminated the phrase as recommended, as well as added these reports to the documents excepted from the requirement at finalized § 483.10(g)(3) that the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Comment: One commenter supported many of the provisions in proposed § 483.11(e)(7) requiring that facilities immediately notify the resident, consult with the resident's physician and notify the resident's representative when there is a change in the resident's condition, when treatment needs to be altered in a significant way, or when the resident is to be transferred or discharged. One commenter stated that physicians should be involved in managing significant injures, and that it is reasonable to allow facilities to notify physicians when the injury is significant enough to require a medical assessment and/or intervention. The commenter suggested that each facility have and use a protocol for physician notification and that the staff make a preliminary assessment and then monitor for delayed complications. Another commenter suggested that we add ''or change'' to the provision ''a need to alter treatment significantly (that is, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment).'' One commenter was concerned that this requirement must be consistent with resident representative state law, or the authority granted by the court in instances of a resident who has been adjudged incompetent, or the authority granted to the individual with the durable power of attorney and another was concerned about the number of notifications that could be required. Another commenter was concerned that the term ''immediately'' was not defined and an expectation on the part of CMS that multiple individuals be notified simultaneously is unreasonable.

Response: We thank the commenters for their support. As suggested, we have added ''or change'' to the parenthetical in finalized § 483.10(g)(14)(i)(C). We believe that a protocol, as suggested by the commenter, could be consistent with our proposal. As written, the requirement is that a facility immediately inform the physician when there is an accident that involves injury that has the potential to require the physician's intervention. A protocol, as suggested, would be a useful tool to help a facility objectively and consistently determine when an injury has the potential to require physician intervention. We noted in the preamble to the proposed rule that effective communication among caregivers is helpful in improving outcomes and quality of care. In addition, with have added ''consistent with his or her authority'' in reference to notifying a resident representative. With regard to the term ''immediately,'' we note that this requirement is not new. We would expect facilities to make such notifications without delay, and, in the case of a resident's death, in accordance with state law.

Comment: A commenter supports proposed changes to information that must be provided to residents, but states that there are differences between proposed § 483.10 and proposed § 483.11 and recommends that we add 'exploitation' consistent with the incorporation of this concept in other areas addressing abuse and neglect.

Response: In response to other comments we have combined § 483.10 and § 483.11. The information in question is now located in § 483.10(g)(4). We have also incorporated 'exploitation' into that provision, as suggested. Information includes both information that must be included in the written description of legal rights and other information of importance to the resident. For example, the written description of legal rights must include a statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community. In addition, the resident has a right to receive, information and contact information for filing grievances or complaints and the facility must post similar information, in a form and manner accessible and understandable to residents, and resident representatives.

Comment: One commenter notes that the term ''support person'' is not defined and appears nowhere else in the proposed regulations.

Response: A patient's ''support person'' does not necessarily have to be the resident's representative who is legally responsible for making medical decisions on the resident's behalf. A support person could be a family member, friend, or other individual who is there to support the resident during the course of the stay. We refer readers to our discussion of the meaning of

''support person'' in the preamble to the final rule, ''Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation To Ensure Visitation Rights for All Patients'' (75 FR 70833, November 19, 2010).

Comment: Commenters recommended that the prohibition regarding admission contracts conflicting with regulatory requirements apply to all admission contracts, whether required by the facility or not.

Response: We agree and have modified final § 483.10(g)(18)(v) to refer to all admission contracts. We emphasize that no language in a contract may permissibly require LTC facility residents or prospective residents to waive any of the rights set out in this provision, and that review of admissions contacts may be part of our facility surveys.

Comment: One commenter recommended that we require the facility to post a list of the names, titles, dates of service and addresses (mailing and email), and telephone number of the members of the facility's governing body, the administrator, and the director of nursing, stating that this would implement section 6106 of the Affordable Care Act.

Response: We thank the commenter for their suggestion. Section 6106 of the ACA added section 1128I(g) to the Act, Affordable Care Act. Section 1128I(g) pertains to the submission of staffing data by LTC facilities, and specifies that the Secretary, after consulting with certain stakeholders, require a facility to electronically submit to the Secretary direct care staffing information based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary in consultation with such programs, groups, and parties. CMS finalized requirements implementing section 6106 of the ACA on August 4, 2015 in the final rule ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46390). That rule added a new § 483.75(u) ''Mandatory submission of staffing information based on payroll data in a uniform format''. Section 6106 of the ACA does not include reporting requirements for management/ownership information.

Privacy and Confidentiality

Comment: Some commenters support our proposed changes to this section.

Response: We thank the commenters for their support. This section now includes language accommodating electronic communications, among other changes. We believe this changes are important in updating the requirements of participation for long-term care facilities.

Comment: One commenter recommended that CMS limit representatives of the Office of the State Long-Term Care Ombudsman access to resident records based on requirements established at 45 CFR 1327.11.

Response: We thank the comment for their suggestion. We note that the Administration for Community Living (ACL) published a final rule amending its regulations to reflect the creation of ACL in 2012 and consolidate all of its regulations under a single subchapter (see 81 FR 35645, 35646, June 3, 2016). As a result, the regulations that the commenter referred to are now found at 45 CFR 1324.11. We have reviewed the language at 45 CFR 1324.11(e)(2), which sets forth requirements for the State Long-Term Care Ombudsman or the State agency to establish policies and procedures for timely access to facilities, residents, and appropriate records. Proposed § 483.10(f)(2) does not conflict with the requirements at 45 CFR 1324.11(e)(2) and reflects the statutory language found in sections 1819(c)(3)(C) and 1919(c)(3)(C) of the Act. Therefore, proposed § 483.10(f)(2) is finalized at § 483.10(h)(3)(ii) without change.

Safe Environment

Comment: Some commenters supported our proposed changes to this section.

Response: We thank the commenters for their support.

Comment: With respect to the resident's right to a safe, clean, comfortable, homelike, environment, one commenter recommended amending the requirement to state that the resident has a right to an equitable balance of a safe, clean, comfortable, homelike environment, and a right to receive treatment safely, as no one right should outweigh nor compromise another right. Some commenters felt that we should use language more reflective of the fact that the long-term care facility is home for many residents. Some commenters recommended avoiding institutional language and changing ''. . . homelike'' environment to ''. . . home''

Response: We thank the commenters for their suggestions. As noted in the preamble to the proposed rule, long-term care facilities are likely to serve multiple populations. Throughout this rule, CMS has tried to maintain an appropriate balance reflecting these multiple populations. While for many residents, the LTC facility is a home and we have striven to make sure this fact is reflected in the regulations, for others, the LTC facility is a temporary stay as they regain the physical capacity to return to their home. Both of these populations deserve high quality care in a safe, clean, comfortable, and homelike environment. We agree that no single right outweighs another right and sometimes this requires balance; however, we believe that residents can and should live in a safe, clean, comfortable, and homelike environment that is also provides safe treatment.

Comment: Some commenters expressed concern that residents could receive contraband or harmful items through the mail and wanted to know what rights the facility has with regard to monitoring for such items.

Response: The right of residents to receive unopened mail is not new. We would expect facilities to already be in compliance with this requirement and have processes in place to address situations where resident rights and resident safety are of concern.

Comment: One commenter requested that we clarify under ''safe environment'' that the physical layout of the facility should maximize resident independence.

Response: We thank the commenter for their suggestion and have revised the requirement, finalized at § 483.10(i)(1)(i) to include ''resident independence.''

Comment: One commenter agreed that facility temperatures should not be extreme, but suggested that CMS add a qualifier to the regulations that would require Medicare and Medicaid-participating facilities to adjust temperatures in different areas of the facility based on resident needs and comfort and/or scientific evidence.

Response: We thank the commenter for their suggestion. We would expect facilities to make adjustments, as suggested, within the permissible range of 71 to 81 degrees Fahrenheit. We note that this is a long-standing requirement on which we received very few comments. We would want to seek specific public input on a specific proposal to change this requirement before making such a change.

Grievances

Comment: Some commenters supported our proposals related to grievances. One commenter commended CMS for significantly enhancing residents' rights to voice grievances, stating that this emphasizes the importance and seriousness of resident concerns. Another commenter stated

that the ability to make a grievance and to have it taken seriously by the facility is an important right and protection for residents. One commenter was pleased to see that facilities must create a grievance policy and appoint a grievance official. Another commenter stated that they are pleased to see that this right has been expanded to give residents the right to voice grievances without fear of discrimination or reprisal. One commenter was pleased to see that CMS is proposing that grievances be investigated and written decisions issued to residents and urges CMS to include this information about grievances in the Resident's Rights section as well. Another commenter was pleased that CMS proposed that the official issue written grievance decisions, and supports the proposed content of the decisions. One commenter stated that it is very helpful to have a person specifically tasked with handling grievances from beginning to end who is required to take immediate action to prevent further potential violations, although this should include any violations of state and federal requirements, not just resident rights.

Some commenters recommended revisions to our proposal. Some suggested we establish timeframes for resolution. One commenter recommended that CMS delete all language from proposed § 483.11(h) regarding the grievance policy and incorporate the policy requirements into § 483.75, QAPI. Some commenters objected to the requirement for a grievance official, stating this this is unnecessary and burdensome. One commenter suggested that designating one individual could hinder timely resolution.

Some commenters were concerned about the scope of actionable grievances. Some commenters feel we have limited the scope of grievances. One commenter stated that the proposed rules omits current language ''including those with respect to the behavior of other residents'' from resident rights, noting it is included in proposed § 483.11(h)(2) and recommends that CMS restore the full language of § 483.10(f)(2).'' Other commenters suggested that we broaden the scope of actionable grievances. One commenter is concerned that the proposed language does not state that the resident can file grievances with the State Survey Agency and another recommends we add adult protective services to the list of independent entities with which grievances may be filed. Some commenters recommended that the subsection be revised to require that facilities make information on how to file a grievance available to the resident upon admission and upon request and also give a copy of the grievance policy to every resident. Some commenters suggested that there are other formats more useful to a resident than a copy of the policy, such as a question and answer document. One commenter suggested that the grievance official should be responsible for protecting the complainant from retaliation, since many residents will not speak up because they fear reprisal. One commenter recommended that residents be given the room number in the facility if the official is housed within the facility and a toll free number if not, and be provided with information about where they can turn within the facility organization if they are not satisfied with the decision. The commenter also suggested that CMS require that the grievance decision be provided to each resident in a form and manner the resident can access and understand and that the grievance official take corrective action in conjunction with the administrator and other appropriate staff. One commenter suggested that the grievance policy include the establishment of a grievance committee that would consist, at a minimum, of the administrator of the facility or his or her designee, a resident selected by the resident population of the facility, the facility social worker, and the grievance official. The commenter further suggested that the work of the grievance official would be reviewed by the full committee so he or she is not operating in a vacuum and there would be resident involvement in the process.

Some commenters were concerned about maintaining evidence related to grievances for 3 years and felt that creating and maintaining such files would be burdensome. Others were concerned about the potential for these requirements to negatively influence surveyors and asked if every complaint would be deemed a grievance. Another commenter suggested that we specifically require that facilities maintain all investigative documentation related to the grievance for three years. This commenter also suggested that, with regard to reporting, we reference federal law. Several commenters offered other specific recommendations for regulatory language.

Response: We thank commenters for their support and their suggestions. We agree that resident concerns should be taken seriously and that the ability to voice a grievance is an important right and protection for residents. The timeframes required to resolve a grievance may depend largely on the issue associated with the grievance and other situation-specific factors. We are not, at this time, requiring prescriptive timeframes, and defer to guidance to suggest what constitutes timely. The purpose of requiring the facility to have a grievance official is to ensure that there is an individual who has both the responsibility and authority for ensuring, through direct action or coordination with others, that grievances are appropriately managed and resolved. This person would be a resource for residents, staff, and oversight entities. We expect that most facilities already have a person or persons who serve this function, if not with the specific title, and that the work of a grievance official would be coordinated with the LTC facility administrator and the director of nursing. It is not our expectation that every facility hire a new, full-time individual to perform this function, but, instead, that every facility have a designated individual to serve this function, consistent with the needs of that facility. We do not agree that this would hinder timely resolution of grievances.

Evidence demonstrating the results of all grievances for a period of no less than 3 years provides a record of this work and can serve as a valuable information resource for facilities. However, we do not agree it is necessary to explicitly require that all investigation documentation be retained for 3 years. Further, such evidence may be maintained electronically, rather than utilizing physical storage space. We defer additional specificity to sub-regulatory guidance.

Grievances may provide valuable input to a facilities QAPI program. In fact, grievances are one likely source of data and feedback from residents and resident representatives; however, we do not believe that addressing grievances should be relegated solely to the QAPI program. Depending on the size of the facility and the number or grievances received, duties associated with grievances may only consume a small portion of the individual's time. In very large facilities, or in facilities with many grievances, more time may be required. Either way, we maintain that it is important that all facilities have a designated point of contact for grievances. While we agree that a grievance official cannot and should not resolve grievances in a vacuum, we are concerned that a grievance committee is not feasible for every facility, and therefore are not requiring such a committee at this time.

With regard to the scope of grievances, we have revised our

proposed requirement, finalizing it at § 483.10(j), to state that grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay. We will finalize proposed requirements regarding notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system. We also finalize the requirement to provide a copy of the grievance policy to the resident upon request. We agree that other formats may be useful to the resident and could be used to provide information on how to file a grievance available to the resident, but if the resident requests a copy of the facility policy, it must be provided. The facility is required, at final § 483.10(g)(16) to provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay; this includes the right to file a grievance. We have added ''federal'' to § 483.10(j)((4)(iv) so that it reads ''immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriate of resident property, by anyone furnishing services on behalf of the provider; and as required by federal or state law.'' Requirements for reporting suspicion of a crime are separately addressed in § 483.12(b). We defer additional detailed information relating to grievances to sub-regulatory guidance.

Contact With External Entity

Comment: One commenter felt that the requirement stating that facilities must not prohibit or discourage a resident from communicating with state and federal representatives was unnecessary.

Response: We disagree. It is imperative that residents and their representatives feel free to discuss concerns, particularly safety and quality of care concerns, with representatives of the state and federal government, surveyors, ombudsmen, and representatives of the protection and advocacy system.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have consolidated proposed § 483.10 and proposed § 483.11 into a single section, § 483.10, ''Resident rights'' and removed or updated all cross-references as appropriate.
- We have replaced the term ''verbal'' with ''oral'' throughout this section.
- Introductory language from proposed § 483.10 and proposed § 482.11, as well as proposed § 483.11(a)(2) are now finalized in § 483.10(a) ''Resident rights.''
- Proposed § 483.10(a)(1) through (5), and proposed § 483.11(a)(1), and (a)(3) through (5) have been consolidated into final § 483.10(b), ''Exercise of rights.''
- We have revised proposed § 483.10(a)(3), finalizing it at § 483.10(b)(3) and incorporating previously existing language clarifying that the provision applies to residents who have not been adjudged incompetent by a state court.
- We have revised language from proposed § 483.11(a)(4), as consolidated in finalized § 483.10(b)(7)(i), to clarify that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it.
- We have consolidated proposed § 483.10(b) and proposed § 483.11(b) into § 483.10(c), ''Planning and implementing care.''
- We have changed the term ''disciplines'' in proposed § 483.10(b)(2) to ''the type of care giver or professional,'' finalizing it at § 483.10(c)(4).
- We have revised proposed § 483.10(b)(5)(v) to state ''the right to sign after significant changes to the plan of care,'' finalizing it at § 483.10(c)(2)(v).
- We have clarified in § 483.10(c)(5) that the physician or other practitioner or professional informs the resident of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options.
- We have consolidated § 483.10(b)(6) and § 483.11(b)(2), finalizing these requirements at § 483.10(c)(7) which now states ''The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.''
- We have withdrawn proposed § 483.10(c)(2) to require that physician's meet facility credentialing requirements and consolidated proposed § 483.10(c)(1) and (3), and proposed § 483.11(c)(1) through (3), finalizing these provisions at § 483.10(d).
- We have re-designated proposed § 483.10(d) at § 483.10(e), revised finalized paragraph (e)(6) to specify that the resident has a right to receive written notice, including the reason for the change when the resident's room or roommate in the facility is change and added a new, final (e)(7)(iii) to clarify that a room change cannot be solely for the convenience of staff.
- We have consolidated proposed § 483.10(e) and proposed § 483.11(d), finalizing these provisions at § 483.10(f), Self-determination.
- We have added ''and other applicable provisions of this Part'' to proposed § 483.10(e)(1) and finalize this provision at § 483.10(f)(1).
- We have consolidated proposed § 483.10(e)(3) and proposed § 483.11(d)(1), finalizing these provisions at § 483.10(f)(4), and clarifying that: (1) The resident's right to deny visitation is ''when applicable;'' (2) a facility must have written policies and procedures for visitation that includes restrictions, when such limitation may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation; and (3) the facility must inform each resident not only of any limitation, but also to whom the restrictions apply.
- We have added a new § 483.10(f)(5)(i) to specify that a facility must take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.
- We have added ''or other guests'' to the list of individuals who may only attend a resident or family group meeting at the group's invitation at finalized § 483.10(f)(5)(ii).
- We have consolidated proposed § 483.10(e)(8) and proposed § 483.11(d)(4) into finalized § 483.10(f)(9).
- We have consolidated proposed § 483.10(e)(9) and proposed § 483.11(d)(5) into finalized § 483.10(f)(10).
- We have changed ''may'' to ''must'' in finalized § 483.10(f)(11)(i).
- We have changed ''health care provider'' to ''physician, physician assistant, nurse practitioner, or clinical nurse specialist'' in finalized § 483.10(f)(11)(ii)(L)(1).

• We have consolidated proposed § 483.10(f) and (h) and proposed § 483.11(e) into finalized § 483.10(g).

• We revised proposed § 483.10(f)(3) to include both personal and medical records and finalized it at § 483.10(g)(2).

• We revised proposed § 483.10(g)(3)(ii) to remove the requirement that a resident must inspect a medical record prior to requesting to purchase a copy and finalized it at § 483.10(g)(2)(ii).

• We updated the cross-reference to § 483.11(e)(2) in proposed § 483.11(e)(1), to cross-reference § 483.10(g)(2) and (g)(11) to reflect that we do not require facilities to translate or summarize personal and medical records and survey reports. Proposed § 483.11(e)(1) is finalized at § 483.10(g)(3).

• We added ''State Survey Agency'' to proposed § 483.10(f)(2), finalized § 483.10(g)(4)(ii), and added ''any suspected violation of state or federal nursing facility regulations'' to proposed § 483.10(f)(2)(vi), finalized at (g)(4)(vi).

• We added ''requests for information regarding returning to the community'' to proposed § 483.11(e)(4), finalized at § 483.10(g)(5)(ii).

• We require at finalized § 483.10(g)(9)(iii) that electronic communications under this section must comply with state and federal law.

• We have revised proposed § 483.11(e)(3), finalized at § 483.10(g)(11), to reflect the stricter standard imposed by the section 1919(c)(8) of the Act, statutory language and to better reflect both sections 1819(d) and 1919(d) of the Act, retaining the addition of availability of any plan of correction in effect with respect to facility, as proposed, and including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

• We have revised proposed § 483.11(e)(11)(v), finalized at § 483.10(g)(18)(v), to specify that any admission contract, whether the facility requires it or not, must not conflict with the requirements of these regulations.

• We have consolidated proposed § 483.10(g) and proposed § 483.11(f), finalized at § 483.10(h), consolidating duplicative language in proposed § 483.10(g)(2) and proposed § 483.11(f)(1)(ii) at finalized § 483.10(h)(1), consolidating proposed § 483.11(f)(1) and (f)(1)(i), finalized at § 483.10(h)(2), and deleting proposed § 483.11(f)(2) as an unnecessary cross-reference.

• We have consolidated proposed § 483.10(i) and proposed § 483.11(g), ''Safe environment'', finalized at § 483.10(i).

• We have added a new § 483.10(i)(1)(ii) to require that the facility exercise reasonable care for the protection of the resident's property from loss or theft.

• We have consolidated proposed § 483.10(j) and proposed § 483.11(h), ''Grievances'' at finalized § 483.10(j).

• We have revised proposed § 483.10(j)(1) by adding ''the behavior of staff and of other residents; and other concerns regarding their LTC facility stay'' to the statement regarding what grievances may include.

• We finalize, as proposed, § 483.11(i) at § 483.10(k).

G. Freedom From Abuse, Neglect, and Exploitation (§ 483.12)

Currently, § 483.13 is titled ''Resident Behavior and Facility Practices.'' We proposed to re-designate and revise this section as § 483.12, ''Freedom from Abuse, Neglect and Exploitation,'' to more accurately reflect the contents and intent.

Currently, paragraph § 483.13(a) addresses the use of restraints. We proposed to address restraints in both the introductory paragraph to proposed § 483.12 and in proposed § 483.25(d)(1). In the introductory paragraph to proposed § 483.12, we maintained the prohibition of the inappropriate use of restraints. We proposed to further address restraints in proposed section § 483.25(d)(1) on Quality of Care and Quality of Life.

We proposed that existing paragraph § 483.13(b) also be included in the new introductory paragraph to revised § 483.12. We proposed to re-designate existing § 483.13(c)(1) as § 483.12(a)(2) and modify the language to clarify that a facility must not employ or otherwise engage individuals who have been found guilty of abuse, neglect, or mistreatment of residents by a court of law; had a finding of abuse, neglect, mistreatment of resident or misappropriation of property reported into a state nurse aide registry, or had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, or mistreatment of residents or a finding of misappropriation of property.

Currently, the regulations require that a facility must not employ an individual who has had a finding entered against them into a state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of property. We proposed to add a new § 483.12(a)(2)(iii) to expand this employment prohibition to include licensed professionals who have had a disciplinary action taken against them by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.

We proposed to re-designate existing § 483.13(c) as § 483.12(b) and to revise it to also require that the facility develop and implement written policies and procedures that prohibit and prevent abuse, neglect, exploitation of residents and misappropriation of resident property. We proposed to add a new § 483.12(b)(2) to require that the facility establish policies and procedures to investigate any allegations of abuse, neglect, exploitation, or misappropriation of property. We also proposed to add a new § 483.12(b)(3) to require that the policies and procedures include training as required by proposed § 483.95. Finally, we proposed a new § 483.12(b)(5) to require that facilities establish policies and procedures to ensure reporting of crimes in accordance with section 1150B of the Act. The policies and procedures have to include, at a minimum, annual notification of covered individuals, posting a conspicuous notice of employee rights, and prohibiting and preventing retaliation.

Annual notification of covered individuals, as defined at section 1150B(a)(3) of the Act, includes notification of that individual's obligation, as specified at section 1150B(b)(1) of the Act, to report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility. Reporting to the State Agency fulfills the statutory directive to report to the Secretary. In accordance with section 1150B(b)(2) of the Act, the reporting required by 1150B(b)(1) must occur immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

We proposed to re-designate existing § 483.13(c)(1)(iii) as proposed § 483.12(a)(3) and revise existing § 483.13(c)(2), (3) and (4) as proposed § 483.12(c)(1), (2), (3) and (4). Specifically, we proposed to add the term ''exploitation'' in paragraph (c)(1) and add adult protective services where state law provides for jurisdiction in long-term care facilities to the list of officials who must be notified in accordance with state law; otherwise the

language would be unchanged from § 483.12(c)(2). We proposed to divide existing § 483.13(c)(3) into two paragraphs, § 483.12(c)(2) and (3), making the investigation of alleged violations distinct from the facility's obligation to prevent further abuse of the allegedly abused resident or other residents while the investigation is in progress.

Comment: One commenter expressed concern that we had moved § 483.13 into § 483.10, ''Resident rights,'' stating that downplayed the seriousness of alleged or confirmed acts of abuse neglect, misappropriation or mistreatment of residents by staff, visitors, family and other residents. The commenter suggested that it should remain its own section.

Response: The provisions of § 483.13 are maintained, with revision, in proposed § 483.12, under a new title ''Freedom from abuse, neglect and exploitation.'' We believed this new title highlights, rather than downplays, the need to ensure that residents of long-term care facilities are free from to abuse, neglect, or exploitation.

Comment: One commenter is concerned that CMS did not address the use of resident alarms (bed alarms, tabs alarms, etc.) in the section addressing restraints. The commenter supports CMS including language to eliminate the use of resident alarms in light of the absence of any documented evidence that alarms are effective in reducing resident falls. In fact, alarms are often used to in place of facility staff to ensure that residents are provided with adequate care and supervision.

Response: We did not address the use of alarms in the proposed rule and would seek additional input prior to considering banning or specifically regulating the use of alarms. We would expect the use of a position alarm to be addressed in a resident's comprehensive care plan. If an alarm is used as a restraint, it is subject to our provisions relating to restraints. We understand that some alarms may have a limited use for diagnostic purposes and a useful role in the assessment process, as facility staff are learning about an individual. In addition, we recognize that there is a clear distinction between position change alarms and door alarms. We will continue to evaluate this issue, address it in sub-regulatory guidance, and consider it for future rule-making.

Comment: A number of commenters supported the addition of this section to emphasize the protection of residents from abuse, neglect and exploitation. Commenters specifically appreciated the reference to chemical and physical restraints, and the inclusion of language that complies with the Affordable Care Act regarding the reporting of crimes. Some commenters also stated that they supported the inclusion of violations in this section in the definition of ''substandard quality of care.''

Response: We thank the commenters for their support. Ensuring that residents of long-term care facilities are protected is an important purpose of these requirements.

Comment: One commenter suggested that we add ''exploitation'' to paragraphs (a)(2)(i) and (a)(2)(ii).

Response: Thank you. We have added ''exploitation'' to proposed paragraphs (a)(2)(i), (ii), and (iii), as finalized at § 483.12(a)(3)(i), (ii), and (iii), since we believe that the comment was intended to apply to all the situations described in what we have now re-designated as § 483.12(a)(3).

Comment: One commenter urges CMS to carefully describe the consequences for violations of the proposed provisions relating to prohibiting certain hiring and urged that they be implemented consistent with the HHS Office of Inspector General's statutory provision related to hiring or retaining people who have been excluded from participating in federally funded health care programs, including but not limited to civil monetary penalties. By increasing the severity of adverse consequences for hiring staff that could potentially harm residents, CMS will properly encourage facilities' compliance with these requirements.

Response: Enforcement is outside the scope of these regulations. We will take this matter under consideration and share this suggestion with the HHS OIG.

Comment: Some commenters supported our proposed revisions at § 483.12(a)(2) to prohibit facilities not only from employing certain individuals, but also from engaging these individuals through other mechanisms and for expanding the prohibition on employment to individuals who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect or mistreatment of residents or misappropriation of resident property. Some commenters expressed concern about the impact of (a)(2) on volunteers and one commenter asked we clarify its application to volunteers or to employees of contracted services such as when a facility hires a contractor to perform renovations. One commenter strongly recommended that subsections (a)(2)(ii) and (a)(2)(iii) be broadened to apply to abuse, neglect, exploitation, or misappropriation of property of any persons serving as nurse aides or other direct care workers and that this requirement be expanded to include all staff employed by the LTC facility.

Response: We thank the commenters for their suggestions and support. Our primary concern is to protect the health and safety of residents. We are not, at this time, requiring criminal background checks on volunteers, but would expect facilities to exercise reasonable care consistent with the volunteers' expected roles and not knowingly engage volunteers who have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law. With regard to the employees of contractors such as those performing renovations, who would not be providing care to or interacting directly with residents, we would expect the facility to exercise reasonable care in selecting the contractor. We defer additional discussion to subregulatory guidance. We are not further expanding the prohibition at this time, but will evaluate the issue and consider it for future rule-making.

Comment: Some commenters expressed concern that these employment prohibitions could involve the application of long-resolved findings against a person. A potential employee might be able to demonstrate extenuating circumstances or rehabilitation after time has passed. The commenters noted that these prohibitions could disqualify a person for life, even if the previous findings were unrelated to their care of LTC facility patients. One commenter asked if the regulations can address a process by which nurse aides and licensed personnel can show successful rehabilitation and be eligible to work in an LTC setting again. Another suggested that it would be appropriate to look at the circumstances and details of each situation, and not exclude all individuals, as proposed. One commenter suggested that the prohibition on employment be based only on felony convictions related to care or services for an individual. Another commenter suggested that CMS consider issuing guidance that would urge states to extend the due process requirements that govern the National Background Check Program, including those requiring an independent process for appealing or disputing the accuracy of the information obtained, and for consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual.

Response: In response to these comments, we have modified proposed § 483.12(a)(2)(iii) relating to licensed personnel to prohibit employment based on disciplinary action for those actions currently in effect, which we will finalize as § 483.12(a)(3)(iii). This provision, as finalized, will prohibit facilities from employing certain individuals who have a disciplinary action in effect against a professional license. We believe that this provides facilities some flexibility to exercise discretion with regard to previous disciplinary actions. Where a facility is aware of previous disciplinary actions against a professional license, but those actions have been resolved, the facility makes their own hiring decisions based on the specific nature and circumstances of those previous disciplinary actions and in keeping with their responsibility to protect the health and safety of residents.

Proposed § 483.12(a)(2)(i) and (ii), which we will finalize as § 483.12(a)(3)(i) and (ii), prohibit facilities from employing or otherwise engaging individuals who have been found guilty of abusing, neglecting or mistreating residents by a court of law, or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property. We believe additional consideration and research is necessary before we propose to further modify these provisions. Any additional changes would be proposed in future rule-making.

With regard to the suggestion that CMS consider issuing guidance that would urge states to extend the due process requirements that govern the National Background Check Program, including those requiring an independent process for appealing or disputing the accuracy of the information obtained, and for consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual, we will consider this for future action.

Comment: One commenter stated that, without a centralized registry for actions against an individual's state licensure, it is impossible for a facility to check with all 50 states for disciplinary action against a professional license. One commenter recommended we delete the language at § 483.12(a)(2)(iii). Another stated that without a centralized registry, it was unreasonable to expect a facility to check for disciplinary action against a professional license and raised the question of what would constitute a disciplinary action. The commenter further stated that his state does not indicate when disciplinary action has been taken against an individual.

Response: We agree that a facility is not expected to query 50 states for information on each licensed individual. We would expect the facility to check with the state in which the facility is located and care is delivered and potentially bordering states or other states that the individual is known to have been licensed in, based on the individuals resume or other employment information available to the facility. We checked the Web site for state nursing board for the state mentioned and found that it does indicate the status of the license (active, revoked, probation, etc.). We would expect facilities to exercise reasonable efforts to determine if a state licensing board has taken disciplinary action against a professional license, based on the licensing board's definition of disciplinary action. We have revised the provision to state ''. . . a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.'' We defer additional discussion the sub-regulatory guidance.

Comment: One commenter recommended that we clarify here or in the definition section what is meant by ''unfitness for service'' and discuss what the State Survey Agency would do with this information once reported as required under § 483.12(a)(4).

Response: Section 483.12(a)(4) requires that the facility report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law which would indicate unfitness for services as a nurse aide or facility staff. Sub-regulatory guidance provides additional information to assist facilities and surveyors in implementing this provision. If a facility determined that action by a court of law against an employee are such that they indicate that the individual is unsuited to work in a LTC facility, or ''unfit for service'', (for example, felony conviction of child abuse, sexual assault, or assault with a deadly weapon), we would expect the facility to report that individual to the nurse aide registry (if a nurse aide) or to the state licensing authorities (if a licensed staff member). Facility reporting to the state nurse aide registry or licensing authorities is not limited to mistreatment, neglect and abuse of residents and misappropriation of their property, but to any treatment of residents or others inside or outside the facility which the facility determines to be such that the individual should not work in a LTC facility environment. Federal requirements related to the state administration of the nurse aide registry, including information disclosure requirements and State Survey Agency responsibilities, are set forth at 42 CFR 483.156 and 488.335.

Comment: One commenter notes that provisions relating to reporting of a crime have already been incorporated into the current survey process and therefore these provisions could be implemented one year following adoption of a final rule.

Response: We deliberately established regulatory requirements based on existing expectations of facilities based on the statutory language. We would expect that all facilities are currently in compliance with the Act.

Comment: A commenter recommends that in § 483.12(b)(4), we say ''coordinate'' instead of ''establish coordination.''

Response: We agree and have made this change.

Comment: Several commenters asked that we harmonize the reporting requirements for reporting a reasonable suspicion of a crime in § 483.12(b) and the requirements for reporting allegations of abuse, neglect, and exploitation to the LTC facility administrator in § 483.12(c). Commenters state that the two provisions should use the same timeframes.

Response: We generally agree and have revised § 483.12(c)(1) to require that all allegations of abuse be reported immediately, but not later than 2 hours after allegation is made, and allegations of neglect or exploitation to be reported to the administrator of the facility immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury. We note that all allegations of abuse, with or without injury, fall into the immediate reporting category, as we believe it is imprudent to allow delay reporting of any abuse. Furthermore, we note that the 2-hour and 24-hour time frames represent maximums and we would expect that most reports would occur more quickly. In all cases, we would expect prompt action to protect individuals and address concerns, and delays in reporting, even within the allowable time frames, must be reasonable and not be related to attempts to obscure events or evade responsibility.

Comment: Several commenters are concerned about the inclusion of the resident representative in proposed § 483.12(c)(4). A few commenters suggested that this was a technical error and should have referred to the administrator's designee.

Response: The commenters are correct that the reference in this paragraph was intended to be to the LTC facility administrator's designee or designated representative. We have corrected the provision.

Comment: One commenter suggests that we add ''as required by state law'' at the end of § 483.12(b)(5).

Response: While facilities are expected to comply with state law, this provision is specific to compliance with section 1150B of the Act. We are not revising at this time.

Comment: One commenter stated that giving covered individuals up to 2 hours to report to law enforcement and the state agency in cases of serious bodily injury is unacceptable.

Response: We revised § 483.12(b)(5)(i)(B) to state ''. . . shall report immediately, but not later than 2 hours . . .'' in accordance with 1150B of the Act.

Comment: One commenter stated that individuals living in the community would immediately call the police if they had reason to believe items had been stolen from their home and the same expectations should apply in a LTC facility, where theft of resident personal possessions continues to be a serious problem. Reporting suspected theft as a crime could serve as a deterrent and send a message that stealing will not be tolerated. The commenter recommends that CMS clarify in guidelines that suspicion of theft of resident property is considered a reportable crime.

Response: This regulation does not preclude a covered individual from reporting theft immediately. However, covered individuals must report suspicion of crimes not resulting in harm no later than 24 hours. Crimes are defined by laws of the applicable political subdivision where the facility is located, therefore, we will defer further discussion of reportable crimes to sub-regulatory guidance.

Comment: One commenter suggests that current CMS sub-regulatory guidelines related to subsection (b) be put into regulation to ensure resident safety, with additional language to specify the rights of staff during investigations, since far too often staff members are inappropriately terminated without a substantiated investigation.

Response: We will review the sub-regulatory guidance and evaluate the appropriateness of incorporating it into regulations in future rulemaking.

Comment: One commenter recommended adding an express prohibition of all forms of discrimination against residents.

Response: We did not propose such a prohibition; however, facilities are expressly required by § 483.70(b) to operate in compliance with all applicable Federal, State, and local laws, regulations, and codes. This includes, for example, the Americans with Disabilities Act and section 504 of the Rehabilitation Act. In addition, § 483.70(c) explicitly requires compliance with other HHS regulations. This would include but not be limited to those regulations pertaining to non-discrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). We note that 45 CFR part 92, non-discrimination on the basis of race, color, national origin, sex, age, or disability, was finalized after the issuance of our proposed rule. Based on this comment, we have added it to the list of regulations at § 483.70(c). We will consider an express prohibition in future rule-making.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We revised paragraphs (a)(2)(i),(ii), and (iii) to include ''exploitation.''
- We revised paragraph (a)(2)(iii) to read ''. . . Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, . . .''
- We revised paragraph (b)(5)(i)(B) to read ''Each covered individual shall report immediately, but not later than 2 hours . . .''
- We revised paragraph (c)(1) to require that allegations of abuse, neglect, or exploitation to be reported to the administrator of the facility immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not involve abuse and do not result in serious bodily injury.
- We corrected paragraph (c)(4) to read ''Report the results of all investigations to the administrator or his designated representative and . . .''

H. Admission, Transfer, and Discharge Rights (§ 483.15)

We proposed to re-designate current § 483.12 ''Admission, transfer, and discharge rights'' as new § 483.15, and revised the general title to ''Transitions of care'' in order to reflect current terminology that applies to all instances where care of a resident is transitioned between care settings.

In new § 482.15(a) we proposed to include requirements for admissions policies and moved these requirements to the beginning of the section to reflect chronological order. We proposed a new paragraph (a)(1) to require that the facility establish an admissions policy.

Additionally, we proposed to re-designate current § 483.12(d)(1) as § 483.15(a)(2) to state that facilities cannot request or require residents or potential residents to waive their rights to Medicare or Medicaid benefits or to any rights conferred by applicable state, federal and local licensing or certification laws. We proposed to add a new paragraph (a)(2)(iii) to prohibit facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. We further proposed to add a new paragraph (a)(6) to specify that a nursing facility must disclose and provide to a resident or potential resident, prior to time of admission, notice of any special characteristics or service limitations of the facility.

We also proposed to relocate existing § 483.10(b)(12) to new § 483.15(a)(7). This section addresses admission disclosure requirements for composite distinct part nursing facility, and is more appropriately located in the section on admissions.

We proposed to re-designate § 483.12(a) as proposed § 483.15(b) and address transfers and discharges. We proposed at § 483.15(b)(1)(ii)(C) to revise existing § 483.12(a)(2)(iii) and clarify that a resident could be discharged when the safety of other individuals is endangered due to the clinical or behavioral status of that resident. In § 483.15(b)(1)(ii)(E), we proposed to revise existing § 483.12(a)(2)(v) and clarify that provisions for discharge as a result of non-payment of facility charges would not apply unless the resident did not submit the necessary paperwork for third party payment or until the third party, including Medicare or Medicaid, denied the claim and the resident refused to pay for his or her stay. Finally, we proposed a new § 483.15(b)(1)(iii) to specify that the facility may not transfer or discharge the

resident while the appeal is pending, pursuant to 42 CFR 431.230 when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to 42 CFR 431.220(a)(3).

In the proposed revision to paragraph § 483.15(b)(2), we made a number of revisions based on the importance of effective communication between providers during transitions of care. First, we proposed to clarify that the transfer or discharge would be documented in the resident's clinical record and that appropriate information would be communicated to the receiving setting. In addition, we proposed to require that, when a facility transfers or discharges a resident because the transfer or discharge is necessary for the resident's safety and welfare, the facility would include in its documentation the specific resident needs that it cannot meet, facility attempts to meet the resident needs, and the service(s) available at the receiving facility that will meet the resident's needs.

We proposed to add a new requirement at § 483.15(b)(2)(i) that the transferring facility provide necessary information to the resident's receiving provider, whether it is an acute care hospital, a LTC hospital, a psychiatric facility, another LTC facility, a hospice, home health agency, or another community-based provider or practitioner. We did not propose a specific form, format, or methodology for this communication. Instead, we proposed specific data elements or a set of information that must be communicated during the transfer process. This includes demographic information, including but not limited to name, sex, date of birth, race, ethnicity, and preferred language, resident representative information including contact information, advanced directive information, history of present illness/reason for transfer, including primary care team contact information, past medical/surgical history, including procedures, active diagnoses/current problem list, laboratory tests and the results of pertinent laboratory and other diagnostic testing, functional status, psychosocial assessment including cognitive status, social supports, behavioral health issues, medications, allergies including medication allergies, immunizations, smoking status, vital signs, unique identifier(s) for a resident's implantable device(s), if any, comprehensive care plan including health concerns, assessment and plan, goals, resident preferences, other interventions, efforts to meet resident needs, and resident status. We did not establish a time frame for this communication, as this may vary based on the circumstances surrounding the transfer; however, in the proposed rule we indicated that we expect communication to occur shortly before or as close as possible to the actual time of transfer and that the facility would document that communication has occurred.

In paragraph (b)(3)(i), we proposed to update the language currently in § 483.12(a)(4)(i) to reflect our ''resident representative'' language and proposed to require that the facility send a copy of the notice of transfer or discharge to the State Long-Term Care Ombudsman with the resident's consent. In paragraph (b)(3)(ii), we proposed a minor revision to the language currently in § 483.12(a)(4)(ii) to clarify that the facility records the reasons for the transfer or discharge, in accordance with proposed § 483.15(b)(2).

In § 483.15(b)(5)(iii), we proposed to modify language currently in § 483.12(a)(6)(iii) by adding the phrase ''expected to be'' to reflect our understanding that when a notice of transfer or discharge is issued 30 days prior to transfer, the transfer or discharge destination may subsequently change. We also proposed in paragraph (b)(5)(iv) to require that the notice include the name, address (mailing and email), and telephone number of the state entity which receives discharge or transfer appeal requests; and information on how to obtain an appeal form, how to obtain assistance in completing the form, and how to submit the appeal request. We also proposed to add a new paragraph § 483.15(b)(6) to require that when information in the notice changes, the facility must update the recipients of the notice as soon as practicable with the new information to ensure that residents are aware of and can respond appropriately to discharge information. We proposed to re-designate § 483.12(a)(7) as § 483.15(b)(7) and revised it to require that the facility provide to the resident an orientation regarding his or her transfer or discharge in a form and manner that the resident can understand. Finally, in § 483.15(b)(9), we proposed to clarify that room changes in a composite distinct part are subject to the requirements of proposed § 483.10(d)(7).

In paragraph § 483.15(c) we proposed to add language to require that the facility provide information to the resident that informs the resident of and distinguishes and explains the difference between the duration of the state bed-hold policy, if any, as well as the reserve bed payment policy in the state plan, required under 42 CFR 447.40, if any. In § 483.15(c)(1)(iv), we proposed to add a new requirement that a facility's notice of its bed-hold policy and readmission must also include information on the facility's policy for readmission, as required under proposed § 483.15(c)(3), for a resident whose hospitalization or therapeutic leave exceeds the bed-hold period under the state plan. Finally, we proposed to redesignate existing § 483.12(a)(3) as § 483.15(c)(3) and revised it to add a new requirement that a resident who is hospitalized or placed on therapeutic leave with an expectation of returning to the facility must be notified in writing by the facility when the facility determines that the resident cannot be readmitted to the facility, the reason the resident cannot be readmitted to the facility, and the appeal and contact information specified in § 483.15(b)(5)(iv) through (vii).

Comment: One commenter found the reorganization of this section confusing.

Response: We thank the commenter for their comment. We have incorporated many suggestions from commenters and believe that the resulting provisions are much clearer.

Comment: Some commenters supported our proposal to re-designate § 483.12 ''Admission, transfer, and discharge rights as new § 483.15 to address all transitions of care. We also received several comments suggesting that the title change from ''Admission, transfer, and discharge rights'' to ''Transitions of care'' may make it more difficult for some readers, particularly residents of LTC facilities and their representatives, to find information on admissions, transfers and discharges and that the term ''transitions'' was not easily understandable and could have unintended implications. In addition, many commenters were very concerned that the term ''rights'' was removed from the title and felt this could negatively impact residents. Several commenters suggested we retain the original title. One commenter suggested we revise the title to ''Resident's Rights and Transitions of Care.'' One commenter suggests moving all content describing resident rights in § 483.15 be moved to § 483.10, Resident rights.

Response: We acknowledge these concerns. Therefore, we will retain the original title ''Admission, transfer, and discharge rights''.

Comment: Several commenters suggested specific wording and punctuation changes throughout this section. This included several changes to make the language used in the regulation less institutional. One commenter stated that some person-

centered language would require a distinction between long-stay and short-stay residents.

Response: We reviewed and considered each suggested wording and punctuation change, but do not discuss each one separately below. If we felt that the suggested change improved clarity, we have incorporated it. If the suggested change does not improve clarity, we have not incorporated it. Comments suggesting wording changes that substantively alter our intended meaning are discussed below.

Comment: Some commenters recommended that we implement similar requirements for exchanging information for hospitals.

Response: Conditions of participation for hospitals are outside the scope of this rule. However, we refer commenters to a proposed rule, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' published on November, 1, 2015 (80 FR 68126) which can be viewed at *https://www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf.* This rule addresses discharge planning requirements for hospitals and other post-acute care providers, including requirements for exchange of information upon transfer.

Comment: Some commenters expressed support for the addition of ''request'' in subsections (a)(2)(i) through (iii) and (3). These commenters felt this would help prevent attempts to evade current law by using the term ''request'' to seek what is intended as a requirement.

Response: We thank the commenter and agree that sometimes the word ''request'' can be used for what is effectively a requirement.

Comment: One commenter suggested that CMS modify the language in § 483.15(a)(2)(iii) to reflect a relatively recent statutory provision that allow a continuing care retirement community to require residents to spend on their care resources declared for the purposes of admission before such residents can apply for medical assistance.

Response: We thank the commenter for this suggestion. We have reviewed the Medicaid requirements at section 1919(c)(5)(B)(v) of the Act. We will develop any necessary regulatory requirements and propose to incorporate them in future notice and comment rule-making. However, we note that LTC facility requirements are for purposes of surveying the facility and the provision applies to a select subset of LTC facilities.

Comment: One commenter was concerned that the term ''service limitations'' is not defined. A number of commenters felt that this provision could allow facilities to improperly discriminate in admissions, transfers, and discharges. One commenter felt that this would allow facilities to reduce or eliminate their responsibility for complying with our requirements. One commenter suggested that it would be more helpful for a resident to understand the services a facility provides instead of requiring disclosure of special characteristics or services limitations. Another commenter suggested we clearly state that facilities must provide all services required by federal law and regulation and cannot refuse to provide any services that it is required by federal law to provide to residents who need such services. Some commenters recommend we delete this provision in its entirety. One commenter recommended that if the provision is retained, any disclosure of special characteristics or service limitations must occur prior to the time of admission.

Response: We agree that this disclosure should occur prior to admission and have modified the regulations text accordingly. We considered deleting this provision or changing it to require that facilities disclose the services they do provide, however, we believe that the proposed requirement is the option that is likely to ensure prospective residents receive information they are not likely to receive absent a requirement and which can inform decision making. We do not agree that providing this information allows or encourages providers to discriminate in the admissions process, nor does requiring it allow a facility to fail to provide required services.

Comment: One commenter suggested removing ''of the residents'' and ''or other responsible parties'' from subsection (b)(8), as these phrases are redundant and create confusion.

Response: We thank the commenter and have revised the paragraph, now (c)(8), as suggested.

Comment: One commenter supported new language at § 483.15(a)(7) requiring facilities that are a composite distinct part to disclose in its admission agreement its physical configurations, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations.

Response: We thank the commenter and agree that this important information for residents and their representatives.

Comment: Several comments objected to our addition of the phrase ''expected to be'' in proposed § 483.15(b)(5)(iii). The commenters suggested this will allow a facility to get the resident's agreement to a transfer and subsequently change the location to a location the resident objects without giving the resident 30 day notice, taking away important resident protections. Commenters suggested either not finalizing the proposal or establishing that the 30 day notice ''resets'' if the notice is changed.

Response: We agree and have removed the phrase ''expected to be'' from this provision, which we finalize at § 483.15(c)(5)(iii), as suggested.

Comment: Several commenters appreciated the addition of ''and implement'' to the statement that facilities must establish an admissions policy. One commenter was concerned that CMS does not clarify what is anticipated by this requirement.

Response: We thank the commenters for their support and agree that implementation of policies at § 483.15(a)(1) is essential to making requirements effective. Our expectations that a facility ''establish and implement'' an admissions policy means that a facility must have such a policy, that the policy must be compliant with the requirements for participation, and that the facility must follow its policy.

Comment: Commenters supported the proposed provision requiring facilities to establish, maintain, and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment.

Response: We thank the commenter for support. We have re-designated this provision as new § 483.15(b)(1).

Comment: Some commenters supported our proposal to revise ''safety'' in paragraph (c)(1)(i)(C) as ''safety due to the clinical or behavioral status of the resident.'' Some commenters suggested that CMS require facilities to demonstrate that the resident poses a legitimate safety concern, what steps it has taken before discharging or transferring, and how it provided access to mental health services for the resident. One commenter felt that this language is too broad and could result in inappropriate discharges of residents whose behavior is challenging.

Response: We thank the commenters who support this revision. Currently, the language simply states that a resident can be discharged if safety of individuals in the facility is endangered. We do not agree that adding the caveat ''due the clinical or behavioral status of the resident'' is broader and would

create greater opportunity for inappropriate discharges. We are implementing requirements in this rule regarding the information that must be documented when a resident is transferred or discharged. Those requirements include the basis for the transfer or discharge. When the basis for the transfer or discharge is the clinical or behavioral status of the resident, we expect that status to be part of the documentation.

Comment: Some commenters suggested that CMS explicitly require that the discharging facility facilitate a transition to another facility.

Response: Facilities are required to provide specific information to the receiving provider and to provide sufficient preparation and orientation to the resident for the transfer to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand. These requirements are intended to facilitate a transition to another facility.

Comment: One commenter stated that they strongly support improved approaches to managing behavior, but opposed the proposal to create a topic called ''behavioral health'' that is not, and cannot be, adequately defined. The commenter feels behavior issues can be covered under other sections; for example, psychosocial assessment and functional status, and underlying causes can be covered under active diagnoses, history of present illness, and current problem list. The commenter stated that, ultimately, regardless of the name, the issue to be conveyed is whether behavior is personally and socially appropriate, or at least not excessively disruptive or destructive to the individual and to others.

Response: We disagree. Please see our discussion of § 483.40 in section L. Behavioral Health of this preamble.

Comment: Some commenters were concerned about charges related to bed-hold policies. One commenter suggested CMS prohibit facilities from asking a family member to hold a bed or at least restrict the fee a nursing facility can charge to no more than the Medicaid per diem direct rate or no more than the amount the state would pay to hold the bed. In addition, the commenter suggested that CMS require facilities to provide information on the current occupancy rate.

Response: We appreciate the commenters' suggestions. We will evaluate the implications of such a policy and consider it for future notice and comment rule-making.

Comment: Some commenters objected to the requirement that facilities not request or require residents or potential residents to waive potential liability for losses of personal property. Commenters felt that, while a facility should offer a secure place to store valuables, it is unreasonable for a facility to be responsible for all losses of resident's personal property and that other requirements addressed the issue. One commenter recommended that facilities include in their admissions policy information on how a resident can safely store personal items to prevent potential loss of personal property. Others suggested that facilities only be liable for items included on an official inventory of the resident's personal items. Several other commenters supported the proposed provision that prohibits waivers of a facility's liability for loss of personal property, but felt that the prohibition should apply to all waivers of liability.

Response: A resident's broad waiver of liability could allow a facility to avoid liability even when the facility is responsible for a loss of personal property. This provision does not make the facility automatically liable for every loss of personal property, nor preclude the facility from having policies that establish when the facility is liable. Rather, we would protect the resident from facilities inappropriately avoiding liability by failing to take reasonable care in protecting residents' personal property.

Comment: Some commenters were concerned that facilities evade the prohibition on requiring a third-party to guarantee payment, which we are finalizing at 483.15(a)(3), by using contracts that require a resident representative to commit to paying facility charges out of resident resources and suing the representative for breach of contract if the resident's bill is unpaid.

Response: We need to further investigate this concern and consider it for future notice and comment rule-making.

Comment: Several commenters were concerned about provisions relating to non-payment. Some commenters were concerned about having to wait for a third-party denial. One commenter felt that residents should have to demonstrate that they have applied for Medicaid or other third-party payment under § 483.15(c)(1)(i)(E) within a specified period of time from the date a facility notifies the resident that Medicare payment will expire in order to be protected by the prohibition on discharging a resident who has applied for third party payment. Another commenter suggested we reword our provision regarding non-payment to state that non-payment only applies if the resident has submitted the necessary paperwork for third party payment or after the third party payor, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. Another commenter suggested that we clarify that non-payment does not apply if the resident is in the process of submitting the paperwork for third-party and that conversion from the private pay rate to payment at the Medicaid rate does not constitute non-payment.

Response: We thank the commenters for their suggestions. In addition to the proposed language regarding reasonable and appropriate notice, we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party payor denies the claim and the resident refuses to pay for his or her stay. We defer additional discussion to sub-regulatory guidance.

Comment: One commenter stated that equal access to quality of care, proposed § 483.12(b)(1) does not make sense in its new location and that equal access to quality of care needs to be its own subsection or added to an entirely new and independent location such as residents rights.

Response: We agree with the commenter that this section should have been its own subsection. We have corrected this and it is now § 483.15(b).

Comment: One commenter was concerned that the prohibition on discharging a resident while an appeal is pending could result in forcing a facility to keep a resident whose care the facility is not able to adequately and safely provide. In addition, the commenter felt that, if the facility cannot discharge the resident, Medicaid must be required to pay for the cost of the resident's care while the appeal is pending. Other commenters supported the prohibition on involuntary transfer or discharge while an appeal is pending. One commenter recommended instituting high dollar fines for any facility that improperly transfers, discharges, or refuses to readmit a resident.

Response: We have clarified that this provision applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose. Instituting fines for improper transfers, discharges, or

refusals to allow a resident to return to the facility are beyond the scope of this regulation. However, we will take these comments into consideration for future rulemaking.

Comment: Generally, all commenters supported efforts to improve transitions of care. We received comments both supporting and objecting to the specific pieces of information we proposed to require facilities to send to a receiving provider when a resident is transferred. Some commenters want CMS to add additional elements to the list of information that a facility must include in transfer documentation. For example, one commenter suggested that we include the name and contact information of the resident's family member(s). Others suggested a number of elements related to diet and nutritional needs and status and another suggest we add behavioral symptoms and triggers to the list of specific information. Other suggestions included indicating the resident's assisted technology, durable medical requirement needs, and communication methods. One commenter felt that transfer information should include portable orders for scope of treatment, if applicable. Another commenter suggested the proposed list includes items that may be irrelevant in many cases and is more extensive than what is required when a hospital discharges a patient. Some commenters oppose this requirement as proposed. One commenter stated that this requirement would be difficult to meet in a timely and accurate manner without interoperable health information exchange, yet LTC facilities did not receive incentives for the adoption of health information technology that would help to enable such exchange. Some commenters suggest that the federal government should provide meaningful use incentives or other funding to LTC facilities if we finalize this requirement.

Response: We thank commenters for their support and their suggestions. We have reviewed our proposed list, concerns about the applicability of items in the proposed list, and suggestions for additional items that could be added. While we continue to believe that much of the information we proposed should be exchanged for residents to whom it applies, as well as many of the additional suggestions we received, at this time, we are requiring a more flexible set of requirements. We understand that the information required may vary based on the circumstances of an individual's discharge or transfer, including the urgency of the transfer. We defer to sub-regulatory guidance for additional discussion of circumstances when a discharge summary would be expected, as in a discharge to home and community based services, versus when it would not be appropriate to delay, such as when a resident requires an emergency transfer. The revised set of requirements includes the following:

- Contact information of the practitioner responsible for the care of the resident,
- resident representative information including contact information,
- advance directive information,
- special instructions or precautions for ongoing care,
- the resident's comprehensive care plan goals,
- all other necessary information, including a copy of the resident's discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include the medication reconciliation, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. Please see our discussion of portable orders for scope of treatment in section D, in the comments and responses relating to planning and implementing care.

While we have increased the flexibility in these requirements, we continue to support alignment discussed in the proposed rule between this approach and the common clinical data set which providers participating in the EHR Incentive Program(s) have focused on electronically exchanging through the use of certified EHR technology (80 FR 62693). We encourage facilities to identify opportunities to streamline data collection and exchange by using data they are already capturing electronically, for instance, as part of the MDS data collection.

Comment: One commenter suggested that CMS mandate a specific form and format for the transmission of discharge information.

Response: No specific form or format has been developed at this time. In addition, some states have their own mandated form. We are not mandating a specific form at this time, but we will consider this for future development and rule-making.

Comment: One commenter supported the requirement that the discharge notice include information on the agency for the protection and advocacy of individuals with intellectual and developmental disabilities when individuals discharged have such disabilities and on the agency for the protection and advocacy of individuals with a mental disorder when discharged residents have a mental disorder, and suggested that we extend this to individuals with related disabilities, such as traumatic or acquired brain injury.

Response: We thank the commenter for their suggestion and have modified these provisions to include individuals with related disabilities.

Comment: One commenter suggested that the information required to be in the discharge notice, as specified as proposed § 483.15(b)(5) include the name, address, and telephone number of the representative of the Office of the State Long-Term Care Ombudsman.

Response: In this final rule, we are requiring that this information be provided to the resident in the written description of legal rights (§ 483.10(g)(4)(ii)), and posted in an accessible manner (§ 483.10(g)(5)). In addition, a copy of the notice must be sent to the Long-Term Care Ombudsman (§ 483.15(c)(3)(i)).

Comment: A number of commenters were concerned that the obligation at proposed § 483.15(b)(5)(iv) to assist a resident with completing and submitting an appeal unfairly turns the facility into the resident's legal representative. Furthermore, the notice of discharge provides contact information for the Ombudsman, who helps residents get in touch with legal resources to file hearing requests.

Response: This provision does not make a facility or any of its employees the legal representative of the resident under state laws; moreover, a facility cannot engage in the practice of law. The provision does not require that the facility provide legal advice or counsel. It does mean that a facility must, as it does in other ways, physically assist a resident in obtaining access to services, and, importantly, cannot act as a barrier to a resident exercising a right. ''Assistance with completing'' could be helping the resident to contact the Ombudsman or helping the resident get a copy of the pertinent form. ''Submitting'' could mean putting a letter in outgoing mail. We defer further discussion to sub-regulatory guidance.

Comment: Some commenters supported our proposal to require that discharge notices be sent to a representative of the Office of the State Long Term Care Ombudsman. Several commenters suggested that requiring resident agreement for sending the notice to the LTC Ombudsman was potentially confusing and unnecessary.

Others suggested that we specify that the notice go to the local ombudsman. Another requested clarification on the intended effect of sending the notice and whether or not sending the notice constituted a request for assistance and if not, what the resident would need to do to make such a request. One commenter stated that it is unclear why the ombudsman's office would need notification of every routine discharge or transfer and that such notification should be reserved for situations where the transfer or discharge is contested. The commenter doubted that ombudsman offices have the capacity to receive and act upon even a small portion of this information.

Response: We have eliminated language requiring resident consent. We consulted with the Administration for Community Living in the development of this proposal and believe that sending these notices to the State Long-Term Care Ombudsman will provide added protection to the resident and assist the State Long-Term Care Ombudsman to keep informed of facility activities.

Comment: Some commenters were concerned that our proposed revision at § 483.15(b)(4)(ii), which changes ''may'' to ''must,'' could imply that a facility has an obligation to always provide the most limited notice period possible and recommend that we retain ''may.''

Response: The facility must give notice at least 30 days in advance unless an exception is met. When an exception is met, the facility must give the notice as soon as it can. The facility does not have the discretion to delay as long as possible because an exception applies. The ''must'' in this provision requires the facility to provide notice as soon as practicable when it cannot provide notice at least 30 days in advance of the transfer or discharge. We defer to sub-regulatory guidance to further explicate this requirement.

Comment: Several commenters supported our proposed requirement that residents who are being readmitted (following a hospitalization or other absence) to a facility should be assigned to the same room he or she was in previously, if such room is available.

Response: We thank the commenters for their support. Particularly for residents whose home is the facility, returning to the same room is important.

Comment: One commenter asked, since we do not regulate private-pay rates, why we include proposed § 483.15(b)(1)(i)(B), which authorizes facilities to charge ''any amount for services furnished to non-Medicaid residents . . .'' The commenter was further concerned that the restriction of state law is too limited if it means solely statutory or regulatory law specifically addressing payment by private pay residents.

Response: As with the provision of the Social Security Act which it tracks, § 483.15(b)(2) is intended as a modifier to § 483.15(b)(1), and is consistent with section 1919(4)(c)(B)(i) of the Act, which states: ''Nothing prohibiting any charges for non-Medicaid patients.—Subparagraph (A) [regarding identical policies and practices regarding transfer, discharge, and the provision of services required under the state plan for all individuals regardless of source of payment] shall not be construed as prohibiting a nursing facility from charging any amount for services furnished, consistent with the notice in paragraph (1)(B) describing such charges.'' We do not intend to limit the application of state law and proposed to add ''unless otherwise limited by state law'' in recognition of the fact that some states may have regulator or statutory law that addresses limits on charges to private pay residents, consumer protection statutes that would prohibit exorbitant charges, or case law that addresses the concern. The Medicare program has a similar provision with respect to equal access to care, but no specific provision regarding statutory construction with respect to private pay residents.

Comment: One commenter suggested that we clarify that documentation requirements in proposed paragraph (b)(2) only apply in non-emergency circumstances.

Response: We have revised the documentation requirements at proposed § 483.15(b)(2)(ii), which we are finalizing at § 483.15(c)(2)(ii), to provide greater flexibility for facilities when providing information about a transferring resident. However, even in an emergency, the receiving facility will need information about the resident.

Comment: One commenter felt that requiring the physician to directly document the information required for transfers was not feasible, especially during an urgent transfer. The commenter suggested we revise this section to state that the documentation must be made by or based on information from the physician. The commenter stated that sending the physician's previously documented history and physical, pertinent progress notes, consultations, and laboratory tests, supplemented by nursing documentation of the events and rationale leading to the transfer, should suffice.

Response: We thank the commenter for their suggestion. This comment is in reference to § 483.15(c)(2)(ii), which specifies the information that a physician must document in the resident's record under certain transfer/discharge scenarios. We have clarified that the physician must document the basis for the transfer, the resident's needs that cannot be met at the facility, the facility attempts to meet the resident's needs, and the services available at the receiving facility to meet the resident's needs. This does not include all of the information required by § 483.15(c)(2)(iii). We agree that sending the physician's previously documented history and physical, pertinent progress notes, consultations, and laboratory tests, supplemented by nursing documentation of the events and rationale leading to the transfer is appropriate when addressing the requirements of § 483.15(c)(2)(iii).

Comment: One commenter suggested that the proposed requirement at proposed § 483.15(b)(2) appeared to ignore the growing presence of telemedicine, which is often highly effective at managing condition changes appropriately and preventing hospitalization. Other commenters more generally recommended that the requirements for LTC facilities address telemedicine.

Response: We are aware of the growing presence of telemedicine and agree it may be useful in managing condition changes and preventing hospitalization. However, when a transfer does occur, it is important that both the sending and receiving facilities communicate effectively with each other, including the exchange of pertinent clinical and non-clinical information. We will consider further addressing telemedicine in future rule making.

Comment: Some commenters supported our proposal to require facilities to document their attempts to meet the resident's needs, and the service available at the receiving facility to meet the need(s). One commenter suggested that this could result in fewer transfer and discharge notices.

Response: We thank the commenters. We believe that this requirement will help ensure that residents are transferred appropriately.

Comment: One commenter suggested we include a cross-reference to § 483.15(b) in § 483.21(c)(1).

Response: We are finalizing proposed § 483.15(b) at § 483.15(c). We have added a cross-reference to § 483.15(c) at § 483.21(c)(1) based on the commenter's suggestion. Please refer to section J. Comprehensive Person-Centered Care Planning (§ 483.21) for a more detailed explanation.

Comment: Some commenters supported our proposal to require facilities to notify a resident who has been transferred to another facility, expecting that he/she will return to the facility, in writing, of the reason the resident cannot be readmitted and the information required in the notice before transfer. One commenter believed this may reduce inappropriate discharges or transfers. Some commenters opposed this proposal. One commenter was concerned that this language encourages and supports the practice of facility dumping.

Response: At the time a facility determines that a resident cannot be readmitted to the facility, the resident is effectively discharged from the facility. We have revised our language to acknowledge this. Specifically, we use the term ''return'' instead of ''readmit'' and we require facilities, at the time they determine a resident cannot return to the facility, to comply with the requirements of paragraph § 483.15(c) as they pertain to discharges.

Comment: Some commenters were concerned that some facilities charge their private pay rate to hold a bed under the bed-hold requirements and suggested that we limit this charge to no more than the Medicaid rate.

Response: We thank the commenters for their suggestion. We need to further investigate and evaluate this practice. Payment rates for bed-hold charges are beyond the scope of this rulemaking, but we will consider addressing it in future notice and comment rule-making.

Comment: One commenter stated that it is not feasible to provide a bed-hold notice upon transfer. The commenter stated that the focus should be on the resident's well-being and not money.

Response: This is an existing requirement which we did not propose to eliminate or substantially modify. We would expect all facilities to already be in compliance with this requirement. We agree that the resident's well-being is of utmost importance. However, the information provided may be very important to the resident or their representative in order to ensure their ability to return to the facility at an appropriate time.

Comment: One commenter suggested that we create a new subsection to address readmission after a state's fair hearing regarding entitlement to continuing coverage or other issues.

Response: Medicaid's State plan requirements with respect to Medicaid fair hearing processes for applicants and beneficiaries are set forth at 42 CFR 431 subpart E. Corrective action is addressed at § 431.246.

Comment: One commenter recommended adding the specific language at proposed § 483.15(b)(5) to the definition of ''substandard quality of care'' at § 488.301.

Response: The provision in question includes information on the contents of a discharge notice. We agree that it is important that this information is provided to the resident and that failure to do so should be addressed, we do not agree that this language should be included in the definition of ''substandard quality of care''.

Comment: Some commenters requested that CMS clarify that residents would have an appeal right of a facility's refusal to readmit a resident after a hospitalization or other therapeutic leave. The commenters further recommended that the regulation specify that a facility could only refuse a bed-hold or a readmission right if the resident's needs could not be met in the facility, the resident's presence in the facility would endanger others' safety or health, or the resident's condition would not allow for the facility to follow the standard notice procedures for involuntary transfers and discharges. The commenter stated that a hospitalization should not be a means for a facility to evade the normal procedural requirements applicable to involuntary transfers and discharges.

Response: As previously noted, our Medicaid State requirements with respect to state fair hearings for applicants and beneficiaries are set forth at 42 CFR part 431 subpart E. Provisions regarding when a hearing is required are set out at § 431.220. Medicare beneficiaries may have separate appeal rights under Medicare. We have revised paragraph (c)(3), ''Notice before transfer'' to better address concerns that, as proposed, it would allow patient dumping.

Comment: One commenter suggests that at proposed paragraph (b)(8), we require that the administrator also be required to notify staff members of the impending closure.

Response: We thank the commenter for their suggestion. In the event of an impending closure, facilities are required to ensure the safe and orderly transfer, discharge and adequate relocation of all residents. As a part of the process, the facility must have closure plans and procedures. The plans and procedures should include, among other items, notification of all facility staff, vendors, contractors, and unions, as appropriate. However, we cannot require notice to staff unless such notice is related to the health and safety of residents.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have withdrawn our proposal to rename proposed section § 483.15, ''Transitions of Care'' and add introductory language, and retain the current title ''Admission, transfer, and discharge rights.''
- We corrected references to ''clinical record'' to ''medical record.''
- We eliminated the introductory language which defined transitions of care, as the term is no longer used.
- We revised paragraph (a)(6) to require that a facility disclose to a resident or potential resident, prior to admission, notice of special characteristics or service limitations of the facility. We redesignated proposed (b)(1) as paragraph (b), and added a cross-reference to the definition of transfer and discharge in § 483.5 and a cross-reference to resident rights at § 483.10(a)(2).
- We redesignated proposed (b) Transfer and discharge, as (c), and renumbered paragraphs (ii) through (iii) to (i) through (ii).
- In paragraph (c)(1)(i)(E), we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party payor denies the claim and the resident refuses to pay for his or her stay.
- We have clarified that paragraph (c)(1)(ii) applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose.
- We revised paragraph (c)(2)(ii) to clarify that the term ''documentation'' refers to the documentation specified in paragraph (2)(i).
- We revised paragraph (c)(2)(iii), documentation, to reflect a more flexible list of elements to be documented in the resident's medical record and communicated to the receiving health care institution or provider. The documentation must include: Contact information of the practitioner responsible for the care of the resident, resident representative information including contact information, advance directive information, all special instructions or precautions for ongoing care, as appropriate, the resident's comprehensive care plan goals, all other necessary information, including a copy

of the residents discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

- We removed the requirement for resident consent in paragraph (c)(3).
- We revised paragraph (c)(5)(iii) to remove the phrase ''expected to be.''
- We revised paragraph (c)(5)(iv) to require the discharge notice to include a statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request; and expanded paragraphs (vi) and (vii) to include individuals with related disabilities.
- We revised paragraph (c)(8) by removing ''of the residents or other responsible parties.''
- We revised ''readmissions'' to ''returns'' in paragraphs (d) and (e).
- We revised proposed paragraph (c)(3) as paragraph (e). Paragraph (e)(1) is revised to state that ''a facility must establish . . .'' and (e)(1)(i)(B) is revised to read ''Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services'' and revised proposed paragraph (c)(3)(ii) as (e)(2)(ii) to state that if the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

I. Resident Assessment (§ 483.20)

Current regulations at § 483.20 require that a facility must initially and periodically conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity and sets forth the requirements a facility must meet to be in compliance. As part of the restructuring of subpart B, we proposed to remove and re-designate current § 483.20(k) and § 483.20(l), which set forth requirements for care plans and discharge planning, to § 483.21(b) and § 483.21(c), respectively. Similarly, we proposed to re-designate § 483.20(m) as § 483.20(k). The removal and re-designation of paragraphs (k) and (l) are discussed below in the section entitled, ''§ 483.21 Comprehensive Person-Centered Care Planning.''

Existing § 483.20(b) sets forth the information that must be included in a resident's comprehensive assessment using the resident assessment instrument. We proposed to revise this section to clarify that the assessment is not merely for the purpose of understanding a resident needs, but also to understand their strengths, goals, life history, and preferences. We also proposed to revise the regulations to specify that CMS (not the State) prescribes the resident assessment instrument. At § 483.20(b)(1)(xvi) we proposed to revise the text from ''discharge potential'' to read, ''discharge planning'' in an effort to encourage facilities to move the discussion of possible discharge away from a facility's judgment and towards a resident's preference and expectation.

Existing regulations at § 483.20(e) require facilities to coordinate assessments with the PASARR program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and efforts. We proposed to add new § 483.20(e)(1) and § 483.20(e)(2). In new § 483.20(e)(1), we proposed to clarify that coordination with PASARR includes incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care. In new § 483.20(e)(2), we proposed to clarify that PASARR coordination also includes referring all level II residents and all residents with newly evident or possible serious a mental disorder, intellectual disability, or related conditions for level II resident review upon a significant change in status assessment (that is, a decline or improvement in a resident's status).

As mentioned earlier in this section, we are proposed to re-designate existing § 483.20(m) as § 483.20(k). In addition, we proposed to make a few technical corrections at proposed § 483.20(k). First, we proposed to re-designate existing § 483.20(k)(2) as (k)(3), and add a new paragraph (k)(2). Sections 1919(e)(7)(A)(ii) and (iii) of the Act provide exceptions to the preadmission screening for individuals with a mental disorder and individuals with intellectual disability for admittance into a nursing facility. We proposed at § 483.20(k)(2) to add these statutory exceptions that were inadvertently omitted when this regulation was initially written. Second, we proposed to add a new paragraph at § 482.20(k)(4). Section 1919(e)(7)(B)(iii) of the Act requires a NF to notify the state mental health authority or state intellectual disability authority when there has been a significant change in the resident's physical or mental condition so that a resident review can be conducted. We proposed at § 483.20(k)(4) to add this statutory requirement that was inadvertently omitted when CMS first implemented sections 1819 and 1919 of the Act). Lastly, we proposed to replace ''mental retardation'' with the term ''intellectual disability'' throughout § 483.20(k), as appropriate.

Comment: Commenters supported CMS' revisions to clarify that the comprehensive assessment of each resident extends to assessing residents' strengths, goals, life history, and preferences. Commenters indicated that such changes are instrumental to providing person-centered care and engaging residents as partners in their care. One commenter noted that information, such as life history and preferences, may not be possible to obtain and this factor should be noted in the regulation. Another commenter indicated that the MDS does not include information such as resident's strengths and life history, so the addition of this requirement is not useful.

Response: We appreciate the feedback from commenters. We agree that information such as a resident's life history may not be readily available; however we believe that facilities have an obligation to make their best attempts to obtain this information because the information could prove to be valuable to the resident's care. While the MDS is not completely structured around a resident's life history, the MDS does have a person-centered focus and contains questions that ask about preferences (see Section F for activity preferences), life history in terms of socioeconomic status, marital status, and prior care. In addition, new Section GG of the MDS addresses a resident's goals related to function and has a person-centered focus on items such as pain. We understand that the MDS is an evolving assessment tool, and we will consider the feedback from commenters for possible efforts to improve the assessment in the future.

Comment: Commenters also asked whether the proposed changes related to coordinating assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of part 483 will add any meaningful benefit to residents. Commenters noted that the current PASARR reporting process is flawed and many residents are admitted into facilities with incorrect or missing diagnoses, confusing medication regiments, and barely controlled symptoms. Commenters further questioned the efficacy of PASARR and whether PASARR continues to serve a purpose for nursing home residents. Another commenter noted that the regulation uses the acronym ''PASARR'', which is inconsistent with the acronym that is used on the *Medicaid.gov* Web site.

Response: The regulations for LTC facilities found in subpart B include some PASARR regulations that apply strictly to nursing facilities. The July 2015 proposed rule provided updates to the regulations for clarity, but did not change the PASARR program or procedures in any state. The requirements specific to the PASARR program are found in subpart C of part 483, which pertain to all entities and includes the responsibilities of various state agencies. The PASARR Technical Assistance Center (PTAC) at *www.PASRRassist.org* is a useful resource for finding answers to questions regarding the PASARR program and for providing feedback regarding how the program can be improved. We are aware that the acronym varies between what is used in the Code of Federal Regulations (CFR) and what is used on the Medicaid Web site. For consistency we are continuing to use the acronym PASARR for purposes of the CFR. We may revise the term in future rulemaking.

Comment: Several commenters requested clarification regarding the meaning of ''direct care/direct access staff members'' as used at § 483.20(b)(1)(xviii) and suggested that the term ''direct access staff'' be defined in the ''Definitions'' section. One commenter suggested that the phrase be replaced with ''staff members of all shifts who provide services directly to the resident.'' Another commenter indicated that the phrase should include housekeeping and maintenance staff, as they often have contact and interaction with residents and may be able to provide valuable information regarding a resident's preferences and needs.

Response: On August 4, 2015 we published a final rule entitled, ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46389), which established a definition of ''direct care staff'' in 42 CFR part 483. When we use the term ''direct care/direct access staff'' we are referring to those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. We were not referring to individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping). For clarity we have removed the reference to ''direct access staff'' at § 483.20(b)(1)(xvii) and elsewhere throughout the regulatory text as appropriate.

Comment: One commenter provided comment regarding the language at § 483.20(k)(2)(ii)(C) which indicates that the state may choose to not apply the preadmission screening program for individuals with a mental disorder if it is anticipated by a physician that the individual will be in a nursing facility for less than 30 days. The commenter noted that if it is discovered that the individual requires more than a 30 day stay, they are not protected against transfer. The commenter suggested that CMS add language ensuring that residents affected by this section be given the same protections as other residents with regard to the transfer/eviction process.

Response: We appreciate the commenters' feedback. However, we believe that the intention of the policy was to limit the program to those with an expectation of staying 30 days or more.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following revision:

- Remove the reference to ''direct access staff'' at § 483.20(b)(1)(xviii).

J. Comprehensive Person-Centered Care Planning (§ 483.21)

In accordance with the proposed reorganization of part 483, subpart B, we proposed to add a new § 483.21 ''Comprehensive Person-Centered Care Planning''. We proposed to retain in this section certain existing provisions of current § 483.20 as well as other additions and revisions discussed in detail below. Currently, the requirements for care plans and discharge planning are set out at § 483.20 along with the requirements for conducting an assessment of each resident's health and completing the MDS. We proposed to remove the requirements for care plans from current § 483.20(k) and discharge planning in current § 483.20(l) (collectively referred to here as care planning) and relocate them to a new § 483.21. In addition to relocating existing provisions, we also proposed to add new requirements as discussed in detail below.

Proposed § 483.21(a)

We proposed to add a new § 483.21(a)(1) to the current care planning regulations and require that facilities complete a baseline interim care plan for each resident upon their admission to the facility. We proposed to require that the baseline care plan be completed within 48 hours of a resident's admission. At § 483.21(a)(1)(ii), we proposed to list the information that would, at a minimum, be necessary for inclusion in a baseline care plan, but would not limit the contents of the care plan to only this information. In the proposed rule, we indicated that information such as initial goals based on admission orders, physician orders, dietary orders, therapy services, social services, and PASARR recommendations as appropriate would be the type of information that would be necessary to provide appropriate immediate care for a resident. However, since care plans are developed specifically for each resident, a facility could decide to include additional information as appropriate.

At § 483.21(a)(2), we proposed to allow facilities to complete a comprehensive care plan instead of completing both a baseline care plan and then a comprehensive care plan. In this circumstance, the comprehensive care plan would be completed within 48 hours of admission and comply with the requirements for a comprehensive care plan at proposed § 483.21(b). We discuss those requirements below.

Proposed § 483.21(b)

Current regulations at § 483.20(k) set forth the requirements for developing a comprehensive care plan. As mentioned above, we proposed to re-designate this section as a new § 483.21(b). In addition, we also proposed to add a new § 483.21(b)(1)(iii), requiring that any specialized services or specialized rehabilitation services that a nursing facility provided pursuant to a PASARR recommendation be included in the resident's care plan.

We also proposed to add a new § 483.21(b)(1)(iv)(B) to require that discharge assessment and planning to be a part of developing the comprehensive care plan. We proposed to require facilities to assess a resident's potential for future discharge, as appropriate, as early as upon admission, to ensure that residents are given every opportunity to attain their highest quality of life. We proposed to require at § 483.21(b)(1)(iv) that facilities document whether a resident's desire for information regarding returning to the community is assessed and any referrals that are made for this purpose.

The IDT is responsible for developing a comprehensive care plan for each resident at proposed § 483.21(b)(2)(ii). Under current § 483.20(k)(2)(ii), the attending physician, a registered nurse with responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs, and to the extent possible the resident or the

resident's family/legal representative are all required to participate in the IDT. We proposed to add the term ''other appropriate staff'', which should be determined based on the specific needs of the resident or at the request of the resident. We proposed to also explicitly require a NA with responsibility for the resident, an appropriate member of the food and nutrition services staff, and a social worker to be a part of the IDT. Additionally, we proposed to revise § 483.21(b)(2)(ii)(F), to provide that to the extent practicable, the IDT must include the participation of the resident and the resident representatives. Further, at § 483.21(b)(2)(ii)(F) we proposed to add the requirement that an explanation must be included in a resident's medical record if the IDT decides not to include the resident and/or their resident representative in the development of the resident's care plan or if a resident or their representative chooses not to participate.

Lastly, we proposed to add a new requirement at § 483.21(b)(3)(iii) to require that the services provided or arranged by the facility be culturally-competent and trauma-informed.

Proposed § 483.21(c)

Current regulations at § 483.20(l) set forth the requirements for a discharge summary. As mentioned above, we proposed to re-designate this section as a new § 483.21(c). At § 483.21(c)(1) we proposed to improve the discharge planning for LTC facilities by adding a requirement that facilities must develop and implement an effective discharge planning process. In the proposed rule, we indicated that the facility's discharge planning process must ensure that the discharge goals and needs of each resident are identified. This process should also result in the development of a discharge plan for each resident and any referrals to local contact agencies or other appropriate entities, should the resident have a desire to receive information about returning to the community. We note that in compliance with the Supreme Court *Olmstead* decision (*Olmstead* v. *L.C ex rel. Zimring,* 527 U.S. 581, 119 S. Ct. 2176 (1999)), we encourage facilities and their community partners to strive to serve individuals in their preferred settings, when feasible. In addition, we proposed to require that the facility's discharge planning process require the regular re-evaluation of residents to identify changes that require modification of the discharge plan. We proposed that the discharge plan must also be updated, as needed, to reflect these changes. We also proposed to require that the IDT responsible for the developing a resident's comprehensive care plan be involved in the ongoing process of developing the discharge plan.

Furthermore, we proposed to require that the facility consider caregiver/support person availability, and the resident's or caregiver support persons' capacity and capability to perform the required care, as part of the identification of discharge needs. We also proposed to require that the discharge plan address the resident's goals of care and treatment preferences. In the proposed rule, we indicated that facilities have to document in the discharge plan that a resident has been asked about their interest in receiving information regarding returning to the community. If the resident indicates interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose and update a resident's comprehensive care plan and discharge plan in response to information received from such referrals. Likewise, if discharge to the community were determined to not be feasible, the facility must document who made the determination and why. We note that on May 20, 2016 the HHS Office for Civil Rights' issued a report entitled ''Guidance and Resources for Long Term Care Facilities: Using the Minimum Data Set to Facilitate Opportunities to Live in the Most Integrated Setting'' (see *http://www.pasrrassist.org/events/webinar/ocr-guidance-and-resources-long-term-care-facilities-using-minimum-data-set*). We encourage facilities to review this guidance for information to assist facilities in complying with civil rights obligations by administering the Minimum Data Set (MDS) appropriately so that their residents receive services in the most integrated setting appropriate to their needs. In addition, the IMPACT Act amended title XVIII of the Act by adding Section 1899B to require that post-acute care (PAC) providers, home health agencies (HHAs), SNFs, inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs) report standardized patient assessment data, data on quality measures, and data on resource use and other measures. The IMPACT Act also requires that this data be standardized and interoperable to allow for the exchange of data among PAC providers and other providers. The IMPACT Act requires the modification of PAC assessment instruments to allow for the submission of standardized patient assessment data and enable comparison of this assessment data across providers. Additionally, the IMPACT Act requires that standardized patient data, quality measures, and resource use measures, along with patient treatment goals and preferences, be taken into account in discharge planning.

As required under section 1899B(i)(1) of the Act, to help inform the discharge planning process, we proposed to require LTC facilities to take into account, consistent with the applicable reporting provisions, standardized patient assessment data, quality measures and resource use measures that pertain to the IMPACT Act domains, as well as other relevant measures specified by the Secretary. For those residents who are transferred to another LTC facility or who are discharged to a HHA, IRF, or LTCH, we proposed at § 483.21(c)(1)(viii) to require that the facility assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data are available. Further, we proposed that the facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use are relevant and applicable to the resident's goals of care and treatment preferences.

Finally, at § 483.21(c)(1)(viii), we proposed that facilities must document in the discharge plan whether a determination is made by the resident, resident representative, or interdisciplinary team that discharge to the community is not feasible. At § 483.21(c)(1)(ix), we proposed to require that the evaluation of the resident's discharge needs and discharge plan must be documented, completed on a timely basis based on the resident's needs, and included in the clinical record. The results of the evaluation must be discussed with the resident or resident's representative. Furthermore, all relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

At § 483.21(c)(2), we proposed to set forth the existing requirements for providing a resident with a discharge summary when discharge from the facility is anticipated. At § 483.21(c)(2)(i) we proposed to revise the current requirements for the post-discharge plan of care to specify that a recapitulation of a resident's stay include, but not be limited to,

diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results. We also proposed to explicitly include a requirement for facilities to include what arrangements have been made with other providers for the resident's follow-up care and any post-discharge medical and non-medical services as needed. These arrangements include any community care options, resources, and available supports and services presented and arranged by the community care provider as needed.

At § 483.21(c)(2)(iii), we proposed to add a new requirement to require facilities to reconcile all pre-discharge medications both prescribed and non-prescription, with the resident's post discharge medications. We proposed that this medication reconciliation be included as part of the discharge summary. Lastly, we also proposed at § 483.21(c)(2)(iv) to require that the post-discharge plan be developed along with the participation of the resident and, with the resident's consent, his or her resident representative.

Comment: Commenters supported the recognition of the need to plan for person-centered care and the incorporation of person-centered care into the care planning process. One commenter did not support specifying that a resident's care plan be person-centered. The commenter noted that the Institute of Medicine (IOM) has identified several major quality attributes including safety, effectiveness, efficiency, timeliness, patient-centeredness, and equitability. The commenter suggests that the regulations should recognize all elements of quality and not just selected ones.

Response: We appreciate the commenters' feedback. The intent of creating a section devoted to person-centered care planning was not to diminish the necessity of other quality attributes. We received insight and recommendations from the OIG ((OEI–02–09–00201), *https://oig.hhs.gov/oei/reports/oei-02-09-00201.asp*), internal workgroups, and stakeholders regarding the lack of resident involvement in the care planning process. In response, we determined that it is necessary to highlight the importance of focusing on the resident as the locus of control when developing care plans. The regulation as a whole focuses on the additional quality attributes mentioned by commenters; safety, effectiveness, efficiency, timeliness, and equitability. Some of the proposals that focus on these attributes include the addition of the QAPI requirements, strengthening the rights of residents, and the overall promotion of resident choice.

Comment: Commenters also supported the need to include discharge planning as part of the comprehensive care plan. Commenters insisted that discharge planning, including referrals for community transition, be initiated as early in the admission process as possible to prevent any unnecessary period of institutionalization.

Response: We agree that discharge planning should be initiated as early as possible in the admission process. In addition to requiring discharge assessment and planning to be a part of developing the comprehensive care plan, we also proposed at § 483.21(b)(1)(iv)(B) that facilities document whether the facility assessed a resident's desire to return the community. We noted in the proposed rule that the discharge assessment may include referral to a community transition planning agency to explore community living options, resources, and available supports and services.

Comment: Multiple commenters questioned whether a qualified mental health professional and a member of clergy would be required to participate on the IDT. Commenters indicated that ''qualified mental health professional'' should be defined and that such a requirement would be costly, while noting that access to these professionals is limited. Some commenters indicated that they offer clergy services to residents and a few noted that many residents may request that their own religious leaders come into the facility to provide them services.

Response: In the preamble discussion of the proposed rule (see 80 FR 42193) we indicated that we proposed to add the term ''other appropriate staff'' to the requirement for the individuals who must participate on a resident's IDT at § 483.21(b)(2)(ii). We provided examples for ''other appropriate staff'' that may be appropriate for participation on the IDT and for inclusion in the development of a resident's care plan. We used the examples of a mental health professional for a resident who is diagnosed with a mental health disorder or a chaplain based on a resident's needs. We did not require that these individuals participate in the IDT. For clarity, we proposed at § 483.21(b)(2)(ii) that a resident's care plan must be developed by an IDT that includes but is not limited to the attending physician, a registered nurse with responsibility for the resident, a nurse aide with responsibility for the resident, a member of food and nutrition services staff, a social worker, the resident or the resident's representative, and other appropriate staff as indicated by the resident's needs.

Comment: Many commenters supported our proposal to add a requirement for a baseline care plan. Commenters indicated that the requirement for a baseline care plan recognizes the planning needed to meet the immediate, short-term needs of newly admitted patients. One commenter recommended that the baseline care plan also include information about the current health condition and diagnosis of a resident rather than be based on admission orders from another facility in order to determine if they are still relevant. Another commenter recommended that the baseline care plan also include information about a resident's customary routines and preferences. A few commenters indicated that the proposed 48 hour timeframe for completing the baseline care plan may be problematic if an individual is admitted on a Friday afternoon or on a holiday. Another commenter indicated that the proposed 48 hour timeframe was too long and stated that the plan should be developed upon admission. One commenter indicated that staff with specific or specialized training would be required to complete the baseline care plan and this would have a negative financial impact of facilities.

Response: We expect that a resident's current health status and diagnosis will be included in the admission orders. Section 483.15(c)(2)(iii) of this final rule requires that certain information be provided to a receiving provider for a transfer including all special instructions or precautions for ongoing care and the contact information of the practitioner responsible for the care of the resident. If a resident is transferred from another facility, the requirements at § 483.15(c)(2)(iii) would apply. If the information provided is missing or unclear, the facility or admitting professional is not precluded from following up to gain additional information. Furthermore, we believe the information necessary to complete the baseline care plan will be readily available or accessible through discussions and follow-up upon admission. Therefore, we do not agree with the commenter who indicated that additional staff with specialized or specific training is necessary to complete the baseline care plan causing a negative financial impact on facilities. While a resident's customary routine and preferences provide valuable information regarding a resident's care, we believe it would be overly burdensome to include this information in the baseline care plan. The purpose

of the baseline care plan is to serve as an interim care plan within the initial period of residency to avoid poor quality care and reduce the risk of hospital readmission as a result of missing information. The comprehensive care plan required at § 483.21(b) is a more detailed and exhaustive plan of care for each resident that is person-centered and includes a resident's needs and preferences.

In addition, we understand that admissions to a facility can take place on a weekend or over a holiday, however we expect that quality care will still be provided including the need to formulate a plan of care for the resident. Furthermore, regulations at § 483.35(b)(1) require the facility to use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week. Therefore, we expect, at a minimum, that a registered nurse will be available to develop a baseline care plan regardless of whether it is a holiday or a weekend. Finally, we expect that facilities will begin developing the baseline care plan upon admission in order to meet the 48 hour timeframe. The 48 hour timeframe serves as a deadline for having the plan completed and does not preclude facilities from completing the plan sooner. We believe that 48 hours is an appropriate timeframe as it will allow the facility sufficient time to obtain necessary information to complete the baseline care plan while also addressing the need for continuity of care during transition, a high-risk period when residents are particularly vulnerable to adverse health events.

Comment: One commenter recommended that the language at § 483.21(a) be revised to clearly state that facilities must not only develop a baseline care plan, but must also implement the plan. The proposed language only stated that the plan must be developed and implied that it must also be implemented. The commenter request that CMS clearly state that the plan must be also be implemented.

Response: We agree and have revised the language at § 483.21(a) to indicate that facilities must both develop and implement a baseline care plan. Similarly, the proposed language only stated that the comprehensive person-centered care plan must be ''developed.'' Therefore, for consistency, we have also revised the language at § 483.21(b) to indicate that facilities must both develop and implement a comprehensive person-centered care plan.

Comment: One commenter recommended that we consider the care plan requirements in regard to short-stay vs long-stay residents due to the significant variation in their treatment regimens. The commenter suggests that residents receive a short-term interim care plan for a period of up to 100 days from admission. Once a resident is no longer ''short-stay'' then the requirement for a comprehensive assessment and care plan to be completed with 14 days of the change could then be completed.

Response: We disagree with the commenter. We believe that a comprehensive person-centered care plan should be developed for all residents regardless of length of stay. The need for an assessment and a plan of care is not dependent on the length of time an individual spends in a facility. Rather comprehensive assessments and care planning is necessary to provide all residents with the proper care and services that will help them to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

Comment: One commenter recommended revising the language at § 483.21(b)(1) by replacing the term ''timetables'' with ''timeframe'' as they are not the same. The commenter notes that timetables are rigid and predictable unlike timeframes. Another commenter requested that § 483.21(b)(1) be revised to also address a resident's goals not just their needs.

Response: We have replaced the term ''timetables'' and revised the language at § 483.21(b)(1) to ''the facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with § 483.10(c)(2) and § 483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment.''

Comment: One commenter suggested that medications or pharmacy services should be added to the list of information necessary for completing the baseline care plan. Another commenter suggested that the terms ''prescriptions'' or ''recommendations'' be used in place of ''orders''. The commenter indicated that the term ''order'' is used in the military which reinforces a resident's feelings that they are ''inmates'' at the LTC facility.

Response: Regulations at § 483.21(a)(1)(ii)(B) require that the baseline care plan include the physicians orders. We expect that the physician orders will include any initial medications and pharmacy services that are needed for the resident. We do not agree that the term ''orders'' as used in ''admission orders'', ''physician orders'', and ''dietary orders'' should be removed. The term ''orders'' is a widely used term throughout the medical field and understood by medical professionals of all specialties and skills.

Comment: A few commenters were against requiring that a nursing assistant with responsibility for the resident and a member of dietary services to be a part of the IDT, while some commenters indicated support for the proposal. Overall commenters supported the intent of the requirement; however commenters opposing the proposal stated that participating on the IDT would require a significant amount of time and would reduce the amount of time that the nursing assistant would be available to provide direct care to residents. Commenters also noted shortages in the number of dietary staff and their limited availability to participate in meetings. Commenters recommended that each facility have the flexibility to determine how best to obtain input from direct-care staff in a manner that is more cost effective and less disruptive to resident care. One commenter noted that they do not hire nursing assistants to provide primary care to their Medicare Part A rehab patients, but rather uses Licensed Practical Nurses (LPNs) and RNs to provide care.

Response: We continue to believe that it is most appropriate for a nursing assistant with responsibility for the resident to be a part of the IDT. Nursing assistants spend much of their time interacting directly with residents providing them day-to day care. In addition, their knowledge of a resident's care plan and medical needs directly relates to how well they can care for a resident and including them on the IDT may also contribute to improved outcomes. For those facilities that do not hire nursing assistants, as indicated by the commenter, we note that the regulation at § 483.21(b)(ii) also requires a RN with responsibility of the resident to participate on the IDT as well. We expect that these facilities will meet these additional requirements for IDT members and be able to demonstrate their lack of nursing assistants on staff. Likewise, we also believe that nutrition is a fundamental part of a resident's overall health and well-being and that a member of nutrition services will provide invaluable information to the IDT. We do not require that any of the members of the IDT participate in person. Facilities have the flexibility to determine how to hold IDT meetings whether in person or by conference call. The facility may determine that participation by the nursing assistant or

any member, may be best met through email participation or written notes. We believe that this added flexibility will help to alleviate concerns of shortage and availability.

Comment: One commenter requested that we provide an explanation for how we expect the social worker to participate on the IDT when facilities with 120 or fewer beds are not mandated to have a social worker and those with more than 120 are only required to have one social worker.

Response: We appreciate the feedback from the commenter. After further consideration, we are removing our proposal that requires the social worker to participate on the IDT. We agree that the proposal would not be appropriate given that all facilities are not required to employ a social worker. However, we strongly encourage facilities to leverage the many valuable assets that social workers can provide to LTC residents and their families. Often social workers can serve as a critical link between the facility and families of the residents, including arranging post-discharge services and addressing mental and behavioral health care needs. In addition, social services can be used by the facilities to promote resident choices and enhance the individualized quality of care and life specific to each resident.

Comment: One commenter recommended that a pharmacist should also be required to participate on the IDT to highlight the importance of medication therapy as part of the care plan. Another commenter suggested that an activity professional should also be required to participate in the IDT and that many activity professionals are already a part of the resident assessment and the IDT.

Response: We considered requiring the pharmacist to participate on the IDT and determined that it would be overly burdensome. However, the pharmacist is not precluded from participating in the IDT if it is determined to be necessary for a particular resident. In addition, we believe that the proposed requirements at § 483.45 strengthen the involvement of the pharmacist in a resident's care including the need for a pharmacist to review the drug regimen of each resident at least once a month and the need to review a resident's medical chart every 6 months (§ 483.45(c)(1) and (2)). Similarly, the activity professional is not precluded from participating on the IDT if it is determined to be necessary for a particular resident, even though they are not specifically listed at § 483.21(2)(ii). Those facilities that currently involve the activity professional may continue to include these individuals.

Comment: One commenter recommended that members of the IDT be required to provide explanation in the resident's medical record if they are unable to attend IDT meeting that discuss the resident.

Response: Given the diversity of long term care providers, we have attempted to develop health and safety standards that can be applied across all types. We want to allow facilities the flexibility to determine how to ensure that the necessary professionals are involved in the development of each resident's care plan. We believe that adding a requirement for each member of the IDT to provide explanation in the resident's medical record of when they miss a meeting would be too burdensome.

Comment: One commenter noted that a cost is associated with having additional individuals participate on the IDT and that CMS did not adequately identify the costs. To reduce the cost, the commenter suggested that instead the additional individuals could be interviewed prior to the meeting to obtain their valuable information.

Response: In the regulatory impact analysis section of the proposed rule we indicated that we estimated that it will cost all long-term facilities $97,911,840 to have the additional individuals participate on the IDT (see FR 80 42237). We envision that these staff members are already regularly discussing resident's needs and their plans of care. In addition, we did not specify the type of communication the IDT must use for their meetings. In the proposed rule, we noted that to reduce cost, the IDT members may use electronic communication to participate in the IDT meetings. Facilities have the flexibility to determine how to conduct the IDT meetings and incorporate the staff who have been added to participate.

Comment: One commenter indicated that the proposed rule does not reflect the expectation that a comprehensive person-centered care plan must include the participation of the resident or their representative. The commenter notes that the regulation includes the participation ''to the extent practicable.'' The commenter noted the failure of facilities to include resident's in the development of the care plan sited in the July 2012 OIG report, ''Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs'' ((OEI–07–08–00151), *https://oig.hhs.gov/oei/reports/oei-07-08-00151.asp*). The commenter further notes that the OIG report references different types of resident representatives including the resident's family or legal representative.

Response: Our proposed regulations at § 483.21(b)(2)(ii)(F) would require that to the extent possible the resident and/or their representative(s) must participate on the IDT that develops the resident's care plan. For clarity, one example of when it may not be practical for a resident to participate in the development of their care plan may be in the case of a resident whose ability to make decisions about care and treatment is impaired, or a resident who has been formally declared incompetent by a court. We would expect that to the extent practicable these residents would be kept informed and consulted on personal preferences regarding their care.

In the preamble of the proposed rule (see 80 FR 42192) we noted the gaps in care planning revealed by the July 2012 OIG report referenced by the commenter as well as another OIG report, ''Skilled Nursing Facilities Often Fail to Meet Care Planning and Discharge Planning Requirements'' ((OEI–02–09–00201), *https://oig.hhs.gov/oei/reports/oei-02-09-00201.asp*), conducted in February of 2013. In response to these reports and the gaps revealed, we also proposed at § 483.21(b)(2)(ii)(F) that the facility must provide an explanation in the resident's medical record if the participation of the resident and their representative is determined not practicable for the development of the resident's care plan. We note that the definition of ''resident representative'' includes individuals of the resident's choice (which may include family members) and individuals with legal standing.

Comment: One commenter recommended that the requirement for a written explanation be provided when a resident or their representative does not participate in the development of their care plan be removed from the regulations and discussed in the interpretive guidance.

Response: We disagree with the commenter. The July 2012 OIG report discussed previously and in the proposed rule (see 80 FR 42192) revealed that 91 percent of the care plans reviewed in the study did not contain evidence that the resident or a representative participated in the care planning process. Given this evidence and feedback from stakeholders, we continue to believe that residents should be involved in making decisions about their care and that it is appropriate for facilities to be held accountable for whether or not they actively include the resident and their representatives in the development of their care plan.

Comment: One commenter indicated that the resident or their representative

should be invited to participate in the review or revision of their care plan in order for it to truly be person-centered.

Response: Regulations at § 483.21(b)(2)(ii)(E) require that the resident and/or their resident representative participate on the IDT that develops their care plan. In addition, regulations at § 483.21(b)(2)(iii) require that the care plan be reviewed and revised by the IDT. Therefore, the resident and/or their representative have the right to participate in the review or revision of their care plan under our proposal.

Comment: Several commenters recommended that the regulations require a resident's participation in developing their care plan be strengthened by adding that the facility must provide advance written notice of the date and time of the care plan meeting, make reasonable accommodation of the schedules of the resident and any resident representatives invited to participate, and arrange for conference calls or video conferencing if necessary to enable resident participation.

Response: Regulations at § 483.10(c)(2) set forth the rights a resident has regarding their participation in the development and implementation of their plan of care which includes, among other rights, the right to request meetings, request revisions to their care plan, and the right to be informed, in advance, of changes to their plan of care. Regulations at § 483.10(c)(3) provide that the facility has a responsibility to inform the resident of their right to participate in his or her treatment and support the resident in this right. Therefore, we believe that the regulations address the commenters' concerns and revisions are not necessary.

Comment: A few commenter asked that ''trauma-informed care'' be defined as used at § 483.21(b)(3)(iii) and added to the definitions section. One commenter noted that it is reasonable to tailor interventions to cultural preferences and difference, but indicated that this is different from requiring facilities to adhere to concepts such as ''culturally competent'' or ''trauma-informed''. The commenter indicated concern for surveyors to consistently and fairly identify whether a facility's efforts are sufficient. The commenter suggested instead requiring that facilities be mindful of and tailor services outlined by a resident's care plan to cultural differences and preferences. Another commenter noted that staff would need to be trained on trauma-informed care and that additional implementation time should be provided to allow for such training.

Response: Culturally-competent and trauma-informed care are approaches that help to minimize triggers and re-traumatization. Care that addresses the unique needs of Holocaust survivors and survivors of war, disasters, and other profound trauma are an important aspect of person-centered care for these individuals. We noted in the proposed rule that person-centered care that reflects the principles set forth in SAMSHA's Concept of Trauma and Guidance for a Trauma-Informed Approach (HHS Publication No. (SMA) 14–4884, available at *http://store.samhsa.gov/shin/content/SMA14-4884/SMA14-4884.pdf*, would help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life. We do not believe that a definition of trauma-informed care should be added to the definitions section, but note that the interpretative guidelines and the resource noted previously will provide further information regarding culturally-competent and trauma-informed care. In addition, as with all of our requirements, surveyors will use uniform sub-regulatory guidance and surveyor training will be provided to promote consistent enforcement. In addition, we note that the requirement related to trauma-informed care at § 483.21(b)(3)(iii) has a delayed implementation deadline that is 3 years following the effective date of this final rule. For more detailed information regarding the implementation timeframe of this final rule, readers may refer to Section II.B., ''Implementation Date''.

Comment: One commenter provided resources for facilities to refer to for information and material addressing culturally competent and trauma-informed care. The resources include The Council on Social Work Education, NASW's standards and indicators for cultural competence (available at *http://www.socialworkers.org/practice/standards/index.asp*), and The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care (developed by the Office of Minority Health in HHS).

Response: We appreciate the commenter's feedback and encourage readers to refer to these resources for information.

Comment: One commenter recommended that the final rule make a better connection between care planning and a resident's quality of life. The commenter suggested that facilities should be encouraged to develop and share care planning documents that highlight resident goals. The commenter notes that a care plan that includes a wheelchair dependent resident's desire to gain strength to walk or a resident's food preference would be more beneficial to a activities director and member of food and nutrition services.

Response: Regulations at § 483.21(b)(1)(iv)(A) require that a resident's comprehensive care plan describe a resident's goals for admission and desired outcomes. In addition, we expect that any person who is involved in the implementation of a resident's plan of care will have access to their care plan. In order to fulfil a resident's plan of care it is necessary for facilities to share information with the appropriate members of a resident's care team. We expect that facilities are already doing this.

Comment: One commenter suggested that facilities be required to provide copies of the care plan to residents when the plan is revised and require facilities to ensure that the plan is written in a manner that is understandable to the resident, not in medical jargon.

Response: Since the comprehensive care plan is intended to be a working document that is constantly being reviewed and updated based on the needs of the resident, we believe that it would be overly burdensome to require facilities to make copies of the comprehensive care plan every time it is updated. However, we note that regulations at § 483.10(c)(2)(iii) indicate that a resident has the right to be informed, in advance, of changes made to their plan of care and regulations at § 483.10(c)(2)(v) indicate that the resident has the right to see their care plan including the right to sign after significant changes are made to their plan of care.

In addition, we note that as discussed previously we received comments requesting that the right to receive a copy of the care plan be added to the list of resident rights discussed in § 483.10. In response to these comments we have added a provision at § 483.21(a)(3) that requires facilities to provide residents and their resident representatives with a summary of their baseline care plan. This summary must include, but is not limited to, the initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary. Note that this summary is subject to the provisions at § 483.10(g)(3) and must be

provided in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Furthermore, we believe that the comprehensive care plan should serve as an important tool for delivering patient-centered care and encourage facilities to explore ways to allow residents, families, and other representatives to access the care plan on a routine basis as appropriate, for instance, using technology solutions that enable real-time access for authorized users and dynamic updating by members of the care team.

Comment: One commenter recommended that a new subsection be added to the care planning regulations to require facilities to engage in an ongoing process of advance care planning that may include the completion of advance directives, education on the National Physician Orders for Life-Sustaining Treatment (POLST) Paradigm, and education regarding do-not-resuscitate and similar state-specific forms. This process should include assisting residents and their representatives to complete any related forms if desired.

Response: We thank the commenter for their recommendations but decline to add additional requirements regarding advance directives and physician orders for life-sustaining treatment at this time. We note that advance directives are currently included in the requirements for participation and we proposed revisions that were primarily to improve clarity and readability (See our discussion of § 483.10 Resident Rights). We recognize that the tools and education recommended by commenters may serve a function beyond advance directives and several of our requirements are also intended to facilitate shared, informed decision making and communication between health care professionals and residents with serious, progressive illness or frailty. We would expect that the issues that are addressed by physician orders for life-sustaining treatment would be raised in the context of advance directives as well in ongoing discussions related to care planning and keeping in mind residents' goals of care and treatment preferences. To the extent applicable, such concerns should also be reflected in resident's discharge plan and discharge summary. All physician orders are documented in a residents' care plans. We note that a few states have developed POLST programs, a few states do not have such a program, and many states are in the process of developing such programs. Consistent with State law, it would be appropriate for facilities to inform residents about POLST, as those tools are referenced and recognized within the state. We note that current requirements already require a facility to provide written information to residents that includes a description of the facilities policies with respect to advance directives and applicable State law.

Discharge Planning

Comment: Several commenters supported the addition of the Discharge Planning section. Commenters noted support for involving the IDT in the ongoing process of developing the discharge plan. Commenters also noted that the proposed requirements are superior to existing regulations and will help protect residents from the dangerous consequences of unexpected discharges. A few commenters indicated that discharge planning starts on the day of admission and is therefore a very time consuming and lengthy process.

Response: We appreciate the commenters' feedback. We believe that the proposed requirements help to highlight the importance of safe transitions across care settings and support the need to safely reduce hospital readmissions and unnecessary hospitalizations.

Comment: One commenter indicated that the discharge planning requirements should be revised to include transfer and discharge rights. The commenter noted that the proposed requirements may be misconstrued to authorize facilitates to discharge residents who still need LTC facility care after their Medicare coverage ends.

Response: Facilities are required to adhere to all of the requirements for participation set forth in subpart B. Therefore, while meeting the discharge planning requirements at § 483.21(c), facilities are also responsible for adhering to the requirements set forth in § 483.15 regarding admission, transfer, and discharge rights and the requirements set forth at § 483.10 regarding the rights of a resident and a facility's responsibility to support those rights. However, to avoid any confusion, we have added to the stem statement of § 483.21(c)(1) a cross-reference to the regulations at § 483.15 which sets forth the requirements related to transitions of care and requires facilities to establish, maintain, and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment. Specifically, we have added language to indicate that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable.

Comment: One commenter requested that § 483.21(c)(1)(i) require that the discharge planning process address a resident's goals not just their needs. The commenter indicated that the revision would be consistent with Section Q of the Resident Assessment Instrument Minimum Data Set (MDS 3.0) which focuses on residents' ability and desire to return to the community.

Response: Regulations at § 483.21(c)(1)(vi) require that the facility's discharge planning process must also address the resident's goals of care and treatment preferences.

Comment: Commenters supported the need to consider the availability of family caregivers, and support persons, during the discharge planning process since these individuals are often involved in a resident's care following discharge from a facility. Commenters suggested that the regulation also require that facilities note whether an individual has a caregiver and their contact information, whether the family caregiver has voluntarily agreed to provide assistance, and whether the caregiver was provided with supports.

Response: We appreciate the commenters' feedback and agree that the availability of a support system is crucial following discharge from a facility. We believe that the requirement at § 483.21(c)(1)(iv) for a facility to consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs, reflects the concerns raised by the commenter. The interpretative guidelines for this final rule would be the appropriate place to discuss specific questions/discussions that can be used to engage with the resident and their caregiver during the discharge process.

Comment: Most commenters supported strengthening the requirements for the discharge summary and the proposal for facilities to reconcile all pre-discharge medications with residents' post discharge medications and to include this information as part of the discharge summary. The majority of commenters noted that strengthening the discharge summary will help to avoid unnecessary medication, prevent adverse drug interactions, and assist individuals and their caregivers post-discharge. One commenter questioned whether the requirement to reconcile all pre-discharge medications with a residents' post-discharge medication would be

necessary in a LTC facility, given that many individuals are there for long periods of time. The commenter suggested that this requirement would be more appropriate for a hospital. Also, one commenter noted that often ''pre-hospitalization medication'' is often inaccurate or not shared with the facility. Another commenter recommended that facilities include a rationale for all the medications that a resident is receiving in the discharge summary. The commenter notes that pre-discharge medications are often not needed and hospitals do not reconsider the need for continuing medications after discharge or advise the next facility that certain medications could potentially be stopped, reduced, or changed. Similarly, another commenter recommended that the discharge summary should also include the rationale for interventions, not just the diagnosis for interventions that a resident received. The commenter indicated that providing the rationale provides a basis for the diagnosis and not just the conclusion. Another commenter recommended that facilities be required to provide the discharge summary in a written manner that is understandable by the resident.

Response: We appreciate the feedback from commenters and agree that strengthening the discharge summary requirements will lead to better outcomes for residents post-discharge. We note that the discharge summary is intended to be a recapitulation of a resident's stay and final summary of the resident's status. We believe that including a rationale for the medications that a resident is receiving and the services that they received for care would be overly burdensome and unnecessary since this information is included in a resident's medical record and available upon request. In addition, regulations at § 483.10(g) of this final rule discuss the extensive requirements that facilities must meet related to providing residents with information. Specifically, the regulations require the facility to ensure that information is provided to each resident in a form and manner that the resident can access and understand, including in an alternative format or in a language that the resident can understand. These requirements would have to be met by the facility in regards to the discharge summary; therefore we believe the need to provide the discharge summary in a written manner that is understandable by the resident is already covered in the regulations.

We note that while some residents may reside in the facility for lengthy periods, that is not always the case. Our regulations are developed in an effort to address the varying services provided by a LTC facility and the different individuals that may reside in the facility. We have not required facilities to reconcile ''pre-hospitalization medication'' but rather those medications a resident was prescribed prior to being discharged from the facility to those they are prescribed when leaving the facility. We expect that this information is readily available and is maintained as a standard practice by a facility in order to provide sufficient care.

Comment: One commenter indicated discontent with the requirements added by the IMPACT Act, stating that the requirement is problematic and unenforceable. Also the commenter noted that it would not be practical or pertinent to use the data mandated by the IMPACT Act. The commenter noted further that the most pertinent information to provide to residents and families about facilities they are being transferred to should include actual experience with care provided, such as case reviews of individuals sent to the facility. The commenter also questioned whether there could be a conflict of interest in requiring facilities to recommend others. Furthermore, the commenter questioned how facilities should use the data to inform residents and how surveyors should judge whether facilities have done so adequately.

Response: We appreciate the feedback from the commenter and agree that additional information may prove to be valuable to residents and their families for purposes of effectively transitioning from one care setting to another. However, we have proposed the requirements specifically mandated by the IMPACT Act. Facilities have the flexibility to present residents with additional information as long as the statutory requirements are met. Once the requirements of the IMPACT Act are implemented we may consider additional ways to improve the information that residents receive. We expect that facilities will not use the data to recommend facilities, but rather present the data to residents and their families in order to assist them in making an informed decision regarding the selection of a post-acute care provider. We note that the data presented must be based on the individual goals and preferences of the resident. In addition, we expect that facilities will demonstrate compliance with this requirement by showing evidence that the relevant data was presented to a resident and their family for consideration. As with any regulation, this final rule will also have sub-regulatory guidance that provides additional resources for how these requirements can be met by facilities.

Comment: A few commenters questioned whether the IMPACT Act requirements at proposed § 483.21(c)(1)(viii) apply to SNFs only or both Medicare certified SNFs and Medicaid certified NFs. Another commenter recommend that the statement at proposed § 483.21(c)(1), ''transition of the resident from SNF to post-SNF care'', be revised to include NFs also.

Response: The IMPACT Act specifically refers to requirements for SNFs and at this time we are aligning our regulations with the statute. Following the implementation of the IMPACT Act we may consider how these requirements may also be applied to NFs. We note that the all of the requirements in § 483.21(c) apply to both SNFs and NFs with the exception of those requirements related specifically to the IMPACT Act at § 483.21(c)(1)(viii). Therefore, to improve clarity, we have revised the text at § 483.21(c)(1) by removing the reference to ''post-SNF care''. We believe that this revision clarifies that the discharge planning process must focus on all residents.

Comment: One commenter indicated that facilities should be required to assist, if requested, with tasks necessary for relocation, such as making phone calls, packing, and obtaining prescriptions.

Response: As part of the discharge summary, regulations at § 483.21(c)(2)(iv) require that resident's receive a post-discharge plan of care that is developed with the resident, which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the resident plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services. We believe that it would be overly burdensome for facilities to also be required to assist residents with relocation tasks such as packing. In addition, we do not consider packing and other relocation tasks to be ''health services'' within the meaning of the Act and therefore these tasks would not be covered under Medicare and Medicaid.

Comment: One commenter indicated that residents should be provided with copies of their discharge plans and the evaluation of the resident's discharge needs.

Response: Existing regulations provide residents with the right to

obtain copies of their medical records, which would include their discharge plan. Specifically, the regulations at § 483.10(g) discuss the extensive requirements that facilities must meet related to providing residents with information. In this final rule the regulations require facilities to allow the resident to obtain a copy of their medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 working days advance notice to the facility. In addition, while we are not requiring the facility provide the resident with a copy of the discharge plan, existing provisions require the facility to provide the resident with a discharge summary when discharge is anticipated, including the post-discharge plan of care (see § 483.21(c)(2) of this final rule).

Comment: One commenter indicated that § 483.21(c)(2)(iv) should be revised to not limit the additional individuals that may be included in the development of the post-discharge plan of care to just a resident's family. The commenter suggests revising the language to state that a resident's representative or family (as defined by the resident) should be involved.

Response: We have removed the language ''his or her family.'' The text § 483.21(c)(2)(iv) is revised to ''a post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative (s), which will assist the resident to adjust to his or her new living environment.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- At § 483.21(a), we have clarified that the facility must implement the baseline care plan.
- At § 483.21(a)(3), we have added a new requirement that facilities must provide residents and their representatives with a summary of their baseline care plan.
- At § 483.21(b), we have clarified that the facility must implement the comprehensive person-centered care plan.
- At § 483.21(b)(1), we have replaced the word ''timetables'' with ''timeframe.''
- At § 483.21(b)(2)(ii)(E), we have removed the requirement for a social worker to participate on the IDT.
- At § 483.21(c)(1), we have added that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable. We have also removed the reference to ''post-SNF care'' to clarify that the discharge planning process applies to both SNFs and NFs.
- At § 483.21(c)(2)(iv), we have removed the language ''his or her family'' and replaced it with ''the resident representative(s).''

K. Quality of Care and Quality of Life (§ 483.25)

Current regulations at § 483.25 establish requirements for numerous aspects of care and special needs of LTC facility residents under the general heading of ''Quality of Care.'' Quality of Care and Quality of Life are two separate and overarching principles in the delivery of care to residents of LTC facilities. We proposed to comprehensively revise and re-organize the current § 483.25 to ensure person-centered, quality care and quality of life for this vulnerable population.

First, we proposed to retitle this section ''Quality of Care and Quality of Life'' and revise the introductory paragraph to reiterate the requirement that each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

Second, in § 483.25(a), we proposed to address the residents' ability to perform activities of daily living (ADLs) and establish that, based on the comprehensive assessment of a resident and consistent with the resident's needs, choices, and preferences, the facility must provide the necessary care and services to maintain or improve, to the extent practicable, the resident's abilities to perform his or her activities of daily living and to ensure that those abilities do not diminish unless the diminution is unavoidable as a result of the individual's clinical condition. We proposed to divide the requirements of existing § 483.25(a)(1) into proposed § 483.25(a) and (b). We proposed to re-designate existing paragraphs § 483.25(a)(2) and (a)(3) as § 483.25(a)(1) and (a)(2), respectively. We proposed to add a new § 483.25(a)(3) to clarify that a facility must ensure that appropriate personnel provide basic life support, including cardiopulmonary resuscitation (CPR) to a resident requiring this emergency care prior to the arrival of emergency medical personnel and subject to accepted professional guidelines and the resident's advance directives.

In § 483.25(b), we proposed to establish those activities that we include as ADLs. These activities are currently listed in § 483.25(a)(1)(i) through (v). We proposed to update the language of that list, although the underlying activities remain unchanged. We proposed to establish as ADLs: (1) Hygiene, such as bathing, dressing, grooming, and oral care; (2) mobility, which includes transfers and ambulation; (3) toileting and use of the bathroom; (4) dining, including eating meals and snacks; and (5) communication, including speech, language and other functional communication systems.

In § 483.25(c), we proposed to relocate the current requirements related to an activities program as required in existing § 483.15(f). We proposed to revise the language to include a required consideration of the comprehensive assessment, care plan and the preferences of the resident as well as potential for independence and ability to interact with the community.

We also proposed a new § 483.25(d), ''Special Care Issues,'' which we revised, re-located, and added requirements for specific special concerns, including restraints; bed rails; vision and hearing; skin integrity; mobility; incontinence; colostomy, ureterostomy, or ileostomy; assisted nutrition and hydration; parenteral fluids, accidents, respiratory care, prostheses, pain management, dialysis, and trauma-informed care. As many of the concerns in this section were previously included in § 483.25, we discuss here only the provisions we proposed to add or modify.

Specifically, we proposed to re-designate and revise § 483.13(a), ''Restraints,'' as § 483.25(d)(1). In the proposed rule, we indicated that while we prohibit the use of any physical or chemical restraint not required to treat the resident's medical symptoms in the introductory language to proposed § 483.12, in proposed § 483.25(d)(1), we require that the facility ensure that residents are free from restraints that are imposed for purposes of discipline or convenience, in addition to ensuring that residents are free from restraints not required to treat the resident's medical symptoms. In addition, we proposed to add new requirements to specify that, if used, restraints must be the least restrictive alternative for the least amount of time. Further, documentation of ongoing evaluation of the need for the restraints is required.

We proposed a new § 483.25(d)(2) to establish specific requirements when a facility uses bed rails on a resident's bed. Specifically, we proposed to require that the facility ensure correct installation, use and maintenance of bed rails, including attempting to use alternatives prior to installing a side or

bed rail, assessing the resident for risk of entrapment from bed rails prior to installation, reviewing the risks and benefits of bed rails with the resident and obtaining informed consent prior to installation, ensuring that the resident's size and weight are appropriate for the bed's dimensions, and following the manufacturers' recommendations and specifications for installing and maintaining bed rails.

We also proposed to revise existing language at § 483.25(c) and § 483.25(k)(7) and re-designate them under a new § 483.25(d)(4), ''Skin Integrity.'' In this section, we proposed to revise the language to include a statement that care must be consistent with professional standards of practice and to clarify that foot care includes care to prevent complications from the resident's medical conditions such as diabetes, peripheral vascular disease, or immobility, and also includes assistance in making and keeping necessary appointments with qualified healthcare providers such as podiatrists.

In § 483.25(d)(5), we proposed to address mobility both range of motion and other limitations of mobility. We proposed to retain, unchanged, the provisions related to range of motion, but to add a new provision to require that residents with limited mobility receive appropriate services and equipment to maintain or improve mobility unless reduced mobility is unavoidable based on the resident's clinical condition.

In § 483.25(d)(6), we proposed to retain existing provisions on urinary incontinence, add a new § 483.25(d)(5)(B) to address residents who are admitted with an indwelling urinary catheter, and add a new § 483.25(d)(6)(iii) to require that residents with fecal incontinence receive the appropriate treatment and services to restore as much normal bowel function as possible. We proposed to retain, unchanged, colostomy, ureterostomy, and ileostomy care in § 483.25(d)(7). In § 483.25(d)(8), we proposed to modify existing provisions on nasogastric tubes to reflect current clinical practice and to include enteral fluids. Other methods of providing assisted nutrition are now common practice. Therefore, we proposed to include gastrostomy tubes with nasogastric tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy. We also proposed to include in this paragraph requirements regarding both assisted nutrition and hydration and specify that the facility must ensure that the resident maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and protein levels, unless the resident's clinical condition demonstrates that this is not possible and that the resident receives sufficient fluid intake to maintain proper hydration and health. Additionally, we proposed to modify the requirement for a therapeutic diet to require that the resident is offered a therapeutic diet when appropriate, recognizing that the resident has a right to choose to eat a therapeutic diet or not. Finally, we proposed to specify that based on the comprehensive assessment of a resident, the facility must ensure that a resident who has been able to eat enough on his or her own or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and a resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding.

In § 483.25(d)(9), we proposed to address only parenteral fluids. We included enteral fluids in § 483.25(d)(8), our proposed provisions on assisted nutrition and hydration, as discussed earlier.

We proposed to add a new § 483.25(d)(13) to ensure that residents receive necessary and appropriate pain management. We proposed that the facility, based on the resident's comprehensive assessment and choices, must ensure that residents receive treatment and care for pain management in accordance with professional standards of practice.

We also proposed to add a new § 483.25(d)(14) to ensure that residents who require dialysis receive those services in accordance with professional standards of practice and the residents choices.

We further proposed to add a new § 483.25(d)(15) to ensure that trauma survivors, including Holocaust survivors, survivors of abuse, military veterans with post-traumatic stress disorder, and survivors of other trauma receive care that addresses the special needs of trauma survivors. Specifically, we proposed to require that facilities ensure that residents who are trauma survivors receive care and treatment that is trauma-informed, takes into consideration the resident's experiences and preferences in order to avoid triggers that may cause re-traumatization, and meet professional standards of practice.

Finally, we proposed to revise and relocate to § 483.45, ''Pharmacy services'', the provisions related to unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations. These provisions are further discussed later in our section on pharmacy services.

Comment: Some commenters support our proposed changes to § 483.25, particularly requiring facilities to take into account a resident's comprehensive assessment, their preferences and choices in activities program and to provide activities that are designed to encourage independence and interaction in the community; and including oral care as a component of a basic hygiene activity of daily living (ADL). One commenter particularly supports proposed regulatory revisions related to nasogastric tubes and assisted nutrition and hydration and notes the importance of nutritional assessment, nutrition and hydration, and eating assistance to the physical and emotional well-being of residents. The commenter further supports sufficient regulatory flexibility to enable incorporation of new theories and emerging research into practice. One commenter recommended more specificity related to the use of nasogastric tubes. Other commenters support the addition of CPR, oral care, fecal incontinence, foot care, mobility, pain-management and/or trauma informed care.

Response: We thank the commenters for their support. In our proposal, we added requirements that support person-centered care as well as those that support the resident in attaining or maintaining his or her highest practicable well-being.

Comment: Many commenters objected to our restructuring of this section and felt that it was very important that quality of life be recognized in its own regulatory section. One commenter strongly opposed combining Quality of Life and Quality of Care into a single requirement, believing that it would distort and erase the focus on quality of life intended by the Nursing Home Reform Law. One commenter suggested we restore Quality of Life as its own section that includes language from the beginning of proposed rule § 483.11; (treat each resident with respect and dignity, etc.); self-determination language from proposed rule § 483.11(e); social services provisions (proposed rule § 483.40(d)); and safe environment language (proposed rule § 483.11(g), in addition to the language in the proposed rule about activities. One commenter believed that the proposed rules diluted the strength and power of the current quality of care regulations and recommends we keep totally intact the quality of care regulations as a separate

requirement. Another commenter stated that deleting quality of life sends a strong message that quality of life is not essential. Some commenters stated that they are troubled by the fact that CMS has scattered the provisions included in the current Quality of Life section throughout the proposed regulations and the only provision remaining in the proposed Quality of Care and Quality of Life section is proposed § 483.25(c), ''Activities''. These commenters object to, for example, moving requirements about unnecessary drugs to the section on pharmacy services. These commenters recommend that Quality of Life be restored as its own section that includes language from self-determination (proposed § 483.11(e)), social services (proposed § 483.40(d)), and safe environment (proposed § 483.11(g)).

Response: We have retained our proposed restructuring that moves the statements of resident rights previously contained in the Quality of Life section to the Resident rights section, § 483.10. This section now also includes all of the provisions in proposed § 483.11, Facility responsibilities. However, we have separated quality of life and quality of care by establishing a new § 483.24, Quality of life, which will establish quality of life as a separate overarching principle in the delivery of care to residents of LTC facilities. Section 483.24 contains proposed § 483.35(a), (b), and (c), which addresses requirements related to activities of daily living, basic life support, and activities programs. Proposed § 483.25(d), special care issues, is retained in § 483.25, ''Quality of care''. With regard to other specific sections, please also see our discussions at sections N. ''Behavioral health services'' (§ 483.40) and O. ''Pharmacy services'' (§ 483.45) of this preamble.

Comment: Some commenters suggested CMS require additional training topics related to quality of care and quality of life for facility staff. One commenter also recommended that facilities be required to use a standardized care needs assessment tool that the public has an opportunity to comment on prior to adoption. The commenter recommends that this tool should include a specific space for facility staff to document why the loss of functioning was ''demonstrably unavoidable''; and facility should set up an internal review process that reviews this section to determine if more training is needed on conditions that could have been improved or maintained with current standards or assistive technology or mental health services and supports.

Response: Please see our discussion of § 483.95 in section Z. of this preamble for comments and responses related to training, including recommendations for additional training topics.

Comment: A number of commenters felt that CMS should further address staffing. One commenter stated that residents cannot maintain or improve their highest level of well-being without good staffing practices and stated that CMS should reinforce the need for strong staffing practices in the proposed rule. Commenters suggest that good staffing practices include adequate numbers of competent, consistently assigned staff working well with the whole care team. Some commenters suggested mandating consistent or dedicated staffing. One commenter suggested regulatory language requiring staffing practices that maximize competency, continuity, and coordination of care.

Response: Please see section K. ''Nursing services'', for our discussion of staffing.

Comment: Some commenters recommend wording changes to make the language less institutional.

Response: We have reviewed and considered each suggested wording change, but do not address each one individually. Where we felt the wording change improved clarity, we have accepted it. In one case, we added the term ''walking'' in addition to the word ''ambulation'' rather than as a replacement because, while ''walking'' is a less institutional term and therefore may be preferable, ''ambulation'' has other meanings, such as in reference to a resident in a wheelchair, where it means the ability to move around.

Comment: One commenter expresses concerns about ''odd terminology'', stating that CMS gives ''titles'' to activities of daily living (ADLs), proposed § 483.25(b)—for example, ''hygiene'' to refer to bathing, dressing, grooming, and oral care. The commenter stated that the term ''hygiene'' does not provide further explanation of the requirements and interferes with ease of reading and understanding. The commenter further suggests that the new modifiers for activities of daily living are unnecessary and should be deleted.

Response: We believe the titles are useful to group similar activities and have retained them as proposed.

Comment: One commenter stated that moving ''activities'' at proposed § 483.25(b) from ''quality of life'', § 483.15(f), to this new section, with its broader language, is not objectionable, but listing professional credentials in this regulation is odd. The commenter stated that all requirements for staff credentials should be located in a single section and recommended that we retain proposed § 483.25(b)(1), but move proposed § 483.25(b)(2) to a new section addressing staff credentials. Another commenter supported language added to this section regarding an ongoing program to support residents in their choice of activities, both group and individual, and the requirement for a facility to encourage independence and interaction in the community.

Response: We often list credentials for specific staff in the sections that address the care the staff provide. For example, we do this for Food and Nutrition Services, Infection Control, and for certified nursing assistants under Nursing Services. We believe it is appropriate to include the credentials for an Activities Director in the section where the activities program is addressed. However, we will evaluate the suggestion for a single section to address all staff credentials and consider it for future rule-making.

Comment: Many commenters recommended that we add board certified music therapist to the list of qualified professions who could serve as an activities program director. These commenters stated that the educational requirements for a music therapist prepare them to become excellent activities directors. Others suggested that an individual with a Master's degree in gerontology or aging studies, or other degree-based qualifications, be added to the list of qualified professionals who could serve as an activities program director. Some commenters did not want us to change the requirements, fearing that this would eliminate qualified candidates. Some commenters wanted to ensure that we did not change the requirements to specify a specific recognized accrediting body, while others suggested specifying a specific recognized accrediting body. Additional suggestions and options were offered as well.

Response: We thank all the commenters for responding to our solicitation of comments regarding whether the requirements for the director of the activities program remain appropriate and what should serve as minimum requirements for this position. We have reviewed all of the comments and believe we need additional time to further evaluate the many suggestions we received. We are not making any changes at this time.

Comment: A commenter felt that the section on ADLs needed an introductory statement as to the expectations for the facility related to the ADL list.

Response: We have added introductory language to state that the

facility must provide care and services in accordance with paragraph (a) for the listed activities of daily living

Comment: One commenter stated that in proposed § 483.25(d) CMS has gathered an odd collection of care concerns and labeled them as ''special care issues,'' some of which are issues common to most residents while other issues are truly ''special,'' in the sense of less common. The commenter recommends that care requirements common to all or most residents should be separately identified, without the modifier of ''special care needs'' and the term ''special care issues'' should be restricted to issues that are truly special, in the sense of uncommon. The commenter suggests that the subsections under the ''Quality of Care'' requirement should be retained in the order that they are in current § 483.25 and language in proposed § 483.25(a) should be incorporated into the preliminary language of the regulation so that the current order can be retained.

Response: In order to more clearly express our intention, we have eliminated the modifier ''special care needs'' and revised this section in consideration of this and other comments.

Comment: Some commenters felt that CMS should provide more information/clarification related to colostomy, ureteostomy, or ilesostomy; parenteral fluids; prosthesis; pain management; and dialysis. In addition, two commenters stated that ''urostomy'' is the correct terminology and should be used instead of ureterostomy.

Response: We thank the commenter for their suggestion. We have changed ''ureterostomy'' to ''urostomy.'' We have also added language to final sections (f) ''Colostomy, urostomy, or ileostomy care,'' (h) ''Parenteral fluids,'' (j) ''Prostheses,'' (k) ''Pain management,'' and (l) ''Dialysis.'' For each section, we have specified that care must be provided consistent with professional standards of practice applicable to that care. We defer to sub-regulatory guidance for additional detailed discussion.

Comment: Some commenter suggested CMS add other documents besides advance directives to the requirements relating to providing basic life support.

Response: We have added related physician orders to paragraph (a)(3). We defer to sub-regulatory guidance for additional discussion.

Comment: One commenter requested that CMS clarify that, where CMS proposes that a resident receive care that is consistent with professional standards of practice, a standard of care that is ''consistent with professional standards of practice'' is not to be interpreted as a maximum standard or to limit care options for residents with complex conditions or unique needs. The commenter urged CMS to clarify that when providing care that is consistent with professional standards of practice, the care also take into account individual residents' needs and complexity of individual residents' conditions.

Response: The requirement that that care be provided in accordance with professional standards of practice is neither a maximum standard nor a limitation on care options. We would expect the resident and/or his or her representative to be informed about care and treatment as required by § 483.10(c), as contained in the comprehensive care plan. The care and services provided to the resident must be provided in a manner that meets the professional standards and principles that apply to such care and services and to the professionals that provide those services.

Comment: One commenter stated that some provisions are already incorporated into the current survey process and can be implemented one year following adoption of the final rule, including proposed § 483.25(a)(3), and (d)(13).

Response: We deliberately included a number of provisions in the regulations that were previously in sub-regulatory guidance as we felt that doing so strengthens the requirements for some very important issues. Please refer to our discussion in Section B, Implementation, for additional information.

Comment: Some commenters expressed concern that facilities would have to hire additional staff in order to meet proposed requirements that residents be assisted to make appointments and to arrange for transportation to appointments.

Response: While we have revised and reorganized this section, the requirement to provide residents with assistance in making appointments and arranging transportation is an existing obligation. Similarly, while prior regulations did not explicitly require that facilities assist individuals to make podiatric appointments, facilities were already required to ensure that residents received proper treatment and foot care. Furthermore, we understand that some facilities have arrangements to provide these services on site, providing added comfort and convenience for residents while negating the need for at least some work to make transportation arrangements. We do not agree that our revised requirements impose a significant new burden.

Comment: Several commenters commented on our proposed requirements regarding bed rails. One commenter stated that proposed § 483.25(d)(2), as written, declares that the existence of a side or bed rail is a deficient practice and recommends we amend the provision to read ''engaging'' a side or bed rail rather than ''installing'' a side or bed rail. The commenter stated that deficient practice is reflected by not implementing/attempting alternatives prior to the use or engagement of a side or bed rails. Another commenter was concerned that this provision lacks adequate qualifiers to all for various real-life situations and puts the facility in violation of the requirement when no viable alternative exists and suggests specific revisions to the regulatory language. Other commenters recommended extensive provisions addressing bed rails as restraints and the criteria to use bed rails when not used as a restraints. Some commenters objected to our including requirements related to bed rails. One stated that there was no clinically justifiable reason to use bed rails. Others stated that few LTC facilities use bed rails. Other commenters stated that some beds have quarter rails to house the bed and TV controls and it would be burdensome to take these on and off as residents are admitted and discharged. Many commenters supported the requirement that facilities try alternatives to bed rails.

Response: We thank the commenters for their suggestions and support. Proposed paragraph (2) sets out several requirements to be met before the bed or side rail is installed. We believe these requirements are important for resident safety before installation can create an expectation of use. We have re-designated this as paragraph (n) and, based on a combination of commenter suggestions, revised it to require that the facility must attempt to use appropriate alternatives prior to installing a side or bed rail, then to require that if a side or be rail is used, such use must meet specific requirements. In addition, we have reworded the provision so that the bed's dimension is appropriate for the resident's size and weight rather than the resident's size and weight being consistent with the bed's dimension, as recommended by a commenter. We defer additional discussion to sub-regulatory guidance. We expect that surveyors will conduct a fair and consistent review of these situations based on the facts of each case.

Comment: One commenter objected to the addition to proposed § 483.25(d)(8)(i) of ''or resident preferences indicated otherwise'' and recommended we delete it. The commenter was concerned that a facility could use this as a means to not meet a resident's nutritional needs. The commenter stated that the facility would need to demonstrate that it served nutritious and appetizing food; identified the resident's food preferences; offered appropriate alternative foods to the resident; had sufficient numbers of trained staff to assist the resident in eating; maintained a pleasant environment for meals; provided assistive devices, as needed; addressed the resident's mental health needs; had received a medical determination from the resident's physician that the resident's medical condition indicated that weight loss was unavoidable; and took other necessary steps before it could justify not meeting a resident's nutritional needs.

Response: This provision addresses assisted nutrition and hydration, and, like all treatments, residents have the right to accept or refuse. Accepting a resident's refusal, or deferring to their documented preferences, does not absolve a facility of its responsibilities to provide adequate nutrition or permit the facility not to meet a resident's nutritional needs. It does recognize that a competent resident has the right to make choices about assisted nutrition and hydration and that there are circumstances where failure to maintain acceptable parameters of nutritional status are not a reflection of failure(s) of care.

Comment: Several commenters supported our proposal to add trauma-informed care at § 483.25(d)(15). Some commenters suggested additional related requirements, including adopting trauma informed care approaches, and requiring facilities to provide training regarding trauma informed care to all staff at all levels. Some commenters recommended deleting this provision entirely. One commenter stated that providing ''trauma-informed care'' is prudent and extremely important for those individuals who have experienced trauma in their lives and continue to live with residual effects from these experiences, but had several concerns about the requirement. The commenter noted that the link to the SAMHSA guidance does not work, and furthermore, SAMHSA's mission is focused on recovery and resilience. In addition, the reference to utilizing ''professional standards of care'' does not provide specific professional standards of care for individuals who are trauma survivors. Without specific identification of recognized and acceptable standards, determining compliance with this requirement will be varied and subjective. Furthermore, there was no clear definition provided for the term ''culturally competent care.'' Another commenter stated that there are other issues and concerns that are equally or more important to other individuals with other conditions that are not specified in regulation or mentioned in guidance.

Response: Culturally-competent and trauma-informed care are approaches that help to minimize triggers and re-traumatization, including care that addresses the unique needs of Holocaust survivors and survivors of war, disasters, and other profound trauma are an important aspect of person-centered care for these individuals. We noted in the proposed rule that person-centered care that reflects the principles set forth in SAMSHA's Concept of Trauma and Guidance for a Trauma-Informed Approach, HHS Publication No. (SMA) 14–4884, available at *http://store.samhsa.gov/shin/content/SMA14-4884/SMA14-4884.pdf*, would help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life. We were able to access this document via the link provided; alternatively, it is available through the SAMSHA.gov Web site by clicking on ''publications'' on the upper right and searching for SMA 14–4884. As discussed in our comments and responses section H, ''Comprehensive Care Planning,'' we do not believe that a definition of trauma-informed care should be added to the ''Definitions'' section, but note that the interpretative guidelines and the resource noted previously will provide further information regarding culturally-competent and trauma-informed care. In addition, as with all of our requirements, surveyors will use uniform sub regulatory guidance and surveyor training will be provided to promote consistent enforcement. Please see our discussion of trauma-informed care in section J. ''Comprehensive care planning.'' We note in the comments and response for that section that one commenter provided resources for facilities to refer to for information and material addressing culturally competent and trauma-informed care. The resources include The Council on Social Work Education (see *http://www.cswe.org*), NASW's standards and indicators for cultural competence available at *http://www.socialworkers.org/practice/standards/index.asp*, and The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care developed by the Office of Minority Health in HHS (see *https://www.thinkculturalhealth.hhs.gov/index.asp*).

Comment: One commenter recommended we amend the requirement to provide trauma-informed care, § 483.25(d)(15), to say ''When a facility is aware that a resident/patient is a trauma survivor, the facility must ensure these residents/patients receive care that takes into account the residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.''

Response: We do not agree with adding the qualifier ''when a facility is aware'' nor do we agree with deleting reference to culturally competent, trauma-informed care in accordance with professional standards of practice. Please see our earlier discussion in this section as well as the discussion in section J, ''Comprehensive Care Planning.''

Comment: One commenter suggested that any requirements related to trauma-informed care have a 5-year phase in period.

Response: Please see our discussion of implementation deadlines in section II.B, ''Implementation.''

Comment: One commenter stated that the current regulation, at § 483.25(c)(1), begins with the statement that the resident who enters the facility without pressure ulcers should not develop them unless the resident's clinical condition demonstrated that they were unavoidable, but the proposed § 483.25(d)(4)(i)(A) omits that language entirely, beginning with the requirement that the facility provide care to prevent development of pressure ulcers. The commenter stated that current language should be restored as a new (A) with the proposed subsections (A) and (B) moved to (B) and (C), respectively.

Response: The commenter is correct that the proposed language omits the statement ''the resident who enters the facility without a pressure ulcer.'' The remaining language is included in the proposed provision. Any resident at any time who does not have a pressure ulcer, even if the resident had one upon admission and it has resolved, must receive care and services to prevent the formation of pressure ulcers unless the resident's clinical condition demonstrates that the development of pressure ulcers was unavoidable. Similarly, any resident who has a

pressure ulcer, no matter when or why it developed, must receive care and services to promote healing, prevent infection, and prevent new ulcers from developing.

Comment: One commenter stated that proposed paragraph (d)(5) mobility should be correctly title ''range of motion'' as in the current rule.

Response: We disagree. Range of motion, defined as the full movement potential of a joint, is important to mobility, but it does not encompass the full extent of the proposed provision. Proposed paragraph (d)(5) includes in (i) and (ii) requirements to ensure that a resident does not lose range of motion and, if the resident has a limited range of motion, receives services to, at a minimum, maintain existing range of motion and, if feasible, to improve range of motion. The proposed provision goes on to address mobility, defined as the ability to move, and to require that residents with limited mobility receive appropriate services to maintain or improve his or her mobility. Each of the three provisions is about a resident's ability to move, thus we have included them together is a provision about mobility.

Comment: A number of commenters expressed concern about our provisions related to the use of restraints in facilities. One commenter stated that although new language about using the least restrictive alternative for the least amount of time and documenting ongoing evaluation of the need for the physical and chemical restraints was helpful, the proposed regulation does not adequately protect residents. Several commenters suggested a separate section specifically addressing restraints. Some commenters recommended additional requirements such as reporting any death which may have resulted from the use of a restraint; an environmental assessment; an in-person evaluation by a physician; informed consent; an in-person evaluation by the resident's physician; one-on-one monitoring; or release and monitoring when the use of restraints is indicated. Some commenters noted that there are more extensive requirements for other provider types (community mental health centers, hospitals). Some commenters requested that we explicitly include bed rails as restraints and strengthen our provisions related to bed rails. Some commenters suggested we only allow the use of bed rails if the resident requests them for mobility or other assistance and any time a bed rail is considered, a safety assessment be conducted using protocols that require an evaluation of residents and bed systems by an interdisciplinary team that includes specific professional staff. Some commenters requested that regulations more explicitly address chemical restraints and that we specifically address the use of wheelchairs as a restraint. One commenter suggested we relocate requirements related to restraints and bed rails to the section on facility responsibilities because inclusion here could imply they were a special treatment or care. The commenter also recommended addressing bed rails as restraints because not doing so implies that bed rails are not restraints. One commenter stated that restraint should be a requirement separate from quality of care because restraints are not an appropriate method for providing care. Other commenters discuss restraints in the context of trauma-informed care.

Response: We acknowledge the commenter's concern that including restraints in this section could create an impression that the use of restraints is acceptable. We have relocated this provision to § 483.12(a) and added a cross reference to § 483.12(a)(2) in § 483.10(e)(1) to ensure that the resident's right to be free of restraints is considered in the context of the requirement now in § 483.12(a)(2). We will continue to review our provisions related to restraints and will consider adding additional, more prescriptive requirements through future notice and comment rule-making.

We considered similarly relocating our provision regarding bed rails, but do not believe that these requirements as clearly belong in § 483.12. Therefore, we have retained this provision as § 483.25(n).

Comment: One commenter suggested we retain assisted nutrition and hydration, prostheses, dialysis, and trauma-informed care as special care issues and move the rest of the issues to another part of the section.

Response: We thank the commenter for their suggestion. We have modified this section based on other comments, however, believe it is appropriate to retain all of the proposed requirements in the section.

Comment: One commenter recommended adding a separate section on honoring sleep.

Response: We thank the commenter for their suggestion. We currently address sleep and wake times at § 483.10(f)(1). We defer additional discussion to sub-regulatory guidance.

Comment: Commenters supported the added specificity of proposed requirements regarding skin integrity, foot care, incontinence, and enteral feeding.

Response: We thank the commenter for their support. We believe the proposed additions will assist in ensuring that LTC facility residents receive necessary care.

Comment: One commenter suggested that in proposed paragraph (d)(4) we clarify that the standard is professional current clinical standards of practice.

Response: We do not agree that this clarification is necessary. The statement ''professional standards of practice'' applies whether or not the issue is clinical, as in direct care delivery, or non-clinical, such as some administrative or physical plant concerns might be considered. In addition, ''professional standards of practice'' inherently means the professional standards that apply at the time that the care or service is delivered.

Comment: Some commenters supported our proposed provision (d)(6) regarding incontinence. One commenter stated that the urinary tract includes more than just the bladder (that is, kidneys, ureters, urethra, prostate) and that various conditions and factors (for example, delirium, metabolic disorders, functional impairments, diuretic use) may affect continence. The commenter suggested that proposed (d)(6)(ii)(C) be revised to more accurately reflect that the goal is to try to improve continence by stating that the resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible. Another commenter suggested we require that if a resident becomes incontinent, a determination regarding why be made. A different commenter recommended requiring that a resident's bathroom needs be anticipated and met to reduce the development of incontinence on because the resident did not get the help she or he needed to get to the bathroom on time.

Response: We thank the commenters for their suggestions. We have modified proposed § 483.25(d)(6)(ii)(C), finalized at paragraph § 483.25(e)(2)(iii), to focus on continence as suggested. We require that a resident who is continent of bladder receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain. We believe that in order to meet this requirement, both assistance to use the bathroom to prevent incontinence in a continent resident and an assessment of the cause of new incontinence would be necessary. We defer additional discussion to interpretive guidance.

Comment: One commenter noted that nutrition status is complex and

recommended revising paragraph (d)(8) to include total parenteral nutrition, to eliminate protein levels as a parameter of nutritional status based on recent research, to add electrolyte balance as a co-equal concern to hydration, and to add the qualifier ''unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise.'' The commenter stated that serum protein levels have significant limitations as a parameter of nutritional status and should not be listed as a measure. The commenter further stated that hydration maintenance is about more than just providing fluids, and should consider electrolyte balance as well and that some dehydration is unavoidable such as occurs with residents on palliative care who are not eating and drinking. Another commenter stated that this proposed provision inappropriately combines two existing sections, mislabeling them, and minimizing the critical importance of nutrition and hydration for residents. The commenter stated that CMS should restore the original two separate regulatory requirements.

Response: We thank the commenters for their suggestions and agree that nutrition status is complex. We have eliminated the requirement for protein levels and added electrolyte balance. We believe it is appropriate to address parenteral fluids separately, as this involves the intravenous infusion of fluids. We also believe the requirements, as proposed, acknowledge the potential for unavoidable variations and recognize the resident's right to refuse treatment. We defer any additional discussion to sub-regulatory guidance. We disagree that nutrition and hydration should be two separate sections. Fluids are a source of nutrition and food is a source of hydration.

Comment: One commenter stated that the proposed change in § 483.25(j) from providing sufficient fluids to offering sufficient fluids is objectionable.

Response: This change was proposed in response to anecdotal accounts of fluids being placed in a resident room without ensuring that the resident was actually able to drink them. While residents' have the right to refuse to drink the fluids, it is not enough for a facility to simply place fluids in a resident room. We would expect that the fluids actually be offered to the resident and assistance provided so that the resident can drink, if they so desire.

Comment: One commenter recommended that proposed § 483.25(c) be amended to read: ''Based on the comprehensive assessment and care plan and the preferences of each resident, the home/community must provide ongoing opportunities for engagement with life or meaningful engagement via group, individual and independent opportunities designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.'' This change in language would remind everyone that individual resident preferences for engagement in meaningful ways should be identified and followed.

Response: We agree and thank the commenter for their support. We have incorporated the commenter's suggestion and are finalizing this provision at § 483.24(c)(1).

Comment: One commenter suggested addressing the use of personal bed, chair, floor mat and laser alarms as devices with restraint qualities.

Response: We discuss alarms in section E of this preamble. As noted there, if such devices are used as restraints, their use must comply with our requirements related to restraints.

Comment: One commenter requested that we clarify that a new intervention is not required after each fall or incident, but that a root cause analysis should be conducted.

Response: We agree that the response to a fall or incident should be episode specific, that a new intervention may not always be necessary, and that frequently a root cause analysis will be necessary. We defer to sub-regulatory guidance for additional discussion.

Comment: One commenter supported our proposed change that a resident be offered a therapeutic diet instead of mandating a therapeutic diet.

Response: We thank the commenter for their support and note that this change is consistent with our person-centered approach.

Comment: Some commenters suggested that CMS address wheelchair use, including need, premature use, a plan of care for maintaining strength and mobility, and other concerns.

Response: We thank the commenter for these suggestions. We believe that these issues should be addressed in the person-centered plan of care. However, we will further evaluate these concerns and consider them for inclusion in future notice and comment rule-making.

Comment: Some commenters requested that we add a new section to special care issue to address dementia care. Others suggested that requirements for dementia care be added to the quality of care requirements. Commenters offered suggestions for such a section, including current language from sub-regulatory guidance.

Response: We thank the commenters for these suggestions. We considered, but did not propose dementia-specific provisions for this rule. We agree that residents with dementia have specific needs as a result of their disease. Resident rights, person-centered care planning, and other provisions of this subpart work together to require that the individual's needs be met. Even among residents who have this diagnosis in common, needs may differ significantly. Residents with different diagnoses may benefit from similar care. We expect all residents to receive care to meet their needs, based on a comprehensive, person-centered care plan that reflects the resident's needs, goals, and preferences. We believe that the person-centered approach to care reflected throughout these regulations will best serve individual residents based on individualized diagnosis and needs. We will continue to evaluate this issue and may consider it for inclusion in future notice and comment rule-making.

Comment: One commenter discussed the importance of a culture of safety and recommended that we incorporate a new section to address worker and resident safety issues, including safe resident handling and lifting, hazard protections, workplace violence, and other safety issues.

Response: We thank the commenter for their suggestions. A culture of safety and worker safety are important issues. However, many of the suggestions provided are outside the scope of this regulation and many are already regulated by the Occupational Safety and Health Administration. Moreover, our statutory authority is limited to regulations that protect the health and safety of residents; we hope that our rules also protect the safety and well-being of staff and employees, but such results cannot be the basis for our authority. We will continue to evaluate the best way to identify and incorporate those elements that may be appropriate for incorporation into requirements for participation and consider them in future rule-making.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have established § 483.24, Quality of life, which contains proposed § 483.35(a), (b), and (c) re-designated as § 483.24(a), (b), and (c), respectively, and revised the introductory language to clarify that quality of life applies to all care and services provided to facility residents.
- We have added an introductory statement to new paragraph § 483.24(b).

• We have added the word ''walking'' in addition to ''ambulation'' at § 483.24(b)(2).

• We have revised the title of § 483.25 to read ''Quality of care,'' eliminated the modifier ''special care issues,'' revised the introductory language to clarify that quality of care applies to all care and services provided by the facility, and re-designated § 483.25(d)(3) through (15) as § 483.25(a) through (m), respectively.

• We have added ''related physician orders'' to paragraph § 483.24(a)(3) regarding the provision of basic life support.

• In § 483.25, we removed (d)(1) relating to restraints and relocated it at § 483.12(a)(2).

• We have re-designated proposed § 483.25(d)(2) Bed rails as paragraph § 483.25(n), added an appropriateness qualifier to the regulatory text and reworded the provision about the bed's dimension for clarity.

• We have re-designated § 483.25(d)(6)(ii)(C) as § 483.25(e)(2)(iii) and revised it to state ''restore continence to the extent possible.''

• We have added language to § 483.25(f), (h), (i), (j), (k), and (l) to require that care be provided consistent with professional standards of practice applicable to that care as well as the comprehensive person-centered care plan, and the residents' goals and preferences.

• In § 483.25(g)(1), we have eliminated the reference to protein levels as a nutritional parameter and add reference to electrolyte balance.

L. Physician Services (§ 483.30)

Under the reorganization discussed earlier, requirements regarding physician services currently located at § 483.40 were proposed to be moved to new § 483.30. We proposed to retain the current requirements but proposed a few additions as discussed below.

We proposed to revise the introductory text of § 483.30 to specify that, in addition to a physician's recommendation that the individual be admitted to a facility, a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must provide orders for the resident's immediate care and needs.

We also proposed to add a new § 483.30(e) to require that a facility, prior to an unscheduled transfer of a resident to a hospital, provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital, unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer.

At § 483.30(f)(2), we proposed to provide the physician with the flexibility to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, to the extent the dietitian or other clinically qualified nutrition professional is permitted to do so under state law.

Similarly, at § 483.30(f)(3), we proposed to provide the physician with the flexibility to delegate to a qualified therapist under proposed § 483.65 below the task of writing therapy orders, to the extent that the therapist is permitted to do so under state law.

Comment: We received a comment in support of our revision to the introductory language to § 483.30 allowing a physician, physician assistant, nurse practitioner, or clinical nurse specialist to write orders for a resident's immediate care and needs upon admission. The commenter stated that they believed this would help ensure more immediate access to care.

Response: We thank the commenter for his support. We understand that the time period around a transition of care, including admission to a facility, can pose added risk. We expect that this provision will help ensure that the resident receives care for his or her specific needs until a comprehensive assessment and care planning can be completed.

Comment: We received a significant number of comments on our proposal to add a new § 483.30(e) to require that a facility, prior to an unscheduled transfer of a resident to a hospital, provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital, unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer. Although a few commenters supported the proposal, the majority disagreed with the proposal, for a variety of reasons. The comments reflected significant concern about the burden this requirement would place on facilities, particularly small and rural facilities. Some commenters were concerned about added expense and suggested this requirement could not be implemented without payment reform. Beyond the cost issue, many facilities were concerned about the impact this requirement would have on their ability to recruit physicians, NPs, PAs, and CNS's to fill this role. In particular, rural facilities suggested that this requirement could not be met in areas where there are professional shortages. Further, some commenters suggested that this requirement would drive practitioners of all types away from working in LTC facilities and would ultimately result in reduced access and reduced quality of care and safety for residents.

In addition, some commenters felt that this proposal would result in delayed access to care, resulting in harm to patients. Some commenters also felt that this requirement could conflict with resident rights, specifically, the resident's or resident representative's right to request such a transfer. One commenter stated that, in many circumstances, a practitioner can make an adequate assessment over the phone and that CMS had shown no reason to adopt this requirement, and facilities already have incentives to avoid unnecessary hospital transfers. Many commenters asked what was wrong with the current system of the nurse and physician speaking about the plan of care over the phone, stating that this is sufficient. Finally, some commenters stated that this proposal failed to recognize an appropriate role for registered nurses, in coordination with a practitioner. Commenters suggested we allow this requirement to be completed through a telehealth mechanism or using registered nurses.

Response: The intent of this provision was to encourage the identification of opportunities to treat residents in their facilities, reducing the risks associated with the transfer to a hospital. In August of 2012, CMS launched ''The Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents'' (see *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/InitiativetoReduceAvoidableHospitalizations/AvoidableHospitalizationsamongNursingFacilityResidents.html*). This effort aims to improve the quality of care for people residing in nursing facilities by reducing avoidable hospitalizations. Under the initiative, CMS supports enhanced care & coordination provider organizations that each partner with a group of nursing facilities to implement evidence-based clinical and educational interventions that both improve care and lower costs. The initiative is focused on long-stay nursing facility residents who are enrolled in both the Medicare and Medicaid programs, with the goal of reducing potentially avoidable inpatient hospitalizations. CMS announced a second phase of ''The Initiative to Reduce Avoidable

Hospitalizations among Nursing Facility Residents'' on August 27, 2015. Under the new phase, a new funding opportunity will allow the organizations currently participating in the initiative to apply to test whether a new payment model for nursing facilities and practitioners, together with the clinical and educational interventions in place under the current initiative, will improve quality of care by reducing avoidable hospitalizations while also lowering combined Medicare and Medicaid spending (see *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/InitiativetoReduceAvoidableHospitalizations/AvoidableHospitalizationsamongNursingFacilityResidents.html*). After consideration of the comments and pending the outcome of the second phase of the initiative discussed above as well as in order to allow further time to evaluate suggested alternatives, we have decided not to finalize this requirement at this time. Therefore, we are withdrawing proposed § 483.30(e) as well as our proposal to redesignate paragraphs (e) and (f) as (f) and (g).

Comment: A commenter noted that existing § 483.40(f) states that at the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician. We proposed to re-designate existing § 483.40(f) as § 483.30(g). The commenter recommended that we remove the phrase ''who is not an employee of the facility but'' from the language in § 483.30(g). Another commenter noted that the provision creates a difference between SNFs and NFs and suggests that the requirement should apply to both SNFs and NFs.

Response: We proposed to re-designate § 483.40(f) as § 483.30(g) but did not propose any changes to the language contained in the current requirement. Therefore, we cannot make any changes at this time, but will evaluate these comments and consider them for future regulatory proposals. Section 1919(b)(6) of the Act permits States to give NFs the discretion to allow a nurse practitioner, clinical nurse specialist, or physician assistant who is ''not an employee of the facility'' but working in collaboration with a physician to supervise the provision of healthcare at an NF. We do not have the authority to modify this.

Comment: We received comments in support of our proposal to allow physicians to delegate the authority to write dietary orders to dietitians acting within their scope of practice under state law and under the supervision of the physician. One commenter noted that these professionals may actually know the resident better than the attending physician. Another stated that this would allow better use of professional's time. One commenter suggested that this authority should be limited to the attending physician or his or her designee. Another suggested that a physician, physician assistant, nurse practitioner, or clinical nurse practitioner should be able to make this delegation.

Response: We appreciate comments in support of this proposal. We agree that it would be appropriate to limit this authority to the attending physician, as that individual retains primary responsibility for the care of the resident. We have modified the regulatory text at proposed § 483.30(f)(2) and § 483.30(f)(3) accordingly and finalize these provisions at § 483.30(e)(2) and § 483.30(e)(3).

Comment: We received comments objecting to our proposal to allow physicians to delegate writing orders to qualified dietitians or other clinically qualified nutrition professionals and to qualified therapists for diets and therapy, respectively. One commenter felt that these proposals were focused on reimbursement concerns or amounted to condoning violation of current regulations. The commenter goes on to state that CMS should not authorize the physician to shift all authority to the therapist and that this would exacerbate the abuse of therapy. Another commenter suggested that such orders could be written without adequate consideration of the whole picture.

Response: Our proposal is intended to improve responsiveness to a resident's needs and is implemented at the discretion of the physician. It does not allow a physician to shift all authority to either a dietitian or a therapist, as the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician. Nothing in this provision would permit ordering of inappropriate or excessive therapy. As professionals acting within their scope of practice and having more frequent direct contact with and observation of the resident, therapists may be able to be more responsive to a resident's needs and to changes in a resident's condition. This could actually reduce the amount of inappropriate therapy. Furthermore, as noted above, the resident's care remains under the supervision of the physician. As one commenter noted, our proposal provides for both oversight and accountability. Finally, based on other comments, we have modified this proposal to limit this authority to the attending physician who is responsible for the care of the resident and who should be aware of the full spectrum of issues and concerns regarding the resident.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have withdrawn proposed § 483.30(e).
- We have removed our proposal to redesignate paragraphs (e) and (f) as paragraphs (f) and (g).
- We have modified the regulatory text at § 483.30(e)(2) and § 483.30(e)(3), respectively, to specify that it is the attending physician who has the authority to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders, to the extent that these professionals are permitted to perform these tasks under state law.

M. Nursing Services (§ 483.35)

Under the proposed reorganization, requirements for nursing services currently located at § 483.30 were proposed to be relocated to § 483.35. The current regulations at § 483.30 address certain aspects of LTC facility staffing but leave gaps related to a number of areas such as the competencies of licensed nurses and the need to take into account resident acuity.

We proposed a competency-based staffing approach that requires the facility to evaluate its population and its resources in accordance with § 483.70(e), including the number and acuity of the residents, the range of diagnoses and resident needs and the training, experience, and skill sets of staff, and base staffing plans and assignments on these assessments. In § 483.35, we proposed to clarify that the facility must take into account its assessment of all residents as well as the skill-sets of individual staff when making staffing decisions. We also proposed revisions to improve the logical order and readability of these regulatory provisions. In the proposed rule, we included a robust discussion regarding the long-standing interest in increasing the required hours of nurse staffing per day and the various

literature surrounding the issue of minimum nurse staffing standard in LTC facilities (See 80 FR 42199). We refer readers to the proposed rule for this background information.

We proposed to clarify at § 483.35(a)(1)(ii) that NAs are included in the term ''other nursing personnel.'' We proposed to add § 483.35(a)(3) and (4) to specify that the facility ensure that licensed nurses have the competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and as described in each resident's individual plan of care. We further proposed to specify that caring for a resident's needs would include but not be limited to assessing, evaluating, planning and implementing resident care plans and responding to each resident's needs.

Consistent with our clarification that NAs are included in the term ''other nursing personnel,'' we proposed to move most of the provisions relating to NAs previously located in § 483.75 to proposed § 483.35. Specifically, we proposed to re-designate § 483.75(f) ''Proficiency of Nurse Aides'' as § 483.35(c). We proposed to re-designate § 483.75(e) as § 483.35(d) and re-title the provision as ''Requirements for facility hiring and use of nursing aides'' to reflect its contents more accurately. We proposed to re-designate the regulations at § 483.75(e) to § 483.35(d)(2) and address non-permanent employees. Non-permanent caregivers are expected to meet competency, knowledge and skill requirements to the same extent as permanent personnel. We also proposed to add the term ''minimum'' to § 483.35(c)(3) to clarify that this paragraph identifies the minimum requirements for hiring a nurse aide.

Comment: Some commenters agreed that CMS should not impose mandatory staffing ratios, including the requirement for a 24/7 registered nurse on the premises. These commenters acknowledged the importance of staffing levels but did not feel that such mandates were the best way to clarify ''sufficient'' and felt that mandatory staffing ratios are not supported by empirical evidence. Some commenters felt that current oversight of staffing was already burdensome. A number of commenters stated that it was often a daily struggle to ensure that the appropriate number and level of staff was available while striving to maintain quality of care and that our proposed requirements would only makes that struggle more difficult.

Response: We thank these commenters. We concur that staffing is important. We continue to be concerned that a mandated ratio could result in unintended consequences, such as staffing to the minimum, input substitution (hiring for one position by eliminating another), and task diversion (assigning non-standard tasks to a position), as well as stifling innovation, and would not result in the improved quality and person-centered care that we seek in facilities. However, we continue to believe that our proposed requirement is necessary to address concerns about inadequate staffing and resulting harm to residents.

Comment: Some commenters supported CMS's proposed competency-based staffing approach, but felt that it should be in addition to minimum staffing standards. One commenter noted that minimum staffing levels and a competency-based approach are not necessarily mutually exclusive. For example, a facility may meet minimum staffing levels and further increase its staffing based on the results of the facility assessment referenced below. This commenter urged CMS to give further serious consideration to these issues. One commenter stated that they recognize the many diverse skills nurses need and the responsibility to have nursing staff with demonstrated competency to care for residents. Their skills need to match resident needs and the scope of services they are expected to provide.

Response: We thank these commenters. We did re-consider our approach, but, ultimately, returned to our original proposal. We agree that staff competency, in addition to sufficient numbers of staff, is critical to quality of care and resident safety. We continue to have concerns about establishing appropriate minimum standards as well as concerns that facilities will justify staffing to the minimum standard even when more are required in the context of a competency based approach. We further address comments regarding minimum staffing ratios below.

Comment: Many commenters stated that CMS needs to establish and require minimum staffing levels and require a registered nurse to be in the LTC facility 24 hours a day, 7 days a week. One commenter stated that CMS is fully aware that facilities are understaffed and that understaffing harms and kills residents and that CMS must do more to strengthen nurse staffing requirements. The commenter further stated that CMS's assertion that it needs more accurate payroll-based staffing data is disingenuous and that CMS's refusal to set nurse staffing ratios and, as the Institute of Medicine recommended in in 1996 and again in 2001, to require a registered nurse 24 hours per day, seven days a week will mean that many residents will continue to receive inadequate, life-threatening care. Other commenters reviewed the literature supporting the need for and value of increasing staffing and RN presence. Several commenters provided examples of instances where insufficient staffing resulted in harm or where sufficient staffing prevented harm. Several commenters provided information on the fiscal impact of insufficient staffing and the cost savings associated with sufficient staffing. One commenter provided information on the changing nature of the LTC facility industry and the advent of for-profit LTC facilities, the purchase of LTC facilities by private equity firms, and the move towards Medicaid managed long-term services and support, all of which create incentives to staff at the lowest possible levels.

Several commenters specifically advocated for CMS to require a 24-hour registered nurse (RN) in every facility. One commenter stated that the current Requirements of Participation only mandate that facilities use a RN 8 continuous hours each day, 7 days a week. These 8 hours would not have to be spent providing care; they could be used to carry out any type of administrative tasks. Registered nurses by training and licensure have skills that are essential for timely assessment, intervention and treatment. The commenter noted that three Institute of Medicine studies have recommended that at least one RN be on duty at all times. They state that 24-hour RN coverage is essential because the acuity level of LTC facility residents has increased dramatically since the federal law was passed and expert nursing skills are required to anticipate, identify and respond to changes in condition; ensure appropriate rehabilitation, and maximize the chances for a safe and timely discharge home. In addition, a resident's condition can destabilize or deteriorate at any time. When that occurs, the individual must be immediately assessed and a determination made about whether the resident needs to go to the hospital for treatment or whether he or she can be properly cared for in the LTC facility. Because physicians do not have to be on-site, registered nurses are often the only medical personnel in a LTC facility with the education and licensure to conduct the assessment required. The commenter noted that substantial evidence that RN staffing is a key element for safe and effective resident care in U.S. LTC facilities has grown substantially over the last 2 decades, typically using quality measures or

deficient practice from the CMS survey data and that higher levels of RN time are associated with positive outcomes, such as reduced unnecessary hospitalizations, lower antipsychotic use and other improved outcome measures (pressure ulcers, restraint use, cognitive decline; reduced incidences of catheterizations, urinary tract infections, and antibiotic use; and less decrease in function and weight loss). The commenter stated that only 11 percent of nursing facilities nationwide report to CMS that they do not have enough RNs on staff for 24-hour RN coverage, therefore it is reasonable to expect the remainder to do so. The commenter's calculation is based on 2012 CMS Expected Staffing Data, assuming, in part, that a minimum of four RNs (A DoN and an RN on each shift) would provide the necessary RN staffing.

Another commenter who advocated mandating a 24/7 RN stated that, as a result of SNF Value-based purchasing and because of the effect of RNs in decreasing unnecessary hospitalizations of LTC facility residents cited above, they anticipate that LTC facilities themselves will be seeking to employ RNs around-the-clock.

Response: We agree that sufficient staffing is necessary, along with the need for that staff to be competent in delivering the care that a resident requires. We also agree that all of these factors are associated with quality of care. However, we do not agree that we should establish minimum staffing ratios at this time. As discussed in the preamble to the proposed rule, this is a complex issue and we do not agree that a ''one size fits all'' approach is best. We have re-evaluated the literature and commenters concerns and remain convinced that additional data will be helpful in determining if and what such ratios should be. Our approach would require that facilities take into account the number of residents in the facility, those residents' acuity and diagnoses. We believe the added specificity of this approach precludes facilities from making staffing decisions based solely on fiscal considerations, without taking these other factors into account. We further believe that this approach can strengthen evaluation of staffing during the survey process. We also agree that RNs are a valuable resource in LTC facilities, however, we are not mandating a 24/7 RN presence in each facility at this time. We note that the current regulatory requirements parallel statutory requirements. While we would have the discretion to impose a more stringent requirement regarding RN presence, we do not have the discretion to eliminate the waiver option, as it is statutory. See sections 1819(b)(4)(C)(ii) and 1919(b)(4)(C)(ii) of the Act. While there are no current RN waivers in effect, such a mandate could result in an increase in such requests. We are also concerned that imposing such a requirement could negatively impact the development of innovative care options, particular in smaller, more home-like settings, for a subset of residents who might benefit from and be appropriate for such a setting. We are also concerned that, while the RN supply overall might be sufficient, geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas. Finally, to the extent that facilities may already be moving in this direction, payroll based reporting, discussed previously in our responses, may give us a better picture of the extent to which increased RN staffing is occurring, although, at this time, we will still lack information on the extent to which this results in 24 hour coverage. We have noted elsewhere in our responses to comments that there are concerns about the validity of self-reported staffing data in accurately reflecting how a facility is staffed throughout the year. This, in concert with our inability to determine to what extent adequate RN hours equate to 24 hour RN coverage, impacted the assumptions we made regarding the number of facilities that would be impacted by imposing a 24/7 RN mandate. Thus our estimate of the number of facilities that would be required to hire additional RN staff is much higher than the commenters'.

We have reviewed the recommendations of the Institute of Medicine in its 2004 report ''Keeping Patients Safe: Transforming the work Environment of Nurses.'' That report reiterates prior recommendations for a mandatory RN presence in LTC facilities and mandatory minimum staffing requirements, although it does not recommend a specific ratio. The report states, in part, that

''Patient safety requires staff resources that are sufficient to prevent an inappropriately high rate of untoward events that could be avoided with adequate staffing levels. For such a standard to be reasonable, it must at least be based on the number of residents in the LTC facility and address NAs, who provide most of the care to LTC facility residents. Such minimum staffing standards are not a precise statement of how many staff are required to fully meet the needs of each specific group of residents on each unit, nor are they a quality improvement tool to optimize quality in each LTC facility. Rather, a minimum staffing level is one that avoids placing individual residents unnecessarily at risk because of insufficient numbers of staff to provide even the most basic care.''

The report discusses CMS's 2001 Report to Congress ''Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes—Phase II Final Report'' and states:

''With respect to the recommendation that DHHS specify staffing standards in regulations that would increase with the number of patients and be based on the findings and recommendations of the Phase II DHHS report to Congress on the appropriateness of minimum staffing ratios in nursing homes, the committee notes that the thresholds identified in that study above which no further benefit from staffing ratios could be identified are above the staffing levels of 75 to 90 percent of facilities, depending on the type of staff. However, a minimum standard set by DHHS need not approach the threshold level above which there is no further benefit. In fact, such a standard would go beyond the expectation for a minimum, which is intended to identify situations in which facilities unequivocally place residents at an unacceptable level of risk. The challenge is that there is no absolute minimum level of risk for untoward events that is considered acceptable.''

The IOM report further states:

''The study does not propose a specific minimum standard for RNs, licensed nurses, and NAs because agreement must first be reached about what is an unacceptable level of risk. However, data exist from this national study with which to determine the staffing levels for each type of staff that are associated with any level of risk for untoward events.''

Finally, the IOM report states:

''At the same time, a number of nursing organizations, policy experts, and HCOs [health care organizations] point out the limitations of staffing ratios. While they may help ensure a baseline level of staffing in HCOs that may be outliers, they are poor instruments for achieving optimal staffing. Depending on the skill mix and expertise of nursing staff and patient acuity, minimum ratios may still not provide the needed levels of safety. Moreover, counts of patients needed to calculate nurse staffing levels consistent with a ratio must be taken at a point or points in time. Yet patient admissions, transfers, and discharges are frequent; therefore, an adequate nurse-to-patient ratio at 7 a.m. may be inadequate at 10 a.m., and an organization that has satisfied a nurse-to-staffing ratio at one point in time may still have inadequate staffing at another point. Thus, while staffing ratios can help protect against the most egregious staffing deficiencies, HCOs will need to employ more sensitive approaches internally to fine-tune staffing levels.''

We include only a few portions of this report to highlight the complexity of

this issue and our concerns about determining a ''right'' number for any staffing ratio. CMS has begun mandatory, payroll-based collection of staffing information from long-term care facilities, to include registered nurses, licensed practical or vocational nurses, certified nursing assistants, or other types of medical personnel as specified by CMS, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day. We believe this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue. In addition, other elements of this regulation, such as QAPI, Infection Control, Compliance and Ethics, and Training, are also intended to put in place systemic process to prevent placing individual residents unnecessarily at risk.

Comment: One commenter was pleased that the proposed regulations require that facilities ''have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial wellbeing of each resident '' However, this commenter as well as other commenters expressed concern about the proposed mechanism for determining what constitutes ''sufficient staff,'' with the ''appropriate competencies and skills.'' The proposed regulations require the facility to conduct an assessment, at least annually, to determine the appropriate level and type of staffing needed. This proposal is of concern because it relies on the facility's own assessment of staffing needs without any enforcement mechanisms or safeguards to ensure that the facility is indeed objectively assessing resident needs, acuity, and other important factors and not unduly relying on other factors such as cost and convenience. The commenter felt that that this proposal requiring a ''facility assessment'' is not materially different from what nursing facilities currently do to determine staffing levels—a method which has produced serious staffing and quality deficiencies. Other commenters felt that the proposal was insufficient in its explanation of expectations. Other commenters were concerned that our proposal did not allow sufficient flexibility for facilities to determine how they staff nursing units. Some commenters stated that a facility's ability to care for residents should be based on outcomes of care, such as annual survey results, quality measures, and the 5-star rating system.

The commenter agreed with CMS that the regulations must not encourage facilities to set staffing levels based solely on regulatory minimum requirements and in lieu of actual resident needs and acuity levels of the residents they serve. They further agreed that the facility assessments should take into consideration all the factors set out in the proposed regulation in § 483.70(e) and that each facility should conduct this assessment itself. However, the commenter suggested that CMS require that the facility assessment be audited by a facility surveyor and that the surveyor be empowered to require, under threat of graduated monetary penalties, the facility to provide additional nursing resources if he or she disagrees with the facility's assessment. Lastly, the commenter believed that the facility should be required to seek and use input from the Long-Term Care Ombudsman, the resident and family groups, and family caregivers when conducting its assessment.

Another commenter noted that instead of establishing a minimum staffing standard or requiring 24-hour RN coverage, CMS proposed a competency-based staffing approach that stems in part from a facility assessment and stated that this assessment appeared to be put forth as the answer to requiring a specific number of staff or hours of nursing care. The commenter was concerned that this would not require facilities to do anything different than they have been doing and that this simply maintains the status quo. The commenter believed that the facility assessment could be useful in addition to a minimum staffing standard if revised to include staffing practices and used as a factor to consider in adjusting staffing levels upward based on resident needs.

Response: We appreciate the commenters concerns and we have re-reviewed the literature as well as additional information. There is no question that staffing and quality are associated, and we direct readers to our concerns about mandatory ratios in the previous response. As one of the commenter notes, the proposed facility assessment is in line with current industry practice. However, our approach would require that facilities document the assessment and take it into account, including the number of residents in the facility, and those residents' acuity and diagnoses, when making staffing decisions. Several commenters have noted that a primary driver of understaffing is that facilities make staffing decisions based solely on fiscal concerns. We believe the added specificity of this approach precludes facilities from making staffing decisions based solely on fiscal considerations without taking resident specific factors and needs into account. Further, the facility assessment is conducted at the facility level and it must be used in making staffing decisions, precluding staffing decisions from being made solely at a corporate level based on fiscal considerations and without taking facility- and resident-specific factors into consideration. We believe this approach provides facilities adequate flexibility while still requiring that there be sufficient staff to care for residents. As noted earlier, we also believe that this approach can strengthen evaluation of staffing during the survey process. We further address comments regarding the facility assessment in our discussion of comments received with respect to proposed § 483.70.

Comment: One commenter stated that, somewhere in the regulations, it is important to ensure that all facility staff, including non-permanent employees, be determined by the facility to be competent to provide care to the residents. The commenter stated that they have seen where the facility counts on the contract agency to determine competency and training, and this has not actually been completed in a timely manner. When a deficiency is cited, neither the facility nor contract agency wants to be held responsible for the resultant care that was provided to the residents. Regardless of whether the individual is a permanent facility employee or a contract employee, the facility should remain accountable for the competency of the individuals who are providing care to the residents. Language should be added to hold the facility is accountable to ensure that the contract staff have received the regular in-service education required every 12 months under § 483.35 (d)(7), otherwise there is no way to ensure these individuals meet their annual in-service education requirements. Many other commenters stated that facilities should not be accountable for ensuring the competency of contract personnel. Many of these commenters stated that the agency that employs the individual should be accountable for their employees' competency. One such commenter stated that they hire the agency, not the nurse or CNA.

Response: We agree that all staff providing care must have the skill sets and competencies to provide that care. Proposed § 483.35(a)(3) and (c) specifically require that licensed nurses and nurse aides, respectively, have the

competencies and skills necessary to provide care to residents in accordance with that resident's needs. These provisions are not conditioned on the manner by which the individual's services are obtained. Further, we establish in proposed § 483.95, training requirements for all staff. Please see our responses for that section for additional information. Furthermore, we re-designated but did not otherwise change the requirements for the use of outside resources, which requires that the facility obtain services under an agreement that specifies, in writing, that the facility assume responsibility for obtaining services that meet the professional standards and principles that apply to professionals providing such services and are timely. Depending on a facility's needs, contract staffing may be used infrequently, routinely, and for extended periods of time. A facility can require in its agreement with a staffing agency that the personnel the agency sends to fill staffing needs meet certain requirements. The facility could use mandatory training requirements as well as its facility assessment, past experience, and other knowledge of its staffing needs to determine what requirements it would expect the staffing agency to ensure personnel have met prior to being sent to the facility. However, when a contract individual reports for duty, the facility must ensure that the work assigned to that individual is appropriate for his or her competencies and skill sets.

Comment: One commenter recognized that nurses need many diverse skills, but felt the meaning of this proposed requirement is unclear. They asked whether we intended to require this of all of nursing in the aggregate, or every nurse individually. They asked whether we intended that each nurse have competencies for all the residents/patients under their care each day, or on the unit on which they work. The commenter felt that it was unclear about how surveyors would evaluate this requirement fairly and consistently, in order to judge a facility's compliance with this provision. The commenter recommended that § 483.35(a)(3) be revised to read: The facility must ensure that its licensed nurses collectively have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care. Other commenters stated that competency and skill set requirements were unnecessary, as these are ensured by education and licensure, and covered by requirements that care meet professional standards of practice.

A commenter also recommended that ''Proficiency of nurse aides'' should be revised to read: ''The facility must ensure that nurse aides have the basic skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.''

Response: The individual providing the care must have the skills and competencies to deliver the care that they are expected to provide to the resident, consistent with the individual's position and, when applicable, their scope of practice under state law. We recognize that education and licensure provide many foundational skill sets. There are many common competencies that every staff member or every member of a specific job position (such as nurse aide) need. We would expect those competencies to be identified through the facility assessment. We understand that not every staff member can have every competency for every resident and that an individual facility, based on the population it serves, may have some unique needs. It is not enough, however, that the staff, collectively, have the competencies and skill sets to provide the care. That could imply that the requirement is met so long as one member of the staff has the required training or knowledge, regardless of whether or not that staff member actually provides the care or is even present in the facility when the care is delivered. The facility must ensure that the individual providing care to a resident has the skills and competencies necessary to deliver that care. For example, if a particular resident is on contact isolation as a result of a medical diagnosis, every individual caring for that resident must know how to comply with those procedures. Similarly, if a resident requires the use of a specialized eating implement, the individual(s) responsible for assisting the resident to eat must know the proper use of the implement. If the individual has to obtain guidance for such use, such guidance must be timely. It would not be enough for one individual to have the knowledge if that knowledge was not actually used in caring for the resident.

Comment: One commenter felt that the language of proposed § 483.35(d)(2) was unclear and could be interpreted to mean that a facility could not have a temporary worker that did not meet the requirements but could have a permanent employee who did not meet the requirements.

Response: § 483.35(d)(1) addresses the use of nurse aides; paragraph (d)(2) establishes that facilities cannot avoid compliance with (d)(1) through the use of non-permanent employees. In context, this does not permit any employee to whom paragraph (d) applies to not meet the requirements. We are finalizing this provision as proposed.

Comment: A commenter stated that traditional in-service education has been largely supplanted by other approaches and may have marginal value in imparting skills and attitudes and in improving performance. Self-education, computer-based training, real-time coaching, mentoring, and other forms of education and training and coaching are often more productive. Furthermore, ''in-service education'' is not defined and lacks pertinent standards. The commenter recommended revising the wording of (d)(7) to reflect more flexible, efficient, effective, and modern approaches to the issue. Otherwise, regulatory compliance is limited by the inflexible specific requirement for ''in-service education.''

Response: ''Regular in-service education'' is required by sections 1819(b)(5)(E) and 1919(b)(5)(E) of the Act. ''In-service'' training is generally understood to be training intended for those actively engaged in the profession or activity concerned. We agree with that there are multiple ways of providing ongoing training that assures that individuals used as nurse aides are competent to perform services as nurse aides. We would encourage facilities to use the most efficient and effective training methods available to them to achieve their training objectives.

Comment: One commenter felt that the final regulation should clearly address a specific, replicable methodology for calculating nursing staff and assessing whether or not it is adequate to meet the needs of residents in each facility. The commenter urged CMS to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. Such an adaptation must be designed to incorporate the more robust payroll-based staffing data that will be in place as a requirement for all certified SNFs and NFs by July 2016. The commenter felt that a competency-based assessment could easily ask for a determination of whether or not the facility has 24-hour RN coverage, and whether all LPNs and CNAs have sufficient training to be able to communicate with and respond to the needs of individual residents who have difficulty communicating, notably individuals with dementia. A

competency assessment could also ask for further details about initial and in-service training, including whether all nursing staff understand ethics and compliance and QAPI standards well enough to use them. Further, a competency assessment could inquire about the composition of interdisciplinary teams, and whether these care teams record and take into account the treatment preferences and quality of life goals that residents express during care planning. The commenter stated that the importance of regulators having clearer yardsticks to understand what constitutes ''sufficient'' staffing in different facilities in order to ensure resident well-being cannot be overstated. Careful oversight by nursing staff serving residents is a core fiduciary responsibility of LTC facilities and the direct responsibility of the Administrator and the Director of Nursing (DoN). This responsibility must be understood to extend to the adequacy of training and the operational deployment of nursing staff—at all times, including night and weekend shifts, and during holidays—regardless of the business structure of the facility, and independent of any policies promulgated by individuals or entities that may be operationally and/or financially connected to a given LTC facility. To be useful, therefore, an annual facility assessment must be able to establish that its staffing will remain adequate throughout the year, both with regard to levels of total nurse staffing, and with respect to the responsibility that certain types of staff, for example, RNs and LPNs, have in overseeing the medical management of residents with regard to medications, falls prevention, development of pressure ulcers, readmission to hospitals and other key areas.

Response: We will consider the commenters' recommendation to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. Please see our discussion of § 483.70 for further discussion of the facility assessment requirement.

Comment: In advocating for mandatory staffing standards, some commenters addressed the high cost of poor care. One commenter noted that CMS itself has recognized these costs. The commenter further noted that nearly 25 years ago, the Senate Labor and Human Resources Subcommittee on Aging issued a report that addressed, and used the term, ''high cost of poor care''—that is, the costs that are incurred by the health care system when inadequate nurse staffing in LTC facilities leads to avoidable medical problems that the health care system spends money to try to correct. The report detailed several poor care outcomes, their causes, and their estimated costs, noting that the costs would be far higher in 2015 dollars and links avoidable hospitalizations to ''the insufficient number of adequately trained nursing staff.'' The commenter notes additional studies that further support this conclusion. The commenter also discussed the use of INTERACT (Interventions to Reduce Acute Care Transfers is a quality improvement program that focuses on the management of acute change in resident condition) to avoid inappropriate hospitalizations and to support hospitalization that is medically necessary. The commenter further stated that considerable research demonstrates that unnecessary and inappropriate hospitalizations can be avoided when nursing facilities have more health care professionals in place on a daily basis—physicians, physician assistants, and registered nurses. Finally, the commenter discussed other costs of insufficient staffing, such as staff injuries. Another commenter stated that the lack of a specific minimum staffing standard and 24-hour registered nurse coverage in the proposed regulations has been a major obstacle to quality care since the Nursing Home Reform Law was passed in 1987 and will continue to be until these standards are adopted. The commenter highlighted the relationship between staffing levels and quality and stated that CMS discounts the numerous studies that support the relationship between nursing staff and quality.

Response: We do not discount the relationship between staffing levels and quality. We disagree that this requires that we set minimum staffing ratios and that we know what that minimum staffing ratio should be. As discussed previously, we believe that there are concerns about utilizing a minimum staffing standard and we do not necessarily find that the 4.1 hours per resident day (hrpd) is the right standard for every facility. LTC facilities are varied in their structure and in their resident populations. Some facilities are Medicare-only SNFs that focus on short term rehabilitation services. Others are primarily Medicaid facilities that include primarily long-stay residents. Many are both. Some facilities specialize in dementia care. Some facilities have pediatric residents, young adult residents, or ventilator dependent residents. The care needs of each of these populations are different. Facilities range in size from the very small to the very large. The capabilities of these facilities are likely to be different. As noted above, we discuss our concerns with establishing a minimum staffing ratio in prior responses. As stated in the proposed rule, our intent is to require facilities to make thoughtful, informed staffing plans and decisions that are focused on meeting resident needs, including maintaining or improving resident function and quality of life.

Comment: One commenter stated that while they believe recommended minimum staffing requirements should be implemented when the revised rules go into effect, an alternative approach would be to phase-in the staffing standards incrementally over a 5 year period. A number of states, such as Florida and Illinois, have used an incremental phase-in period. This approach would give facilities ample time to increase staffing to the required levels.

Response: We are not finalizing a minimum staffing requirement at this time. We will consider a phased-in approach if we determine to impose minimum staffing standards through future rulemaking.

Comment: Several commenters stated that, despite industry claims to the contrary, they believe it is not necessary for CMS to increase Medicare and Medicaid LTC facility payment rates if CMS requires minimum staffing standards. One commenter noted that the actual facility-reported average RN staffing levels increased to 0.85 hours per resident day (hprd), LVN staffing increased to 0.83 hprd, and total staffing steadily increased to 4.15 hprd in 2015. Because the average LTC facility staffing is already 4.1 total hprd and 0.8 RN hprd, most homes should be able to meet these standards without an increase in reimbursement rates. The commenter felt that the for-profit chains who in general report lower staffing levels are in the best position to increase staffing without additional reimbursement.

Response: We thank the commenters for this information. We are aware of concerns that current, self-reported staffing data may not fully reflect a facility's staffing across time. We expect our understanding of how facilities are staffed on an ongoing basis to improve with the collection of payroll-based staffing data. Also, it is important to note that changes to these requirements

do not necessarily drive changes to Medicare or Medicaid payment rates.

Comment: Several commenters questioned the accuracy of the cost estimates CMS presented for the proposed rule. They believe that the salary figures appeared to be overly inflated and asked CMS to review its cost estimates. The commenters suggested that CMS use the BLS OES wage data that are specific to SNFs and felt that the 48 percent fringe benefit and overhead factor appeared overly generous. Finally, the commenters stated that it would be helpful for CMS to provide additional information on the justification and methodology for determining the benefit factor and what the specific elements of overhead costs are.

Response: We have reviewed our calculation and believe that we provide a good faith estimate of the cost of requiring 24/7 RN coverage. We note that the overhead percentage used in our calculations is based on guidance from the Office of Management and Budget. After eliminating facilities that already require a 24/7 RN, we estimate that there are 13,279 facilities that will likely need to 'staff-up.' We believe that ''staffing-up'' would entail hiring an additional one to four RN FTEs to cover an additional two shifts per day (14 eight hour shifts per week) in the 13,279 facilities that are not currently required to have a 24/7 RN presence. Given the 2015 mean annual wage of $62,440 for an RN working in a nursing care facility (*http://www.bls.gov/oes/current/oes291141.htm*), and assuming either 48 percent or 100 percent overhead, we estimate the burden of implementing such a mandate to be $92,411 to $124,880 per additional RN, for a total of between $1.2 and $6.6 billion in addition to the current estimated first year costs of the proposed rule. Particularly given existing concern that current self-reported staffing data may be inflated, we believe that payroll based staffing data will help us better estimate the burden.

One commenter suggested that we should use $42.82 hourly wage based on the BLS OES Median for NAICS 623100, inflated by 48 percent. If we used that number, assuming 40 hours per week for 52 weeks, we get an estimate of $1.1 to $4.7 billion for an additional one to four RNs at 13,279 facilities. Some commenters believe that we have over-estimated the number of facilities that would need to hire one or more additional RNs. One commenter believes that 89 percent of facilities, already meet or exceed four RN FTEs per day (1 DoN and 1 RN on each shift), based on a calculation of RN hours per resident day and currently reported staffing data. That would mean only 1,777 facilities would need additional RN staffing. Using this estimate and the $42.82 median hourly wage, the burden estimate is $158 to $633 million for one to four additional RN at 1,777 facilities. However, we believe this calculation significantly underestimates the number of facilities that would be required to hire additional RNs. We based our estimate on the number of facilities that are not currently required to have an RN 24/7.

Comment: Several commenters stated that, given the relationship between staffing and outcomes, increased staffing levels could save the Medicare and Medicaid programs billions of dollars, and cite studies demonstrating the possible cost savings. They noted that, while the trauma inflicted upon LTC facility residents and their loved ones from understaffing could not be easily categorized and calculated, the financial costs are quantifiable.

Response: We agree that improved staffing, as well as improvement as a result of several of our proposals, could result in savings to the Medicare and Medicaid programs. In developing our proposals, we considered possible cost savings from these proposals. Those cost savings were not included in our estimates as they were deemed to potentially be the aggregate result of more than one requirement or activity, as well as speculative in nature.

Comment: Some commenters are concerned that our requirements related to the DoN can be waived and note that the role of the DoN is critical to quality resident care. The commenter stated that the DoN is responsible for administrative, clinical, educational, staff and public relations; the core competencies include such skills as conducting root cause analysis, setting benchmarks, directing change, and mentoring and teaching and, with the increased acuity level and medical complexity of LTC facility residents, a DoN with the expertise, training and skills of a RN is necessary. The commenter recommends that we delete the waiver so the regulation reads: ''The facility must designate a registered nurse to serve as the director of nursing on a full time basis.''

Response: We agree that the position of DoN is very important and that an RN should fill this position. However, the waiver in question is established by statute and we do not have the discretion to eliminate it. We note that the waiver only applies to rural facilities where the supply of RNs is not sufficient, and only when specific conditions are met. Further, we note that no such waivers are currently in effect.

After consideration of the comments we received on the proposed rule, we are finalizing these provisions as proposed.

N. Behavioral Health Services (§ 483.40)

Currently, § 483.25 requires that each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. We proposed to add a new section § 483.40 to address this requirement as it relates to behavioral health services and include requirements for social workers. These provisions work in conjunction with other provisions we proposed, including those related to reducing the inappropriate use of psychotropic medications, to address the behavioral health care needs for residents.

We proposed at § 483.40(a) to require that the facility have sufficient direct care staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at proposed § 483.70(e). We proposed to specify in § 483.40(b) that, based on the comprehensive assessment of a resident, the facility must ensure that a resident who displays or is diagnosed with mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental health and psychosocial well-being. In addition, we proposed to specify that a resident whose assessment does not reveal or who does not have a diagnosis of a mental disorder or psychosocial adjustment difficulty will not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that the pattern was unavoidable. Furthermore, if rehabilitative services such as physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for a mental disorder and intellectual disability are required in the resident's comprehensive plan of care, the facility must provide the required

services, including specialized rehabilitation services as required in § 483.40(c)(1); or obtain the required services from an outside provider of specialized rehabilitative services in accordance with proposed § 483.65(a)(2).

General Comments

Comment: Some commenters were very supportive of our proposed requirements for behavioral health services, but noted that these requirements focused substantially on behavioral and psychiatric conditions. They supported the focus on sufficient direct care staff with the appropriate skills and competencies to provide the necessary care to residents with a mental disorder and cognitive impairment, including how to implement non-pharmacological interventions. Some commenters supported requiring facilities to provide social services to the residents and that all of the behavioral health services that are indicated in the resident's comprehensive plan of care must be provided by the facility.

Response: We thank the commenters for their support. We believe these proposals, which have been finalized in this rule, are essential for residents who need behavioral health services. We also agree that having a focus on behavioral health through having a separate section on behavioral health with a focus on, among other things, sufficient direct care staff with the appropriate skills and competencies and non-pharmacological interventions, emphasizes the importance of providing the behavioral health services residents need to obtain their highest practicable physical, mental, and psychosocial well-being. Facilities will be required to provide the behavioral health services indicated on the resident's comprehensive plan of care; however, § 483.65(a)(2) also allows for the facility to have these services provided by an outside source.

Comment: Some commenters were supportive of the proposed requirement for sufficient direct care staff with the appropriate skills and competencies to provide the necessary care to residents who need behavioral health services and for this to be determined by a facility assessment. However, the commenters were concerned that it was the facility itself that would conduct this assessment. Without any enforcement mechanism or safeguards to ensure that the facility is objectively assessing its residents' needs, acuity, and other important factors, the commenters were concerned that the assessment could be influenced or rely upon other factors, such as the cost or convenience to the facility. In addition, the commenters stated that this requirement was not materially different from what facilities currently do and that current practice has resulted in serious staffing and quality deficiencies. Some commenters proposed that we require the facility to seek out and use the input from outside sources and that a surveyor audit the facility assessment and impose monetary penalties if the auditor disagreed with the facility assessment.

Response: We understand the commenters' concerns about facilities performing their own facility assessment to determine staffing and other resource requirements and that the assessments could be based upon factors other than the care needs of the resident population, such as justifying their current staffing and other resources, as well as taking into consideration the facility's cost and convenience. However, we believe that facilities need the flexibility to determine the best way to perform their facility assessments to comply with this requirement. The facility can certainly perform this assessment itself or it may choose to have an outside entity perform the assessment. We believe that if a LTC facility does not objectively assess its resident population and resources, surveyors will be able to detect this during the survey, not only from reviewing the facility assessment but also from the LTC facility's compliance with the other requirements in this final rule. For further discussion on the facility assessment, please see the discussion for § 483.70(e) below.

Comment: Some commenters were very concerned about not having sufficient resources that would be needed to comply with these requirements. Some commenters noted the shortage of behavioral/mental health providers in their areas, especially qualified psychiatrists. Others noted that Medicaid per diem rates do not include any compensation for specialized behavioral health services. Other commenters were concerned they would have insufficient resources to obtain additional staff and provide the training, both initial training and continuing in-services, that would be required to comply with the requirements.

Response: We understand that there are concerns about how to comply with the requirements in this final rule. However, sub-regulatory guidance will be published for these requirements. This guidance should provide the detailed information that LTC facilities need to understand what is needed to comply with these requirements.

Comment: Some commenters believed that complying with the proposed requirements is unrealistic and problematic due to the high staff turnover in LTC facilities. A commenter noted that in 2012 there was a median turnover rate of 43.9 percent turnover for all employees and 50 percent or more for direct care RNs, and CNAs. The turnover rate for LPNs and LPNs was 36.4 percent.

Response: We acknowledge that the high turnover rates for staff in LTC facilities present a challenge. However, as discussed in other areas of this rule, we believe that these requirements will not only improve the quality of care and life for residents but also the quality of the work environment for the staff. We believe that over time this will result in lower turnover rates for staff and savings for LTC facilities.

Comment: Some commenters were supportive of the emphasis on behavioral health; however, they also recommended a more holistic approach to improve care for residents with behavioral and psychiatric impairments, including dementia. They noted that all psychiatric and behavioral disturbances have a significant medical and biological component. In addition, there were many reliable and reputable resources in medicine, neurology, psychiatry, and other disciplines that explain how health professionals, other than psychiatrists, should be able to properly assess, diagnose, and manage behavioral and psychiatric issues. They are concerned that these requirements would perpetuate ''silos'' of care, which is managing each body part or symptom by a particular discipline, which could undermine managing all of a resident's symptoms and conditions holistically. Some of the commenters believed that mental health professionals are not often needed and may actually be unhelpful for some residents. Some commenters did not believe that having consultants provide behavioral care is unlikely to improve vital staff and practitioner understanding and performance.

Response: We agree with the commenters that behavioral health issues have a medical and biological component and that healthcare, including the healthcare in LTC facilities, requires a holistic approach. We proposed and have finalized this section, not to elevate the treatment of mental disorders and emotional issues above physical health issues, but to ensure that assessment and treatment of behavioral health issues are viewed with the same importance as the physical and receive the resources necessary to provide appropriate

treatment to residents in need of behavioral health services. This is why we have also finalized requirements for assessments, personalized care plans, the involvement of an IDT, the involvement of the resident or their representative in the resident's care, as well as other requirements. We also agree with the commenters that behavioral health care can be provided by healthcare personnel other that psychiatrists. In this final rule, we have not required that the individuals who provide behavioral health care and services have specific degrees or certifications; however, the facility must have sufficient staff with the appropriate competencies and skill sets to provide nursing and related services to residents in need of behavioral health care and services.

Comment: Some commenters were concerned that the behavioral health section requirements appear to be implying that facilities would be responsible for ensuring that people with mental or emotional disorders maintain stable emotions and behaviors. They also believed that the proposed requirements appeared to imply that the facility would be held responsible if residents could not adjust or behave adequately in a social setting, or if they withdrew, got angry, or failed to interact well with others. However, commenters noted that many residents may have long-standing, and often misdiagnosed or inappropriately or inadequately managed, behavioral health problems prior to being admitted to a LTC facility. They asserted that this indicates how widespread the problem of inadequate behavioral health care is in our healthcare system.

Response: According to § 483.40, LTC facilities are responsible for providing each resident with the necessary behavioral health care and services for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with his or her comprehensive assessment and plan of care. No healthcare provider, including a LTC facility, can guarantee any particular result for its residents. In addition, an LTC facility can only be responsible for the care they provide and not the care the resident received prior to admission. However, they can, and are expected to, properly assess residents, develop plans of care, and provide residents with the appropriate behavioral health services that they need to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

Comment: Some commenters stated that the requirements were increasingly mandating certain approaches and discouraging or prohibiting the use of others. Commenters believed there was an emphasis on non-pharmacological interventions over the judicious and appropriate use of medications. The commenters did not believe that the approach in the proposed rule was based upon sound clinical judgment. Some commenters were supportive of the efforts to reduce unnecessary anti-psychotic drug use in LTC facilities, but they also believed in the judicious use of medications for appropriate indications with adequate monitoring of efficacy and side effects. They were particularly concerned about what they perceived as an anti-medication orientation that was obsessive and counterproductive and could inhibit the appropriate use of necessary medications that can effectively and safely relieve symptoms such as distressing delusion, hallucinations, and self-harming behaviors. Commenters recommended the wording be changed to focus on objective support for all potentially useful interventions that could be used in the appropriate context after a clinically competent assessment has been performed.

Response: We appreciate the commenters concerns; however, these requirements neither mandate specific techniques or care nor do they require facilities to forego the use of any medically acceptable drugs or techniques. The requirements finalized in this rule regarding behavioral and non-pharmacological interventions, as well as those concerning psychotropic and anti-psychotic drugs in § 483.45, are all intended to encourage appropriate care for the residents. We disagree that these finalized requirements have an anti-medication orientation. The requirements regarding medications are intended to promote the safe and effective use of medications and discourage the inappropriate use of these medications. Non-pharmacological or behavioral interventions are required in an attempt to reduce or eliminate psychotropic medications, but only if these non-pharmacological methods are not clinically contraindicated for the resident.

Comment: Some commenters indicated that CMS failed to specify the elements of the facility assessment that would be required to determine the facility's direct care staff needs; the expectations CMS would have regarding how facilities would determine the competencies and skill sets necessary to provide behavioral health services; and whether facilities would need to ensure expanded access to outside professional behavioral health services, which are costly and already difficult to access in rural and geographically underserved areas. Numerous commenters recommended that we delay the behavioral health requirements due to their lack of specificity, especially what ''appropriate'' is, who will determine what the competencies should be, and who will determine if the staff meet the competencies.

Response: We have not provided specific instructions on how to conduct the facility assessment. We believe that each facility needs to have the flexibility to decide the best manner in which to conduct that assessment, as long as it addresses or includes the factors or items set forth in § 483.70(e). We understand that the commenters' concern about how to comply with the requirements in this final rule and how they will be surveyed. However, such specificity is not suitable for these requirements; this is more detailed information than is usually incorporated in the requirements and would likely need to be modified more frequently than the requirements. In addition, after this rule is published, sub-regulatory guidance on complying with these requirements will be published.

Comment: Some commenters recommended that we reverse the order of proposed § 483.40(b)(1) and (b)(2). They stated that the first statement is not expecting a resident who does not have behavioral health problem at admission to develop one, unless there is a medical reason specific to that individual that makes the problem unavoidable. This first statement would then be followed by the statement requiring a facility to provide appropriate care to a resident who needs the service.

Response: We do not believe it is necessary to reverse the requirements. Thus, we will finalize those requirements as proposed.

Comment: Some commenters supported our proposal that the facility have sufficient staff with ''the appropriate competencies and skill sets,'' but they believed that the behavioral needs of residents could not be met unless CMS also specified that each facility have staffing practices that include the number and types of staff, staffing assignments (such as rotating or consistent assignment), schedules, and systems that affect communication, teamwork, and participation. Commenters recommended specific language for such a provision.

Response: We agree with the commenters that staffing practices are important. Some staffing practices, such as consistent assignment, are also best

practices. We encourage LTC facilities to use best practices with staffing when it is feasible. However, we have not mandated the use of specific practices in these requirements because we believe that LTC facilities need the flexibility to ensure they have sufficient staffing for their residents.

Comment: Some commenters recommended that the final rule strengthen the requirements related to assessment of behavioral health and other psychosocial concerns. Commenters specifically recommended that the final rule require that there be a comprehensive psychosocial assessment and social history completed upon admission according to § 483.21(b), with the assessment portion updated annually or when significant changes in the resident's health or behavioral health occur. They also recommended that care plans be required to address psychosocial and behavioral needs identified by the IDT assessments, social histories, and applicable sections of the MDS and associated Care Area Assessments.

Response: According to § 483.21(b), LTC facilities must develop a comprehensive care plan, which among other things, must include measurable objectives and timetables to meet a resident's mental and psychosocial needs that are identified in the comprehensive assessment. This comprehensive care plan must be reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments. We believe that by complying with these requirements LTC facilities should be able to provide the behavioral health care their residents need.

Comment: Some commenters agreed that mental health care and services are integral to the goal of assuring the highest practicable well-being for residents; however, they also believed that any discussion of the existing requirements or proposals required consideration of the history, structure, and function of LTC facilities. Commenters were particularly concerned about the suggestion that LTC facilities are appropriate settings to care for seriously mentally ill residents or perhaps even being required to admit these residents and provide the specialized behavioral care and services these residents need. They noted that historically LTC facilities were not expected to admit residents that required specialized behavioral health services. They noted that residents with psychiatric illnesses are complex and require a thoughtful plan and that LTC facilities should not be expected to fill in the gaps in the behavioral health care system.

Commenters said that expectations regarding the mental health care that LTC facilities can provide must be balanced against these facilities' ability to provide those services and the possible ramifications for the residents with mental disorders and the remaining resident populations in those facilities. A serious unintended consequence could be frail, elderly residents with dementia being housed with residents with a serious mental disorder, which could result in a dangerous situation. Other commenters were concerned that they would be pressured to admit residents with serious, complex behavioral health needs that they could not meet.

Response: These requirements do not mandate that a LTC facility admit any resident with a serious mental disorder. However, if a resident does have behavioral health issues, the LTC facility is responsible for providing the appropriate care for that resident. As discussed in the proposed rule, by 2012, more than 48 percent of LTC facility residents were estimated to have some form of dementia, including Alzheimer's disease, and/or depression (80 FR 42202) Thus, residents requiring behavioral health services are already being cared for in LTC facilities.

Comment: Some commenters were confused about the intent of the behavioral health services requirements and what was expected of providers. They requested clarification and some recommended that CMS not finalize the proposed behavioral health requirements, but work with the state survey agencies and providers to address how residents with complex behavioral challenges can best be served.

Response: We understand that some of the requirements related to behavioral health services are new and will require time and resources to comply with the requirements. We will also be publishing sub-regulatory guidance to assist LTC facilities in complying with these requirements.

Comment: Some commenters were concerned that some of the proposed requirements regarding behavioral health services were inconsistent with a proper, objective assessment of a resident. They believe that instead of emphasizing sound clinical reasoning and problem solving the proposed requirements would encourage inflexible ''cookbook'' approaches that impeded adequate consideration of causes and treatment options. Commenters were concerned that the proposed regulations are primarily psychosocial and focuses on psychosocial interventions while largely ignoring or underemphasizing the reality of dementia as a neurological disorder and the benefits of competent medical assessment and diagnosis. In addition, some commenters were concerned that the proposed rule emphasized non-pharmacological interventions over pharmacological treatments. Commenters noted that competent and reputable sources, such as the World Health Organization (WHO) have emphasized the judicious use of medications in appropriate situation to produce remarkable improvement in the function and quality of life for individuals. They believe that amounts to an attempt to influence clinical practice that is unlikely to promote an improvement in the quality of care provided to residents.

Response: We disagree with the commenters. Person-centered care is a focus of these requirements. Each facility is responsible for assessing every resident and developing care plans upon admission and periodically thereafter in accordance with § 483.20 and § 483.21 for each resident. Section 483.45 ''Pharmacy services'' includes safeguards concerning specific types of medication; however, it does not require or prohibit the prescription or use of any medically acceptable medication for a resident. In addition, although behavioral or non-pharmacological interventions are required for residents on psychotropic medication in an effort to discontinue these drugs, this is only required if it is not clinically contraindicated for the resident (§ 483.45(e)(2)). Hence, there is no ''cookbook'' approach for the care for any resident. We have specifically addressed dementia below.

Comment: Some commenters were concerned about some of the language in § 483.40(a) and (a)(1). They were concerned about identifying specific conditions, especially the language concerning residents with a history of trauma and/or post-traumatic stress disorder. They do not believe that these conditions are neither more nor less relevant than other psychiatric and behavioral disorders. This could divert attention away from other disorders and problems that are equally important. Commenters provided recommendations on specific changes to the regulatory text.

Response: The inclusion of certain issues, such as ''history of trauma and/or post-traumatic stress disorder'' is not intended to exclude other types of disorders or problems. We believe that the remaining language in § 483.40(b)

clearly indicates that those requirements pertain to other behavioral health issues.

Comment: Some commenters recommended that the behavioral health requirements not be contained in a separate section. Instead, they recommended that these requirements be relocated into the quality of care requirements, under special services, since it appears to be the intent for these services for residents who have a mental disorder, psychosocial disorders, and trauma or post-traumatic stress disorders.

Response: In the previous requirements, the requirements related to behavioral health services were integrated throughout the requirements. However, we became aware of concerns that behavioral health services were either not always being addressed or not addressed to the extent required, in LTC facilities. We proposed, and are finalizing, these requirements in a separate section to emphasize the importance of behavioral health and ensure that LTC facilities address these issues (80 FR 42203).

Definitions

Comment: Some commenters were concerned about what care and services were encompassed within the behavioral health requirements. They recommended that there be a definition of behavioral health in the final rule.

Response: We agree with the commenters that there should be a definition of ''behavioral health'' in this final rule. LTC facilities are also the residence for residents. Hence, we believe there needs to be a holistic approach to behavioral health and that it should encompass a resident's mental, emotional, and physical well-being. We believe this holistic approach should also encompass prevention. Additionally, we do not want to limit the behavioral health requirements to residents who have been diagnosed with mental or substance use disorders. Therefore, we have inserted the following definition into the stem statement at § 483.40, ''Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.''

Comment: Some commenters were concerned about how ''direct care/direct access'' staff would be interpreted. Some commenters also recommended that the wording be changed to, ''[t]he facility must have sufficient staff who provide direct services to residents and who have the appropriate competencies and skills to provide nursing, social work, and other services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being . . .''

Response: We acknowledge that there could be some confusion concerning the use of ''direct care/direct access'' staff. Depending on the setting, this term could be interpreted as applying to virtually every staff member in the facility or more narrowly to nursing staff and any applicable therapist. We believe that ''sufficient staff who provide direct services to residents'' is more appropriate language and have finalized that language in § 483.40(a). Thus, the facility would be responsible for ensuring that every staff member that provided direct services to residents has the appropriate competencies and skill sets to provide nursing and other services. Those competencies and skill sets would depend upon the services the staff members were providing to the residents. However, we do not agree that ''social work'' needs to be specifically mentioned in this requirement. Although ''social work'' is very important, other services are also important to the residents. In addition, ''social work'' is clearly included in ''other services''.

Social Workers and Social Services

Comment: Some commenters noted that we proposed to move the requirement that the facility provide medically-related social services from the previous quality of life requirement at § 483.15(g), to § 483.40(d). Commenters said that this implies that medically-related social services were only for those with mental disorders or psychosocial adjustment difficulties, a history of trauma and/or post-traumatic stress disorder. They indicated that social workers also provide services that benefit all residents, such as contributing to ongoing care planning, facilitating transitions of care, and advocating for residents' rights and helping facilities. These commenters believed that many residents could benefit from the services of social workers, in addition to those residents that have behavioral health or mental health issues. Other commenters wanted to move the behavioral health requirements to a stand-alone section on Quality of Care and Quality of Life requirement section.

Response: We agree with the commenters and believe that this is already required. Section 483.40(d), both as proposed and finalized, requires the facility to provide medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident. Thus, this requirement for medically-related social services goes to all of the facility's residents, not just those with identified behavioral or mental health issues.

Comment: Some commenters recommended that the requirement for medically-related social services be strengthened. They noted that the current requirement is for a full-time social worker in facilities with 120 or more beds; however, smaller facilities also need clinical social workers to assist residents and their families with concerns about care and rights. Commenters noted that while non-clinical social services staff are also important for helping arrange for and coordinate services not provided by the facility, discharge planning, and identifying ongoing care and services for residents who are moving out of facilities, they thought it was important for the staff providing medically-related social services to have clinical credentials. Some commenters recommended that LTC facilities be required to employ sufficient numbers of social workers who are professionally credentialed to provide clinical services to residents. Some commenters also noted that the current inability of social workers to bill Medicare Part B had created a barrier to these services.

Response: We agree with the commenters that residents in smaller facilities could also benefit from medically-related social services. However, the requirement that facilities with 120 or more beds must employ a full-time, qualified social worker is a statutory requirement (sections 1819(b)(7) and 1919(b)(7) of the Act). While we believe we have statutory authority to require facilities with fewer beds to employ full-time social workers, we did not propose changing this provision. We will retain these comments for consideration if there is future rulemaking concerning social workers or social work services.

Comment: Some commenters noted that proposed § 483.40(d), which reads, ''[t]he facility must provide medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident.'' Commenters noted that ''physical'' was included in § 483.40 and § 483.40(a). They recommended that ''physical'' be inserted before ''mental''.

Response: We thank the commenters for pointing out that ''physical'' was left out of § 483.40(d). We have finalized that section so that the word ''physical'' is included.

Comment: Some commenters stated that residents had limited access to

clinical social workers and that this posed a significant barrier to a facility's ability to meet residents' mental and behavioral health needs as identified in proposed § 483.40. Commenters also stated that social work is essential to realize the goal of § 483.40(a). Clinical social workers have either a master's or doctoral degree in social work, at least two years of post-degree supervised experience in a clinical setting, and a state-issued clinical social worker license, certification, or registration. They also noted that the Health Resources and Services Administration (HRSA) recognizes social work as one of the five core mental health professions. Commenters noted that some LTC facilities do employ clinical social workers to provide social services to residents and that this staffing pattern can certainly contribute to staff identification and response to residents' mental and behavioral health concerns. Commenters discussed how reimbursement contributes to this lack of access. Specifically, they stated that psychotherapeutic diagnosis and treatment is not included in the services covered by the SNF Part A resource utilization group payment. They also noted that even if these services were included in the payment, many clinical social workers employed in a social services capacity would not have the time or flexibility to provide the mental health services some residents would require. In addition, many LTC facilities contract with Medicare-certified independent practitioners to provide mental and behavioral health services to LTC facility residents. However, at this time, clinical social workers are only reimbursable under Medicare Part B if the resident is not receiving SNF benefits under Medicare Part A. The commenters believe that it was the implementation of the requirements in the Balanced Budget Act of 1997 (Pub. L. 105–33), which bundled all social work services in the per-diem SNF payment (section 4432 of the BBA), failed to distinguish between medical social work services provided to all SNF residents and discretionary psychotherapeutic services provided by clinical social workers with specialized needs. They argued that this revocation of the clinical social workers ability to bill Medicare Part B for psychotherapeutic services to SNF residents contrasts with the privileges retained by psychiatrists and psychologists, whose services are not bundled in the SNF per-diem rate. They recommended that correcting this discrepancy would reduce costs to both the beneficiaries and the Medicare program by helping to prevent unnecessary transfers to the emergency department or psychiatric hospital, as well as to decrease avoidable re-hospitalizations related to mental and behavioral health.

Response: We agree with the commenters that social workers offer valuable services to residents. LTC facilities with less than 120 beds are not required to have a full-time social worker on staff. However, in this final rule, LTC facilities are required to have sufficient staff with the appropriate competencies and skill sets to provide the care needed by their residents. Thus, LTC facilities must ensure that their residents have the social services, including medically-related social services, they require. Policy governing billing and payment for the services of social workers is beyond the scope of this regulation.

Relationship to Other Requirements

Comment: Some commenters requested clarification on how the behavioral health services section requirements intersect with the current pre-admission screening and resident review (PASARR) process, particularly with respect to the Level II screening when it results in a finding that a resident would require specialized behavioral health services.

Response: According to § 483.40, LTC facilities are required to provide the necessary behavioral health care and services to residents for those residents to attain or maintain their highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Comment: Some commenters were concerned about LTC facilities being confused with Institutions for Mental Diseases (IMDs) or Institutions for Individuals with Intellectual Disabilities (IIDs). The primary focus of the regulatory design for LTC facility was based on meeting the nursing and/or medical needs of residents. While the commenters noted that we have progressed to a more holistic, person-centered approach, LTC facilities continue to lack the capability in terms of specialized staffing, access to resources and specialized care, and the overall character of their population, to provide the appropriate care for residents with serious mental disorders or who require long-term and intensive psychotherapy. Commenters also pointed out that there is a provision for mental health services under the Medicaid program that prohibits federal financial participation (FFP) to centers for services rendered in LTC facilities that CMS finds qualify as an IMD. Commenters described the criteria used to determine if a facility is an IMD, including whether more than 50 percent of the residents need to be in an institution as a result of a mental disorder and an unusually large proportion of the staff has specialized psychiatric/psychological training.

Response: The requirements in § 483.40 Behavioral health, as well as the other requirements on staffing finalized in this rule, do not require any LTC facilities to admit any resident for whom the facility cannot provide appropriate care. According to the requirements in this final rule, facilities must perform a facility assessment, which includes both their resident population and the resources the facility needs to care for their residents. The facility must then provide those resources, including the sufficient number of staff with the appropriate competencies and skill sets, to care for their resident population. We are not requiring that LTC facilities admit residents with behavioral health needs that the facility cannot meet. However, the facility must provide the appropriate care for the residents it does have.

Dementia

Comment: Some commenters were very concerned about the proposed rule not having specific requirements that addressed dementia. Some noted that the word dementia was not even included in the behavioral health section; however, the preamble implies that the proposed regulation would apply to residents with diagnoses such as dementia and Behavioral and Psychological Symptoms of Dementia (BPSD). They insisted that nothing was more central to the purpose of LTC facilities than providing good care to individuals with dementia. Dementia is increasing among LTC facility residents and two-thirds of those dying with dementia are dying in LTC facilities. They also noted that consumers and advocates have said that the quality of care that is provided in LTC facilities to residents with dementia is frequently poor and these residents are often chemically restrained and deprived of needed care and not treated with dignity. These commenters believed that establishing standards for dementia care in LTC facilities is a necessity. Some of these commenters recommended that there be a separate section and new standards for dementia care. Other commenters recommended adding a requirement to § 483.40(b)(1) stating, ''[a] resident whose assessment reveals a history of or potential for dementia-related behavior receives appropriate

care and interventions to prevent or de-escalate dementia-related behaviors.'' Some commenters recommended that we incorporate into the requirements the guidance on dementia contained in the survey and certification letter, ''Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309—Quality of Care and F329—Unnecessary Drugs'' (S&C: 13–35–NH) that was published on May 24, 2013.

Response: We believe and intended that dementia be included in our requirements that address behavioral health. However, we understand the commenters' concerns regarding the lack of specific requirements concerning the care of residents with dementia. The survey and certification letter recommended by some of the commenters (S&C: 13–35–NH) does contain valuable guidance for LTC facilities concerning care for their residents with dementia. However, we did not propose specific requirements for the care of residents with dementia. We believe that this would require more research and discussion than we have completed at this time. However, we will retain these comments in case there is future rule-making concerning dementia. At this time, we can specifically include dementia as a condition that the facility must address. Thus, we have inserted at § 483.40(b)(3), the following, ''[a] resident who displays the signs of or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.''

Comment: Some commenters were concerned about the burden associated with these requirements. Some commenters were concerned about imposing additional reporting and documentation requirements. Others were concerned about whether facilities would need to ensure expanded access to outside professional behavioral health services, which are costly and already difficult to access in rural and geographically underserved areas. Some commenters also noted that facilities would incur potentially significant cost to provide required behavioral health training to their entire staff under the proposed § 483.95(i).

Response: We do not believe that the costs associated with the behavioral health services requirements are burdensome for LTC facilities. In the previous requirements, § 483.25 ''Quality of care,'' LTC facilities were already required to ensure that, ''[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.'' In addition, concerning mental and psychosocial functioning, facilities were already required to ''ensure that—(1) [a] resident who displays a mental disorder or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem; and (2) [a] resident whose assessment did not reveal a mental disorder or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable'' (former § 483.25(f)). Hence, LTC facilities should already be complying with many of the requirements in this rule and that should reduce the costs associated with complying with these requirements.

After considering the comments, we are finalizing as proposed, with the addition of the definition for ''behavioral health.''

O. Pharmacy Services (§ 483.45)

The LTC requirements regarding pharmacy services were located at § 483.60. We proposed to relocate these provisions to § 483.45. Section 483.60(c) required a pharmacist to perform a drug regimen review (DRR) for each resident at least once a month. At § 483.45(c)(2), we proposed that the pharmacist be required to review the resident's medical record concurrently with the DRR when: (1) The resident is new to the facility; (2) a prior resident returns or is transferred from a hospital or other facility; and (3) during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug the QAA Committee has requested be included in the pharmacist's monthly drug review. The previous LTC requirements at § 483.25(l)(2) specifically identified antipsychotic drugs and provided specific safeguards for their use. We proposed to re-designate these requirements to § 483.45(e) and at § 483.45(c)(3) to expand the drugs to which § 483.45(e) applies to include psychotropic medications (anti-psychotic drugs are included in the definition of psychotropic drugs). We proposed to use the definition of psychotropic drug used in the November 2001 OIG report, ''Psychotropic Drug Use in Nursing Homes'' (OEI–02–00–00490), which is a drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (1) Anti-psychotic, (2) anti-depressant, (3) anti-anxiety, (4) hypnotic, (5) opioid analgesic, and (6) any other drug that results in effects similar to the drugs listed above.

The previous LTC requirements also required the pharmacist who conducted the monthly DRR to report any irregularities to the attending physician and the director of nursing. The term ''irregularities'' was not previously defined in the regulation and no examples were given. We proposed at § 483.45(c)(4) to define ''irregularities'' as including, but not limited to, the use of any drug that meets the criteria set forth in proposed paragraph (d) for an unnecessary drug. In addition, previously the pharmacist performing the monthly DRR was required to report any ''irregularities'' to the attending physician and the facility's director of nursing, and that these reports must be acted upon.

We proposed that the medical director be added to the individuals who should be notified of irregularities identified by the pharmacist during the residents' DRRs. We also proposed that the pharmacist create a written report that is dated, and contains, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. To ensure that the reported irregularities are acted upon, we also proposed that the attending physician must document in the resident's medical record that he or she has reviewed the report of the identified irregularity and what, if any, action has been taken to address it. If there is to be no change in the medication for which an irregularity was identified, the attending physician should document his or her rationale in the resident's medical record.

The current description of ''unnecessary drugs'' and the specific requirements for antipsychotic drugs are set forth in § 483.25(l)(1) and (2), respectively, under the ''Quality of Care'' condition of participation. We proposed to relocate these requirements from § 483.25 ''Quality of Care'' to proposed § 483.45 ''Pharmacy services.''

In addition, we proposed at § 483.45(e)(3) that LTC facilities ensure that residents would not receive psychotropic drugs pursuant to a PRN order unless that medication was necessary to treat a diagnosed specific condition that was documented in the clinical record. In addition, at § 483.45(e)(4), we proposed that every PRN order for a psychotropic drug be limited to 48 hours and not be

continued beyond that time unless the resident's primary care provider, for example, his or her physician, documented the justification for this continuation in the resident's clinical record.

General Comments

Comment: Some commenters were generally supportive of the proposed requirements for pharmacy services. One commenter said the section strengthened the role of both the physician review and accountability in regards to psychotropic medications and added additional oversight by the pharmacists. One commenter believed CMS already had, and had used, its authority to enforce requirements concerning unnecessary drugs and inappropriate drug use.

Response: We thank these commenters for their support for the proposed requirements for pharmacy services. Although CMS already exercises its authority to regulate the use of unnecessary and inappropriate drugs, we believe that the requirements finalized in this rule will strengthen the protections for residents concerning pharmacy services and improve our oversight of the drugs used in LTC facilities.

Comment: Some commenters believed that our proposals were insufficient to protect residents from the inappropriate use of psychotropic medications or otherwise questioned the value of the proposals. Some commenters also recommended additional provisions, such as informed consent from the resident or resident representative prior to administering any psychotropic or anti-psychotic drug. Another commenter believed that LTC facility resources would be better spent on enforcing and reinforcing existing requirements, combined with an intensified focus on some of the key underlying reasons for problematic prescribing and use of medications (including medication-related problems during care transitions and acute changes of condition), regardless of the medication category or underlying medical condition.

Response: We believe the requirements finalized in this rule strengthen the protections for residents from the use of inappropriate drugs. For example, the finalized requirements for the monthly DRRs, which include a requirement that each resident's medical record be reviewed in conjunction with the monthly DRR, should result in more frequent and thorough reviews of residents' drug regimens. Please see the section on DRRs below for further explanation. The requirement to copy the facility's medical director on the report of irregularities, in addition to the attending physician and the facility's director of nursing, should result in medical directors becoming more aware of, if not involved in, the residents' medication management. Requiring the attending physician to document his or her review and action taken with respect to any identified irregularity should ensure that the irregularity is reviewed, and that medication errors and potential adverse events related to medications are minimized. Expanding the requirements for antipsychotic drugs to psychotropic drugs will expand protections for residents prescribed drugs that have an increased potential for being prescribed inappropriately or for reasons other than the resident's benefit, such as for the purpose of a chemical restraint.

Comment: One commenter disagreed with our proposals regarding pharmacy services because the proposals did not address the root cause of the medication issues in LTC facilities. The commenter stated that most medication management and related issues emanate from shortcomings in the care delivery process and clinical reasoning and diagnosis. They said that the proposed changes would only create another ''silo'' by reorganizing more requirements into the Pharmacy Services requirement. Since implementation is the primary challenge, the commenter stated that everyone's time and effort would be better spent in enforcing and reinforcing existing requirements, combined with an intensified focus on some of the key underlying reasons for problematic prescribing and use of medications (including medication-related problems during care transitions and acute changes of condition), regardless of the medication category or underlying medical conditions. They believe that the most effective approach would be to focus all providers and practitioners on a thorough evaluation of each resident to establish a clinically valid rationale for all current treatments, and to effectively use existing requirements and surveyor guidance to look for evidence of appropriate clinical care, documentation, and implementation.

Response: The ''Pharmacy Services'' requirements are a part of a comprehensive update of the long-term care requirements. As finalized, we believe all of the requirements in this rule, including the ''Pharmacy Services'' section, will work together to protect the residents' rights and improve the quality of care they receive in LTC facilities. For example, the pharmacist must do a medical record review when the resident is taking an antibiotic or any drug the facility's QAA committee has requested be included in the monthly DRR (42 CFR 483.45(c)(2)(iii)). Reviewing the medical record concurrently with the MAR or other list of current medications during the monthly DRR if the resident is taking an antibiotic supports the infection control program, especially the antibiotic stewardship program (§ 483.80(a)(3)). Since the QAA committee coordinates and evaluates QAPI activities under the QAPI program, the pharmacist reviewing the medical record for those residents taking a drug identified by the QAA committee also contributes to QAPI activities. Thus, the requirements finalized in this rule should work together to address the care delivery process and promote improved clinical care for the residents.

Comment: Some commenters were concerned that the pharmacy services requirements appeared to place the primary responsibility for medication management, especially for antipsychotic or psychotropic drugs, on the pharmacist. They argued that other disciplines, especially prescribers and nursing, have the primary accountability for the residents' drug regimens. One commenter also noted that while the consultant pharmacist and the IDT provide input to the prescriber, it is the prescriber, not the consultant pharmacist, who determines which medications are appropriate, based on the resident's clinical condition, goals of care, and the risks, benefits and alternatives to specific medications.

Response: It is the physician or the prescribing practitioner who is responsible for prescribing medication. Nurses also bear the responsibility for the medications they administer to residents. Hence, we disagree with commenter that the proposed requirements place the primary responsibility for medication management on the pharmacist. The pharmacist is performing a DRR designed to identify irregularities, which is within their scope of practice. When the pharmacist identifies an irregularity, he or she is identifying a medication that they believe presents an issue that needs to be addressed. However, it is not the pharmacist but the attending physician who would review the identified irregularity and the resident's medical record and then determine if there should be any change to that medication. Thus, the resident's medication regimen is the responsibility of the physician or the prescribing practitioner, not the pharmacist.

Comment: Some commenters were concerned that the proposed requirements were intended to have an overall chilling effect on the prescription of psychotropic drugs in LTC facilities. One commenter asserted that the proposed requirements established a default position that basically psychotropic drugs were not to be prescribed and, if a resident was on one of these drugs, the facility was to do everything it could to get the resident off the drug. This could result in anti-psychotic and other psychotropic medications not being prescribed even when they are appropriate and needed for the resident's health and for their benefit.

Response: As we said in the proposed rule, ''[w]e want to emphasize that the proposed requirements concerning psychotropic medications are not intended to have a chilling effect or in any manner discourage the prescription or use of any medication intended for the benefit of a resident who has been diagnosed [with] a specific condition that requires these medications. Our proposed requirements are intended to protect LTC facility residents from drugs that are not being prescribed for their benefit'' (80 FR 42204). In addition, as described below, we have not finalized all of the requirements as proposed. As discussed below in responses to comments, we have made modifications in this proposed rule in response to such comments. We do not believe that the requirements finalized in this rule are so burdensome that any practitioner should be discouraged from using any psychotropic medication when it is appropriate for the resident and is being prescribed for the resident's benefit.

Comment: Some commenters were concerned about reorganizing these requirements from the quality of care section to the pharmacy services section. They believed this created the impression that antipsychotic or other psychotropic drugs were not a matter for quality of care or a fundamental human right. They also expressed concerns about how this reorganization would affect the surveyor's ability to be able to extend surveys due to a finding of substandard care. Some commenters wanted the pharmacy requirements retained in the quality of care section. They believed that only requirements related to procedures, staff, credentials, and so forth should be included in the pharmacy services requirements. They were also concerned that it would create an undesirable ''silo''.

Response: We acknowledge that there will need to be changes in the survey process due to some of the changes encompassed in this final rule. However, any changes to the survey process will be managed through sub-regulatory guidance. We disagree with the commenters regarding the reorganization. As we explained in the proposed rule, we believed that there needed to be improvements in the overall readability and logical order of the requirements (80 FR 42178). We believe that the requirements in the pharmacy services sections should logically be grouped together and their new location makes them more accessible, especially to individuals who are not familiar with the requirements.

Comment: One commenter recommended that the pharmacy services section be re-written to specify the goal and purpose for the use of psychotropic medications. They suggested that we specify in the requirements that the goal of caring for individuals with cognitive impairment is to limit the use of psychotropic medications. They recommended that the classes of medications along with exceptions or drugs in those classes to which the requirements should not apply, be included in the sub-regulatory guidance.

Response: The goal or purpose of the requirements finalized in this rule is not to limit the overall amount of psychotropic drugs used by the facility or to supplant the judgment of a physician or other prescribing clinician concerning the use of psychotropic medications. As stated above, the purpose of these requirements is to ensure that residents receive psychotropic drugs only when these medications are appropriate and intended for the resident's benefit. These requirements are intended to decrease, and hopefully eliminate, inappropriate psychotropic drug use and the use of medications for reasons other than the resident's benefit.

Drug Regimen Reviews

Comment: Some commenters approved of the proposed requirements concerning drug regimen reviews (DRRs), especially the requirement for periodic review of residents' medical records and monthly reviews when the resident is taking certain medications or during transitions in care. One commenter believed that requiring a medical record review for residents taking drugs identified by the QAA Committee was a good idea. However, some commenters recommended that the requirements be strengthened by requiring the concurrent review of each resident's medical record during the monthly DRRs. Another commenter wanted to require that all residents have their medical records reviewed during the DRR at least quarterly, instead of every six months. Another commenter supported the proposed requirements for reviewing the medical record in conjunction with the DRR under the proposed circumstances; however, the commenter also noted their concern about polypharmacy. Some commenters even stated they believed that a DRR by definition implies review of the resident medical record. This would enable any issues with the resident's medications to be identified sooner.

Response: After reviewing the comments we received concerning the proposed requirement for the pharmacist to review residents' medical records in conjunction with the monthly DRR under certain specific circumstances, we agree with the commenters that the pharmacist should review each resident's medical record during every monthly DRR. We also agree with the commenter that expressed concern over the large number of drugs that many residents are being prescribed or polypharmacy. In addition, we agree that reviewing the medical records for all residents with each monthly DRR would likely identify irregularities sooner. Identifying irregularities sooner could assist in preventing adverse medication reactions and aid in earlier identification of medication issues. Requiring that the pharmacist review the medical record for each resident during his or her monthly DRR provides residents with protection from inappropriate drug use without being burdensome for the facility. Thus, we will not be making the commenters' recommended changes to require monthly or quarterly review of medical records in conjunction with the DRR, but modifying § 483.45(c)(2) by requiring that the monthly DRR include a review of the resident's medical record.

Comment: Some commenters were concerned about situations in which there is no action concerning an irregularity identified by the pharmacist during the DRR. Some commenters recommended a requirement for the pharmacist to report the irregularity and the lack of any action concerning that irregularity to an outside authority, such as the state's office of the long-term care ombudsman, state licensing authority, or CMS, if the pharmacist's believes that the irregularity detected requires action.

Response: While we appreciate the commenters' concerns for residents, we do not believe that it is appropriate to require pharmacists to report to an outside entity if they do not agree with the action or lack of action taken by the attending physician or other prescribing

practitioner. The attending physician is notified of the irregularity, as well as the facility's medical director and director or nursing. It is the attending physician's responsibility to review the identified irregularity and take any action, or no action, based upon his or her professional judgment. If there is no action and either the facility's medical director or DoN has questions or disagrees, we would expect that either or both of these individuals would follow-up with the attending physician. Unless specifically allowed under the relevant state law, it is outside the scope of practice for pharmacists to prescribe medication. The appropriate action to take after an irregularity is identified is the responsibility of the attending physician. However, we do believe that the resident's medical record should demonstrate that the attending physician has reviewed the identified irregularity and what, if any, action was taken. If no action was taken, the medical record should indicate why no action was appropriate. Thus, we have finalized § 483.45(c)(4)(iii) that requires the attending physician to document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

Comment: Some commenters wanted there to be more transparency with the monthly DRR process. They recommended that the report of irregularities become part of the resident's medical record. Another commenter wanted the resident or the resident's representative to be notified of the irregularity.

Response: According to the SOM, Appendix PP-Guidance to Surveyors for Long Term Care Facilities (Rev. 149, 10–09–15), the pharmacist's findings are part of each resident's active medical record. These findings should be maintained in the resident's medical record or in the facility where it is readily available for review. According to proposed § 483.10(f)(3), finalized at § 483.10(g)(2), the resident has the right to access any medical record that pertains to him or herself. Thus, the pharmacist's findings are already available to the resident or the resident's representative. However, we decline to require that the resident or their representative be notified of the pharmacist's findings. The irregularity identified by the pharmacist may require no action, updating or modifying documentation, or some other action that does not affect the quality of care for the resident. Unnecessary notifications could lead to confusion and anxiety for the resident. We believe that it is the responsibility of the attending physician to determine whether to notify the resident or their representative. In addition, each facility could also make that determination and address notification of the resident and the resident's representative in the policies and procedures for the DRR process that is now required at § 483.45(c)(5).

Comment: Some commenters expressed concerns over various aspects of the DRR. Some were concerned about the absence of timeframes concerning how much time the pharmacist should have after discovering an irregularity to submit a report of irregularities to the attending physician, medical director, and the director of nursing or how long the facility or attending physician has to take action on any identified irregularities. In addition, some commenters were concerned there were no requirements related to what a pharmacist should do if he or she believed the identified irregularity required urgent or emergency action to protect the resident. Some commenters also recommended that there be designated circumstances or triggers for an emergency review. One commenter proposed that the supervising or attending nurse should be able to request an emergency medical records review from the pharmacist for residents taking psychotropic drugs upon observation of adverse side effects, significant changes in the resident's condition, the absence of a diagnosis of a major mental disorder in the medical records, or the presence of a primary diagnosis of Alzheimer's Disease or another form of dementia. If the irregularity involved the inappropriate use of psychotropic drugs, the facility should be required to take immediate steps to gradually reduce the drug and implement behavioral intervention with the goal of discontinuing the use of the drug as soon as it is safe and practicable. Other commenters were concerned about the increased documentation required by physicians, especially in cases where physicians might have to repeatedly document rationales for the same medications for the same residents after a pharmacist noted the medication on the report of irregularities. These commenters recommended that accommodations be made in cases where there had been previous irregularities noted for the same medication for a particular resident and even provided specific language for the regulatory text. Other commenters recommended that the facilities have policies and procedures that cover different aspects of the DRR process.

Response: We agree with the commenters that LTC facilities should have policies and procedures concerning the monthly DRR, including appropriate time frames. We also agree that pharmacists should have a procedure to follow so that the appropriate individuals are notified if the pharmacist believes that an irregularity needs to be reviewed immediately due to the potential for harm to a resident. However, we do not believe that we should establish those time frames. We believe that each facility should establish policies and procedures that address the entire DRR process, especially the timeframes for various actions in the process and a procedure for a pharmacist to follow when he or she believes the irregularity must be addressed immediately due to the potential for harm to the resident. We disagree with the commenter that recommended that the attending or supervising nurse be able to request that the pharmacist perform an emergency DRR for a resident under certain circumstances or, if the drug in question is a psychotropic, institute gradual dose reductions (GDRs). The facility should have its own policies and procedures for the nurse if she or he is concerned about any medication order. We generally believe that the nurse, not the pharmacist, should be contacting the attending physician or the prescribing practitioner if there are any questions concerning the safety or appropriateness of a medication for a resident.

We also agree with the commenter that physicians should not be required to repeatedly document the same rationale in the resident's medical record, once a clinically acceptable rationale is already documented in the medical record for a specific medication. However, we believe that each facility should have the flexibility to determine the best manner in which to handle this situation. We encourage facilities to address this situation in their policies and procedures concerning the monthly DRR. Concerning the other recommendations, we believe that each facility needs the flexibility to determine how the monthly DRRs will be conducted and how the facility will comply with the requirements in this final rule. Thus, in this final rule we are adding a requirement at § 483.45(c)(5) that the facility must establish and maintain policies and procedures that addresses the monthly DRR, including but not limited to, timeframes for the various steps in the process and procedures a

pharmacist is to take when he or she believes immediate action is required due to potential harm to the resident.

Comment: One commenter disagreed with the amount of detail and specificity in the requirements for the DRR. They also did not believe the regulatory text was sufficiently flexible to accommodate likely changes related to medication usage without modification. One commenter stated that with the increasing adaptation of e-prescribing real time reviews will become more frequent. With these types of reviews, some of the pharmacy requirements will become outdated. They recommended more general language, such as that in the preamble. They suggested we amend § 483.45(c)(2) to read: ''[t]his review must occur on a regular basis including more frequent targeted reviews for medications that may be associated with an increase of adverse events or overutilization as well as when the resident experiences transitions in care or when requested by the facility.'' Written communication, they believed, did not allow for new and more effective methods of communication. By specifying specific elements, it would not provide for new data elements. Some commenters also argued that there was too much specificity concerning when the medical record review must be done in conjunction with the DRR.

Response: We do not believe that the preamble language cited by the commenter would be appropriate for the regulatory text. The regulatory text must be specific enough to inform the facility of what activities are necessary to comply with the requirement. While it may be appropriate under certain circumstances to use more general language such as that suggested by the commenter, we do not believe it is appropriate for the monthly DRR. The inappropriate use of drugs has the potential to be very dangerous for residents. We believe that there are specific times when the medical chart must be reviewed concurrently with the DRR to ensure a thorough review of the resident's drug regimen and provide the resident with protection from inappropriate drugs. We believe that the requirements are specific enough to clearly indicate what is necessary to comply with the requirement, but flexible enough to allow facilities to decide how to comply. Thus, we have finalized as proposed the requirements for when a pharmacist must review the resident's medical record in conjunction with the DRR and the report of irregularities.

Comment: One commenter was concerned about adding the facility's medical director to the list of individuals to whom the report of irregularities must be forwarded. The commenter noted that by increasing the number of persons the report must be forwarded to, it increased the likelihood of miscommunication and errors. Other commenters wanted the report forwarded to the appropriate prescribing practitioner, not just the attending physician.

Response: We believe that it is crucial that the facility's medical director be notified of any irregularities detected by the pharmacist in the monthly DRRs. The medical director is responsible for the medical care provided in the facility. In addition, as a physician, the medical director is in the best position to discuss the identified irregularity with the attending physician, especially if there are continuing concerns about the medication after the attending physician has reviewed and acted upon the identified irregularity. Concerning the report of irregularities, although the pharmacist is required to forward the report of irregularities to the attending physician and the facility's medical director and director of nursing, this does not preclude the facility from forwarding the report to any other individuals they believe is appropriate, such as a prescribing practitioner.

Comment: Some commenters were concerned about conflicts of interest between the facility and the pharmacists who are conducting the monthly DRR. These commenters wanted us to address the issue of independence for these consulting pharmacists.

Response: Requirements addressing the independence of the consulting pharmacist were not included in the proposed rule. Therefore, we will not address this issue in this final rule. However, we will consider these comments if there is any future rulemaking concerning this issue.

Definition of ''Psychotropic Drug''

Comment: Some commenters supported the proposed definition of ''psychotropic drugs.'' One commenter noted that use of inappropriate psychotropic medications is prevalent in nursing facilities. They indicated that psychotropic drugs are powerful and often given to sedate or control elderly people with behavioral challenges caused by dementia, rather than major mental disorders as defined at 42 CFR 483.102. Thus, these drugs are not being prescribed or administered in accordance with the safeguards set out in the current regulation.

Response: We thank the commenters for their support. We believe that the definition of ''psychotropic drug'' finalized in this rule will not only ensure additional scrutiny when prescribed, but will also enhance the protection for residents from inappropriate use of these and other medications not prescribed for the residents' benefit. However, based upon our review of the public comments, we have made some modifications to the definition as described below.

Comment: Several commenters stated that the proposed definition was so expansive as to make the use of psychotropic drugs unmanageable. The commenters indicated that the proposed definition would also include medications that do not warrant the resident protection safeguards and additional scrutiny required when a psychotropic drug is prescribed for a resident. One commenter recommended we use the term ''psychopharmacological medication'' instead of ''psychotropic drugs.'' One commenter said the new definition was unlikely to improve or correct process problems.

Some commenters were especially concerned about the last part of the definition, ''any other drug that results in effect similar to the drugs listed'' in the previous sections. They believed this was too expansive and included nearly all medications, such as drugs for seizures and Parkinson's disease, NSAIDs, beta-blockers, and eye drops for glaucoma. Another commenter also argued that the proposed definition would include commonly used drugs that do not merit additional scrutiny, such as Compazine, which is used for nausea. Another commenter recommended we define the classes of drugs, but provide exceptions in sub-regulatory guidance.

Response: After reviewing and analyzing the comments, we believe that the definition of psychotropic drugs should be modified. We share the commenters' concerns that the proposed definition for ''psychotropic drugs'' at § 483.45(c)(3) might include many drugs for which the additional requirements in this section would be superfluous and unnecessary. Hence, we have removed the last element in the proposed definition of ''psychotropic drug,'' specifically, ''(vi) Any other drug that result in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section.'' We have also modified the language in § 483.45(c)(3) to read, ''[e]xamples of these drugs, include but are not limited to, drugs in the following categories . . .'' We modified this language to clarify that the definition includes drugs from the four identified categories (anti-psychotic, anti-depressant, anti-anxiety, and hypnotic)

and that CMS has the authority to add other drugs to the definition through sub-regulatory guidance.

Comment: Some commenters support the goal of reducing the use of unnecessary psychotropic medications in long-term care facilities, but were concerned that the proposed requirements, including the drugs included in the definition, were so extensive that it could result in under-treatment of pain and other distressing symptoms and reduce the efficacy of palliative care and the overall quality of life for the residents. They argued that individuals suffering from pain have the right to be informed of, choose, and receive effective pain and symptom evaluation, management, and ongoing monitoring as part of basic medical care, even if such pain and symptom management may result in analgesic tolerance, physical dependence, or as an unintended consequence, shorten the individual's life. They believe that the inclusion of both antidepressants and opioid analgesics in the definition of ''psychotropic drugs'' would inevitably cause LTC facilities to avoid the use of such interventions, because they would be scrutinized as closely as anti-psychotic drugs, which have too often been misused in long-term care settings. The proposed regulation could potentially cause not only under-treatment but also unnecessary hospitalizations due to necessary medication not being prescribed or lapses in prescriptions due to limitations on PRN prescriptions of psychotropic drugs. One commenter stated it would be difficult to survey facilities consistently, using that definition.

Response: We agree with the commenters that the proposed definition of ''psychotropic drug'' is too broad. We especially agree with the commenters that objected to including opioid analgesics in the definition. We are particularly concerned about the possibility that including opioid analgesics in the definition could result in negative consequences for pain management, especially since they are usually given PRN and there could be interruptions in the prescriptions due to the proposed limitation on PRN prescriptions. Therefore, we have removed the drug category of ''opioid analgesics'' from the finalized definition of ''psychotropic drug.'' Although we have not removed anti-depressants from the definition, we have made modifications to the PRN limitation that we believe addresses the commenters' concerns, which are discussed below.

Although we are not finalizing ''opioid analgesics'' in the definition of ''psychotropic drug,'' it is not our intention to in any way to either diminish the importance of these drugs in the alleviation of pain nor the serious consequences of their inappropriate use. Opioid abuse is a serious public health issue with devastating consequences. Currently, the United States is in the midst of a prescription opioid overdose epidemic. According to the Centers for Disease Control (CDC), in 2014, more than 28,000 people died from opioid overdose, and at least half of those deaths involved a prescription opioid. Many more became addicted to prescription and illegal opioids.[1] Overall, overdose deaths from opioids, including prescription opioids and heroin, have nearly quadrupled since 1999.[2] In response to this crisis, HHS has made addressing the opioid epidemic a top priority.

HHS continues to build upon current efforts to combat the opioid abuse epidemic, including continuing to help health professionals to make the most informed prescribing decisions by:

- Teaching medical professionals how and when to prescribe opioids by working with lawmakers on bipartisan legislation requiring specific training for safe opioid prescribing and establishing new opioid prescribing guidelines for chronic pain;
- Supporting data sharing for safe prescribing by facilitating prescription drug monitoring programs (PDMP) and health information technology integration and further adoption of electronic prescribing practices;
- Increasing investments in state-level prevention interventions, including PDMPs, to track opioid prescribing and support appropriate pain management.

In addition, HHS supports efforts that encourage the increased use of naloxone, which reverses potentially fatal overdoses caused by opioids, and expand the use of Medication-Assisted Treatment (MAT), which combines behavioral therapy and medications to treat substance use disorders. In addition, we strongly encourage prescribing practitioners to follow CDC guidelines for prescribing opioids for chronic pain. The CDC guidelines provide recommendations which focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. The CDC guidelines are available at the following Web site: *http://www.cdc.gov/drugoverdose/prescribing/guideline.html*. We note that additional information and guidance on the CDC guidelines, as well as guidance on how practitioners can help to combat opioid abuse, will be included in the sub-regulatory interpretive guidance, which will be available after the publication of this final rule.

We believe that the requirements we have finalized in this rule provide residents with the protections they need from the inappropriate use of drugs, including opioids. However, we will continue to assess the opioid epidemic and will consider whether to propose additional requirements for providers in future rulemaking.

Comment: One commenter said that good medical practice requires that all issues and conditions be viewed and managed in the proper context, and not as isolated conditions or risks. Singling out certain topics actually limits and reverses the current requirement, because it distracts attention from other equally or more important issues. Facilities learn only to address those medications that are on the radar screen, resulting in problematic use of many medications that are not under intense scrutiny.

Response: The pharmacy services requirement at § 483.45 in this final rule addresses all medications. Although any drug could be used inappropriately, we believe that certain medications, such as psychotropic drugs, do have more potential for inappropriate use. Such drugs also merit additional scrutiny for the protection of the residents. Hence, we are finalizing the requirements related to psychotropic drugs, as modified by this rule.

Comment: One commenter recommended that instead of the proposed definition of psychotropic drug and the PRN limitation, CMS should instead take steps to develop palliative care quality indicators focused on assuring that the care received is in accordance with resident and family priorities.

Response: We did not propose the development of palliative care quality indicators in the proposed rule. This comment is beyond the scope of this rule. However, we will keep this comment in mind if there is future rulemaking on this issue.

Comment: Some commenters stated that while psychotropic drugs are a problem in LTC facilities, they opposed including anti-psychotic drugs. They argued that combining anti-psychotic drugs into a new category called

[1] Centers for Disease Control and Prevention. *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014.* MMWR 2015; 64;1–5.

[2] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at *http://wonder.cdc.gov*.

psychotropic drugs dilutes or takes attention away from anti-psychotic drugs, which are harmful and deadly when given to most LTC facility residents, who have dementia but no psychosis. There is less evidence that other psychotropic drugs are as frequently prescribed inappropriately or are as harmful for LTC facility residents. Some suggested that the current requirements for anti-psychotic drugs be maintained or expanded and that a separate section for psychotropic drugs be finalized. One commenter supported expanding the definition of drugs of concern, but also supported continued collection of data specific to anti-psychotics. Some expressed the belief that the proposed requirements actually diminished or reduced the focus on antipsychotic drugs.

Response: We do not believe that expanding the requirements that previously only applied to anti-psychotic drugs to all psychotropic drugs would diminish or dilute the attention given to antipsychotic drugs. Antipsychotic medications are included in the definition of ''psychotropic drugs,'' and are a focus for CMS. Since 2012, CMS has partnered with other federal and state agencies, LTC facilities, other providers, advocacy groups, and caregivers to form the ''National Partnership to Improve Dementia Care in Nursing Homes'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*, accessed December 30, 2015). The initial focus of this partnership was to encourage reduction in the use of anti-psychotic medications. Since the launch of this initiative, there have been significant reductions in the use of anti-psychotic medications in LTC facilities. For specific information on the National Partnership to Improve Dementia Care in Nursing Homes, see their Web site that can be accessed at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*. We also disagree with the commenter that other medications should not receive the same scrutiny as anti-psychotic drugs. However, we do agree that anti-psychotics do merit more scrutiny under some circumstances. Anti-psychotic drugs continue to be a particular concern for us due to the serious side effects, including death, to elderly residents. In response to comments, we have modified the general PRN limitation on psychotropics specifically with respect to anti-psychotic drugs, which is discussed below. We are finalizing the definition of ''psychotropic drugs'' to include four specific categories of drugs, including anti-psychotic drugs.

Comment: Some commenters expressed concern that the proposed pharmacy services requirements do not include sufficient protection against antipsychotic and psychotropic medications being used as chemical restraints. They noted that there are epidemic levels of chemical restraints in LTC facilities. They also expressed their belief that there was likely underreporting of the residents who were being given antipsychotic drugs, despite the significantly increased risk of death from these drugs. Some commenters recommended a new section, which would specifically address chemical restraints and the unnecessary use of psychotropic drugs and one commenter suggested the regulation be based on a proposed rule published in 1992 by HHS (''Medicare and Medicaid Programs: Omnibus Nursing Home Requirements'', 57 FR 4516, February 5, 1992). Some commenters also recommended that the final regulation establish a presumption that chemical restraints are harmful, require written informed consent before the use of psychotropic drugs, strengthen rather than diminish focus on misuse of anti-psychotic drugs, require physicians to both examine residents before prescribing antipsychotic drugs and justify that the potential benefits clearly outweigh the potential harmful effects. Another commenter expressed concerns about the current enforcement of the right to be free from chemical restraints by the state survey agencies and CMS. A commenter wanted to define ''chemical restraint'' as the unnecessary use of a psychotropic drug.

Response: Residents have the right to be free from chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms, as already specified in § 483.12. We do not believe that a separate section on chemical restraints is necessary. We also believe that the special requirements previously imposed on anti-psychotics should be applied to psychotropic medications to protect residents from inappropriate use, especially to ensure that these medications are not used as chemical restraints and are only used for the benefit of the resident. In addition, we do not believe that it would be appropriate to characterize the unnecessary use of a psychotropic drug as a chemical restraint. Concerning the proposed rule published by HHS in 1992, we reviewed that rule during our research for this proposed rule (80 FR 42168). We did not re-propose some of the requirements in the 1992 proposed rule because we believed they were too prescriptive. We do not agree that the unnecessary use of a psychotropic drug should be defined as a ''chemical restraint.'' Some psychotropic drugs could be used unnecessarily or have some other type of irregularity associated with their use, and this would still not be considered a chemical restraint. For example, a facility could fail to properly monitor a resident who is taking a psychotropic drug; however, if this is the only irregularity, its use would not qualify the drug as a chemical restraint.

Specific Requirements Related to Psychotropic Drugs

Comment: Some commenters were concerned about the requirement for gradual dose reductions (GDRs) and behavioral interventions for all psychotropic drugs. Commenters argued that GDRs are not appropriate for many residents on psychotropic drugs. The commenters argued that GDRs are not appropriate for, among others, residents with mental disorders who are stable on their current drug regimen, such as residents diagnosed with depression, schizophrenia or bi-polar disorder or residents with seizure disorders. Another commenter stated that the term ''behavioral interventions'' is dated and misleading. One commenter recommended a broader requirement that ''[n]ursing homes should be required to use individualized care, services, attention and environmental modifications that are directed specifically towards the elimination or modification of the symptoms and distress for which the drugs are prescribed.'' Another commenter questioned why the proposal assumed that any psychotropic drug started prior to admission to the LTC facility was appropriate and did not require the documentation but that all of them would need a GDR along with behavioral intervention, unless contraindicated.

Response: We agree with the commenters that GDRs are not appropriate for all residents taking psychotropic drugs. Based upon the comments, it is apparent there was confusion about this proposal. The requirements finalized in this rule are intended to reduce the inappropriate use of psychotropic drugs and the use of these drugs for reasons other than the resident's benefit. This is consistent

with one of the central themes of this final rule, which is person-centered care (see § 483.21). For many residents, psychotropic drugs are clearly appropriate to address a diagnosed disorder, necessary for their health, and prescribed for their benefit. For those residents taking psychotropic drugs, we expect that each resident would be evaluated by their attending physician to determine whether GDRs and behavioral interventions for a psychotropic drug are clinically contraindicated. If GDRs and behavioral interventions for a particular psychotropic drugs are clinically contraindicated, the physician should document that in the resident's medical record. Many of the examples provided by commenters would likely be determined to clinically contradict GDRs and behavioral interventions. For example, a resident who is taking an anti-anxiety or anti-depressant medication for a diagnosed condition and who was prescribed the medication for their benefit and who is stable would likely not need these interventions. Otherwise, we would expect that the attending physician, in conjunction with the IDT (§ 483.21((b)), to consider GDRs and behavioral interventions and institute a plan that is appropriate for that resident. For that reason, we are finalizing as proposed the requirement for GDRs for residents taking psychotropic drugs, ''unless clinically contraindicated'' (§ 483.45(e)(2)).

Concerning the recommendation that we not finalize the term ''behavioral interventions,'' we note that facilities may use any terminology they choose to describe these activities; however, we believe that behavioral interventions is a commonly used term that is universally understood. Thus, we have finalized this requirement using the term ''behavioral interventions.''

We disagree with the commenter that said our proposal assumed that any psychotropic drug prescribed prior to admission to the LTC facility was appropriate and did not require the same documentation. Section 483.45(e) requires that residents who have not used psychotropic drugs not be given those drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record, but that all resident who received psychotropic drugs receive GDRs and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. This requirement does not assume that psychotropic drugs that were prescribed prior to admission are appropriate. It is intended to ensure that residents are not put on psychotropic drugs without there being a diagnosed and documented condition for which they are appropriate. Then, all residents who are on psychotropic drugs must then receive the GDRs or behavioral interventions, unless they are clinically contraindicated, as discussed above.

Comment: One commenter recommended that psychotropic drugs should only be administered to a resident after the facility obtained informed consent from the resident or their representative.

Response: We have finalized the requirement for comprehensive person-centered care planning, which requires that the participation of the resident and the resident's representative, to the extent practicable (§ 483.21(b)). The resident and their representative should be involved in the resident's care. We believe that requiring a separate informed consent solely for psychotropic drugs would be burdensome for the facilities and unnecessary. It could also interfere with the resident's care if the resident needs a psychotropic drug urgently.

Comment: One commenter recommended that we require that psychotropic medications be used for FDA-approved conditions without limitations. We understand this to mean that the commenter wants to have psychotropic medications used only for the conditions set out in the medication's FDA approval. Alternatively, they suggested we change the language to either define ''antipsychotic use in dementia'' or ''psychotropic in dementia to treat'' whatever condition or disorder the drug is intended to treat the resident.

Response: We do not believe that the additional language recommended by the commenter is necessary. In addition, restricting the ability of health care practitioners to prescribe medication for uses other than those that have received FDA approval could violate the prohibition against interference with the practice of medicine at section 1801 of the Act.

Comment: Some commenters were concerned about the effects these requirements could have on the facility. Another commenter was concerned that with such an increase in documentation requirements, some LTC facilities could unintentionally be out of compliance, with our requirements, resulting in a cascading sequence of penalties. The additional time and resources to correct any non-compliance would take away from resident care.

Response: We believe that the requirements in this final rule are reasonable and necessary. We also believe that these requirements are not overly burdensome for the LTC facilities. Additional sub-regulatory guidance to assist LTC facilities in complying with the requirements in this final rule will be provided after this final rule is published.

Limitations on PRN Prescriptions of Psychotropic Drugs

Comment: Many commenters were concerned about the 48 hour limitation on PRN prescriptions for psychotropic drugs. One commenter wanted to prohibit PRN orders for all anti-psychotic drugs. The commenter stated that physicians should not delegate the responsibility for PRN order for psychotropic drugs to the nursing staff. They believed that it was inappropriate to have the nursing staff determine when and for how long anti-psychotics and other psychoactive drugs were to be administered to a resident.

Response: Based upon our own experience with LTC facilities, as well as other comments, there are situations in which PRN prescriptions for psychotropic drugs are appropriate for residents. Some residents may require a therapeutic trial to determine if a particular medication addresses the diagnosed disorder and what the correct dosage should be. In addition, some residents may only require a psychotropic drug for intermittent symptoms. We are also concerned that prohibiting PRN prescriptions for psychotropic drugs could result in either overmedication from physicians prescribing these drugs on a specific schedule when a PRN order would be appropriate or under medication from physicians not prescribing drugs they believe are needed for the resident's health. In addition, we believe that it is appropriate, and within their scope of practice, for nurses to make decisions on when drugs prescribed via PRN orders should be administered, including psychotropic medications. We also believe that prohibiting PRN orders for psychotropic drugs could violate the Act's prohibition against interference with the practice of medicine at section 1801 of the Act. Thus, we will not prohibit the PRN prescription of psychotropic drugs.

Comment: Many commenters stated that the 48-hour limitation on PRN prescriptions for psychotropic drugs could result in serious unintended consequences. Some commenters argued that the 48-hour limitation could be difficult, if not impossible to comply with, especially in rural areas which may have limited access to physicians or other prescribers. Some commenters stated that the physicians or other health care practitioners who covered

their facilities, such as nurse practitioners, not only covered their facilities but also had their own private practices or covered other facilities. By increasing the burden to these providers, it could become more difficult to locate providers who would be willing to provide services in their facilities. Other facilities also noted having limited access to a physician or other health care practitioner who could renew a prescription for a psychotropic drug every 48 hours. Unless the physician was coming to the facility, the nurse would likely have to call the physician and get a verbal order to renew the prescription. Depending upon the number of these prescriptions, this could be time-consuming for both the nurse and the physician. This requirement also does not provide for the physician to assess the resident in person. If the prescription was renewed over the phone, there might be minimal, if any, assessment of the resident before the prescription would be renewed. Commenters indicated that the proposed requirements could also result in more frequent transfers to the emergency room due to interruptions in residents' drug regimens of essential drugs, such as could happen if the resident was on antipsychotic drugs or pain medication. Since it could require longer than 48 hours to assess a resident's response to some medication, such as during therapeutic trial or GDR, this proposed requirement could result in numerous renewals of the same prescription before the physician would have time to reasonably assess whether there should be any change in the prescription. In some cases, physicians might avoid this limitation in cases in which they believe it is not appropriate by writing the prescription for regular intervals when they would otherwise determine that a PRN prescription would be appropriate for a resident. Other commenters suggested a longer timeframe, such as 72 hours or 7 days. One commenter recommended at least 7 days and some commenters recommended CMS delete the limitation on PRN medications entirely. One commenter stated that the current surveyor guidance defines an acute psychiatric situation and allows use of psychopharmacological medications for up to a week before additional documentation is needed. One commenter suggested there be a requirement that facilities develop policies with the medical director and/or medical staff to define the review process for all PRN medications, including timing of the review and documentation expectations. Another commenter recommended an exception for residents who are expected to be in the facility for a short-term, since these residents are expected to return to their primary care providers upon discharge.

Response: We agree with the commenters that our proposal for a 48-hour limitation on PRN prescriptions for psychotropic drugs could result in unintended consequences that could be detrimental to the residents' health in some cases and might also be burdensome for some facilities. In addition, based on our experience with LTC facility residents and comments we received, there are cases in which it is appropriate for a particular drug to be given PRN for a prolonged period of time. For example, some residents could require anti-depressants or anti-anxiety medications long-term but only intermittently based upon the resident's symptoms. As described above, we believe that some of the commenters' concerns have been addressed by the modifications made to the definition of ''psychotropic drugs'' in this final rule, especially by not finalizing opioid analgesics as a category of drugs to be included. However, we continue to be concerned about PRN prescriptions. As we were conducting research for the proposed rule, we became aware of concerns about residents remaining on PRN prescriptions for prolonged periods of time when it might not be appropriate. Based upon comments, we now believe that a 48-hour limitation is overly restrictive and burdensome.

As finalized in this rule, all residents, including those on psychotropic drugs, will have their medical records reviewed by a pharmacist in conjunction with their monthly DRR. This requirement provides additional review, which we believe is beneficial; however, we are concerned that a resident that is, for instance, treated for 30 days with a psychotropic drug, especially on a PRN basis, could be receiving treatment that was inappropriate or detrimental. We proposed a 48-hour limitation on PRN orders of psychotropic drugs to address this concern. However, as noted above, many commenters disagreed with the 48-hour limitation. Some commenters recommended different limitations, such as a 72-hour or 7 day limitation on PRN prescriptions of psychotropic drugs. Another commenter suggested at least 7 days. We are concerned that the recommended 72-hour or 7 day limitation could be detrimental to some residents and still be burdensome for facilities that have limited access to physicians and other prescribing practitioners. When a facility has limited access to physicians and other prescribing practitioners, there could be an interruption in a resident receiving necessary medication due to a PRN prescription expiring before the prescribing practitioner could renew or write another prescription. This interruption could be detrimental to the resident. For example, as one commenter pointed out, an interruption in anti-anxiety medications could result in the resident experiencing withdrawal symptoms. Based on the limited access some facilities have to physicians and other prescribing practitioners and the potential for detrimental effects to residents from interruptions in their medication regimen, we believe the limitation on PRN prescriptions for psychotropic drugs should be longer and agree with the commenter that recommended at least a 7 day limitation. As finalized in this rule at § 483.45(c)(2) all residents will have a pharmacist reviewing their drug regimen monthly. However, a physician is only required to visit a resident at least once every 30 days for the first 90 days after the resident is admitted to the facility and every 60 days after that (42 CFR 483.70(c)). We believe that 30 days is too long for a resident to be on a psychotropic drug on a PRN basis without the physician or other prescriber having to evaluate whether the resident should continue on the subject drug according to the PRN order. Thus, we are establishing a 14-day limitation on psychotropic drugs. By establishing this 14-day limitation, each resident who is taking a psychotropic drug will have his or her prescription reviewed by the physician or prescribing practitioner every 14 days and also by a pharmacist every month. Since there was no previous limitation on PRN prescriptions for psychotropic or anti-psychotic drugs, this will provide residents receiving this type of medication on a PRN basis additional protections against unnecessary drugs, drugs with another type of irregularity, and drugs that might be prescribed for reasons other than the resident's own benefit. We also believe that a 14-day limitation on PRN prescriptions for psychotropic drugs should not be burdensome for facilities. Therefore, we have finalized a 14-day limitation on PRN prescriptions for psychotropic drugs, subject to the exceptions discussed below.

We are also aware that some residents might require psychotropic drugs on a PRN basis for prolonged periods of time. Thus, we have established an exception to this 14-day limitation. For psychotropic drugs that the attending physician believes a PRN prescription

for longer than 14 days is appropriate, the attending physician can extend the prescription beyond 14 days for the resident by documenting their rationale in the resident's medical record. However, we believe this exception would be inappropriate for anti-psychotic drugs. If the attending physician believes that the resident requires an anti-psychotic drug on a PRN basis for longer than 14 days, he or she will be required to write a new PRN prescription every 14 days after the resident has been evaluated. Detailed requirements for this evaluation will be developed in sub-regulatory guidance.

Concerning the recommendation that we require a facility to have policies and procedures regarding PRN prescriptions and the facility's review of these prescriptions, we disagree with the commenters. Facilities need to have the flexibility to determine the policies and procedures they require, consistent with this rule and other sub-regulatory guidance, to manage their facility. We believe that the requirements finalized in this rule are sufficient to provide the scrutiny psychotropic drug prescriptions require to protect residents. However, we encourage facilities to develop their own policies and procedures concerning PRN prescriptions for their facility.

Concerning an exception for short-term residents, we disagree with the commenter. All of the requirements in this final rule, as well as other requirements and sub-regulatory guidance, apply to all residents, regardless of the length of their stay in the facility. Short-term residents deserve the same quality of care and protection of their rights as any other resident in a facility.

Comment: One commenter recommended that LTC facilities be required to draft and complete an Antipsychotic Drug/Dementia Care Compliance Report for each resident taking an antipsychotic drug. The facility would be required to identify the resident's diagnoses, all attempted non-pharmaceutical interventions, consent, and recommendations for, and physician response to, consultant pharmacists' recommendations for gradual dose reductions. These reports would be signed by all members of the IDT, certifying compliance with all federal requirements. Surveyors would then review these as part of the annual survey or any relevant complaint survey.

Response: We believe that the requirements in this final rule provide the necessary scrutiny and protections residents need from inappropriate drug use. We also believe that requiring a separate report, especially with all the requirements suggested by the commenter, would be overly burdensome for some facilities. However, facilities themselves could choose to prepare such reports.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have added § 483.45(c)(5) to require LTC facilities to develop and maintain policies and procedures for the monthly DRR, which include but are not limited to, timeframes for the various steps in the process and procedures a pharmacist must take when he or she believes immediate action is required to protect the resident.
- We have modified the definition of a psychotropic drugs in § 483.45(c)(3) by removing paragraphs (v) and (vi).
- We have modified the limitation for PRN prescriptions of psychotropic drugs by extending the time for PRN prescription to 14 days by modifying § 483.45(e)(4).
- We have added a specific limitation on PRN prescriptions for anti-psychotic drugs by modifying § 483.45(e)(5).

P. Laboratory, Radiology, and Other Diagnostic Services (§ 483.50)

Currently, § 483.75(j) sets forth requirements regarding laboratory services and § 483.75(k) sets forth requirements for radiology and other diagnostic services that a facility must provide or obtain to meet the needs of its residents. These regulations are currently located in § 483.75 ''Administration,'' which largely focuses on the manner in which a facility must operate to provide quality care to its residents. Following the reorganization of subpart B, we proposed to relocate and re-designate both § 483.75(j) and § 483.75(k) to a new § 483.50 entitled, ''Laboratory, Radiology, and Other Diagnostic Services.'' This section includes all of the content from current § 483.75(j) and § 483.75(k) relocated to § 483.50(a) and § 483.50(b), respectively. We proposed to retain the existing requirements with some revisions, as discussed in detail below.

Current § 483.75(j)(a)(2)(i) and § 485.75(k)(2)(i), require that a facility must provide or obtain laboratory and radiology and other diagnostic services ''only when ordered by the attending physician.'' We proposed to clarify these requirements by removing the phrase, ''the attending physician'' and replacing it with ''a physician, a physician assistant, nurse practitioner, or clinical nurse specialist.'' The revised requirements were proposed to be located at § 483.50(a)(2)(i) and (b)(2)(i), respectively. Furthermore, we proposed to allow for these orders only if the practitioners were acting in accordance with state law, including scope of practice laws and facility policy.

Additionally, current § 483.75(j)(2)(ii) and (k)(2)(ii) require that facilities ''promptly notify the attending physician of the findings'' once laboratory results have been obtained. We proposed to allow increased flexibility under this requirement to provide that other practitioners have the ability to receive laboratory and radiology and other diagnostic results if these practitioners ordered the tests. Specifically, we proposed to revise § 483.50(a)(2)(ii) to permit that the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist to be notified of laboratory results. In addition, we proposed in § 483.50(a)(2)(ii) to clarify that the laboratory would have to promptly notify the ordering professional if results fell outside of clinical reference or expected ''normal'' ranges, unless the orders for the test or the facility's policies and procedures required otherwise.

Comment: Commenters supported the proposal to clarify that a physician assistant, nurse practitioner, or clinical nurse specialist could order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope of practice laws. Commenters noted that this revision aligned with the literature that supports better quality with the use of non-physician practitioners and is consistent with state licensure laws. Commenters also supported the proposal to allow other practitioners to receive laboratory, radiology, and other diagnostic results if these practitioners ordered the tests. Commenters noted that this revision would help to provide results in a timelier manner and improve care to the resident.

Response: We appreciate the feedback and support from commenters. We agree and believe that this revision will ultimately increase access to care and also reduce some of the burden on facilities.

Comment: Some commenters opposed our proposal at § 483.50(a)(2)(ii) to clarify that the laboratory would have to promptly notify the ordering professional if results fell outside of clinical reference or expected ''normal'' ranges; the commenters were skeptical that the policy would improve the notification process. Commenters noted that the term ''promptly'' is not defined, and used multiple times throughout the regulation with varying timeframes. Commenters also did not believe there

was a need to notify practitioners of results that fell outside of the clinical reference range. Specifically, the commenters indicated that the proposed language was too broad, did not provide enough flexibility, and stated that the revision would actually increase unnecessary notification of practitioners and result in unnecessary repeat testing. One commenter recommended revising the language to require that practitioners be notified when results fall outside a ''critical value'' because this term is defined by laboratories and would avoid unnecessary calls when a result was outside the clinical reference, but not critical and trending in the right direction. Another commenter noted that many abnormal lab values are not necessarily associated with any medical problems, nor do they require immediate intervention. The commenter recommended removing the phrase ''lab values that fall outside of normal range'' and revising the language to require facilities to develop a policy and procedure for notifying the ordering practitioner of test results in a timely manner to assure that results requiring intervention or new orders are addressed. Another commenter also recommended replacing the term ''promptly'' with ''timely''.

In contrast, some commenters indicated that facilities should be urged to notify practitioners of abnormal results as soon as possible and recommended that the term ''promptly'' be replaced with ''immediately''. Commenters noted that the standard of practice for nurses is to notify practitioners immediately of results that fall outside of clinical reference ranges regardless of facility policy or physician order. One commenter recommended further that the language be revised to remove the flexibility allowing notification to be based on facility policy or procedure. One commenter recommended that facilities also be required to notify the resident and their representative when they notify the practitioner of test results.

Response: We appreciate the commenters' feedback, but disagree that the proposed language will increase unnecessary notifications of practitioners. In the proposed rule we indicated that the proposal would revise existing language at § 483.75(k)(2)(ii) which stated that facilities must ''promptly notify the attending physician of the findings''. We believe that by specifying that the ordering practitioner be notified of the results, many ''unnecessary'' notifications will be eliminated by ensuring that results are received by the individual who requested the information. We also disagree that the proposed language is too broad and does not provide flexibility. The proposed language provides that notification of the ordering physician should align with facility policy and procedure. It is also common practice for health care settings to establish procedures for determining normal/abnormal lab values. Therefore, in situations that may provide an abnormal result, but do not warrant an emergency response or repeat test, facilities have the flexibility to address these situations in their policies and determine how notification should take place. In addition, we note that the interpretative guidance to this final rule may also provide more detailed information regarding how a facility may choose to establish guidelines for promptly notifying practitioners of test results.

We do not believe that facilities should notify the resident and their representative of results when they notify the practitioner. As commenters have indicated, there are many aspects of a person's care and medical condition to balance when reviewing the results of laboratory tests. We believe that it would be inappropriate to prematurely notify a resident of results before a practitioner responsible for the resident's care has had an opportunity to assess the results. This action could cause unnecessary anguish or result in the delivery of improper information to the resident and their representative.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal without modification.

Q. Dental Services (§ 483.55)

Under the reorganization of subpart B, requirements regarding dental services remain at § 483.55. In the proposed rule, we indicated that section 1862(a)(12) of the Act states, in part, that Medicare does not cover dental services such as the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Medicaid state plans, by contrast, vary in their coverage of dental services. However, both sections 1819(b)(4)(A)(vi) and 1919(b)(4)(A)(vi) of the Act include requirements related to the provision of dental services. Currently, § 483.55 requires that facilities assist residents in obtaining appropriate dental services at the resident's expense for SNF residents and as covered under the state plan for NF residents.

We proposed limited changes to update and clarify this section. First, we proposed to add a new § 483.55(a)(3) to clarify that a facility may not charge a resident for the loss of or damage to dentures when the loss or damage is the responsibility of the facility. Second, we proposed to re-designate existing § 483.55(a)(3) as § 483.55(a)(4) and revise § 483.55(a)(4) by adding the phrase ''or if requested'' to clarify that if a resident asks for assistance in scheduling a dental appointment, the facility would be required to provide the assistance. Third, we proposed to modify the section by adding language at new § 483.55(a)(4)(ii) and § 483.55(a)(5) regarding transportation and referrals for dental services. Finally, we proposed to re-designate § 483.55(a)(4) as § 483.55(a)(5) and would require that referral for dental services occur in 3 business days or less from the time the loss or damage to dentures is identified unless the facility can provide documentation of extenuating circumstances that resulted in the delay. We also proposed to make the same changes at § 483.55(b)(2) and § 483.55(b)(3) to apply to nursing facilities and add a new § 483.55(b)(4) to require that facilities assist residents to apply for reimbursement of dental services as an incurred medical expense under the state plan as appropriate.

Comment: Several commenters recommended we include stronger requirements for dental care and oral hygiene, as good dental care and oral hygiene can result in cost savings.

Response: We agree that dental care and oral hygiene are important. In the proposed rule we discuss the importance of dental care and oral hygiene (80 FR 42197). We have included requirements related to oral hygiene at finalized § 483.25(a)(2), which requires that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. With respect to dental care, as noted in the proposed rule, 80 FR 42205, pursuant to section 1862(a)(12) of the Act, Medicare does not cover many dental services. Medicaid states plans vary widely in providing dental services. In keeping with these limitations, we address facility responsibilities related to assisting residents in obtaining dental services in § 483.55. We did not propose to change existing regulations at 42 CFR 483.55(a)(1)and (2) and (b)(1), which require facilities to provide or obtain dental services to meet the needs of each resident.

Comment: One commenter suggested we explicitly recognize dental hygienists.

Response: We thank the commenter for this suggestion, but decline to incorporate it at this time. We proposed and are finalizing changing references to

a ''dentist's office'' to ''dental services'' in order to recognize that dental care may be provided in dental clinics, dentals schools, or even on site. These requirements are broad enough to encompass dental services provided by a dental hygienist working within their scope of practice under state law.

Comment: Some commenters stated that obtaining dental services for residents is difficult due to difficulty finding providers, limitations in Medicaid coverage, and resident preferences regarding dental care. Some commenters felt existing regulations already address dental concerns and our proposed revisions were unnecessary.

Response: We thank the commenters for their information. A resident or, when applicable, their representative, has the right to determine what dental care they will consent to, just as they have the right to request or refuse treatment as specified in § 483.10. Medicaid coverage of dental services is outside the scope of this regulation. We would expect a facility to document extenuating circumstances that delay obtaining necessary dental care. We disagree that our proposed revisions are unnecessary. Our proposed revisions address areas where we are aware problems have occurred or where we are aware of opportunities to improve access to care. We note that other commenters have suggested that these revisions are useful and that we do not go far enough in ensuring adequate resident protections in this area.

Comment: One commenter recommended we modify proposed § 483.55(a)(3) and § 483.55(b)(4) by adding ''A facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility . . .''

Response: We agree that adding this statement adds clarity and have modified these provisions to state that the facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility.

Comment: Commenters expressed concern that facility policies for lost or damaged dentures would be written in order to absolve the facility of any responsibility. One commenter stated that this would allow a facility to develop a policy that would allow staff to damage the resident's property and not replace it and this would affect the resident's ability to consume meals. Other commenters stated that the facility should not be held financially responsible when residents throw away, damage, or lose dentures or when the loss is a result of a resident's actions or failure to abide by facility policies.

Response: As noted above, we have modified the proposed requirement to state that the facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility. We do not believe a blanket policy of facility non-responsibility would meet the modified requirement. In addition, proposed § 483.15(a)(2)(iii) prohibits facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. We have also modified the provision to require that the facility not only document extenuating circumstances that cause a delay in making a referral for dental services, but also require that the facility document efforts to ensure that the resident is able to eat and drink adequately while awaiting the dental services. We believe that the cumulative effect of these provisions address the commenters' concerns. We defer additional discussion to sub-regulatory guidance.

Comment: Some commenters objected to the three day time frame for making a referral for dental services to replace lost or damaged dentures, stating that it was unreasonable. One commenter asked that we clarify that the 3-day time frame applied to the referral, not to obtaining repaired or replaced dentures. One commenter suggested that 5 to 7 business days would be a more appropriate time-frame for requiring a facility to make a referral.

Response: The three-day time frame is to make the referral, not to complete the dental appointment, or obtain repaired or replaced dentures. We continue to believe that such a time frame is necessary to ensure prompt referrals and minimize avoidable delays, but understand that there may be circumstances that prevent a timely referral. Extenuating circumstances could include issues such as the resident's preferred provider's office not being open or the need to obtain an insurance pre-authorization. Facilities would be expected to document such circumstances.

Comment: One commenter suggested the focus should be on ensuring that residents could eat and drink adequately while awaiting dental services.

Response: We agree and have added this to the regulatory requirement. However, we do not believe that this should be in lieu of documenting extenuating circumstances and maintain our proposed requirement that facilities document extenuating circumstances that lead to delayed referrals.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We are adding a requirement at § 483.55(a)(3) and (b)(4) that the facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility.
- We are adding a requirement at § 483.55(a)(5) and (b)(3) that the facility must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

R. Food and Nutrition Services (§ 483.60)

We proposed the revisions described below in an effort to improve the nutritional status of LTC facility residents. In the proposed rule, we included a detailed discussion regarding dietary standards for residents of LTC facilities. We encourage readers to refer to the proposed rule for this discussion.

We proposed to re-designate existing § 483.35 ''Dietary Services'' as new § 483.60 ''Food and Nutrition Services'' and revise the introductory language to include taking resident preferences into consideration. We proposed to revise § 483.60(a) to require that the facility employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population.

In § 483.60(a)(1) we proposed to retain the requirement that a facility employ a qualified dietitian on a full-time, part-time or consultant basis and update the requirements to be considered a qualified dietitian. We also proposed to require minimum qualifications for dietitians working in SNFs or NFs. We proposed to require that a qualified dietitian must either be registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics, or be recognized (licensed or certified) by the state in which the SNF or NF operates as a dietitian or clinically qualified nutrition professionals. We also proposed to allow up to 5 years after the effective date of the regulation for dietitians hired or contracted prior to the effective dates of the revised regulations to meet these requirements.

In re-designated § 483.60(a)(2), we proposed to continue to require that, if a qualified dietitian or other clinically qualified nutrition professional was not employed full-time, the facility would have to designate a person to serve as the director of food and nutrition

services who would receive frequently scheduled consultation from a qualified dietitian. We proposed to require that the director of food and nutrition services, if hired or designated after the effective date of these regulations, would have to be a certified dietary manager or certified food service manager as evidenced by meeting national certification standards for a certified dietary manager such as those by the Association of Nutrition and Foodservice Professionals (ANFP), or for a certified food manager such as those by the International Food Service Executives Association or the Food Management Professional certification through the National Restaurant Association. If already serving as a director of food and nutrition service on the effective date without one of these certifications, the individual must obtain a certification no later than 5 years after the effective date of the rule. Alternatively, we proposed that the director of food and nutrition services could also meet the proposed requirement through specialized education or training in food service management and safety resulting in an associate's or higher degree in hospitality or food service management. Finally, we proposed that the director of food and nutrition services could meet our proposed requirement if he or she met applicable state requirements to be a food service manager or dietary manager.

In § 483.60(a)(4), we proposed to require that the facility provide sufficient support personnel with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and a facility assessment that includes the number, acuity and diagnoses of the facility's resident population.

We proposed a new § 483.60(b) to specify that a member of food and nutrition services also participate in the IDT. At § 483.60(c)(1), we proposed to change ''Recommended Dietary Allowances'' to ''established national guidelines or industry standards.'' We also proposed to add a new § 483.60(c)(4) to require that menus reflect the religious, cultural, and ethnic needs of the residents, as well as input received from residents or resident groups.

At § 483.60(d), we proposed minor revisions to incorporate the addition of drinks, to clarify that ''proper'' meant both safe and appetizing, to include consideration of allergies, intolerances, and preferences in preparing food, and to ensure that water and other dietary liquids are available to residents and provided, consistent with resident needs and preferences.

At new § 483.60(e) ''Therapeutic diets,'' we proposed to retain the requirement in current § 483.35(e) that therapeutic diets be prescribed by the attending physician. However, we proposed to add a new § 483.60(e)(2) to allow the attending physician to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by state law.

We proposed to modify § 483.35(f) in re-designated § 483.60(f) regarding frequency of meals. Specifically, we proposed to modify the requirement that facilities provide and residents receive three meals per day at regular times by adding language to clarify that meals should be served at times in accordance with resident needs, preferences, requests and the plan of care. We further proposed to eliminate the requirement that there be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a substantial bedtime snack is provided. Instead, we decided to focus on when residents prefer to eat and on ensuring that meal service is provided to meet residents' clinical and nutritional needs. We proposed to require that the facility provide suitable, nourishing alternative meals and snacks for each resident who want to eat at non-traditional times or outside of the facility's scheduled meal service times, in accordance with their respective plans of care. We indicated in the proposed rule that ''suitable, nourishing alternative meals'' would mean that when a resident missed a meal or snack, an alternative of comparable nutritive value to the missed meal or snack would be provided.

We proposed to re-designate existing § 483.35(g) as new § 483.60(g) and revise it to require that the facility provide not only adaptive eating equipment and utensils for residents who need these devices but also provide the appropriate staff assistance to ensure that these residents can use the assistive devices when consuming meals and snacks.

We proposed to re-designate existing § 483.35(h) as new § 483.60(h) and retain, with some revisions, provisions for paid feeding assistants, as set out in the 2003 final rule (68 FR 55528). Section 483.35(h)(2)(ii) currently requires that, in an emergency, a paid feeding assistant must call a supervisory nurse for help ''on the resident call system.'' We proposed to eliminate the reference to the resident call system. We also proposed to have the IDT make the determination of whether a paid feeding assistant would be appropriate for a resident.

We proposed to clarify in new § 483.60(i)(1)(i) that facilities could procure food directly from local producers, farmers or growers, in accordance with state and local laws or regulations. We further proposed to clarify in new § 483.60(i)(1)(ii) that this provision would not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and handling practices, such as the use of pesticides in accordance with manufacturers' instructions. Consistent with § 483.70(b), we proposed to specify in § 483.60(i)(2) that facilities would be required to store, prepare, distribute, and serve food in accordance with professional standards for food service safety. We proposed to add a new § 483.60(i)(3) to require a facility to have a policy in place regarding use and storage of foods brought to residents by visitors to ensure safe and sanitary handling.

Comment: One commenter suggested that we reference the new Dining Practice Standards agreed to by 12 national standard setting organizations.

Response: We thank the commenter. We mentioned in the preamble to the proposed rule an August 2011 report by the Pioneer Network Food and Dining Clinical Standards Task Force but did not provide the location of that resource. We would encourage facilities and practitioners to read the report. It is available at *http://www.pioneernetwork.net/Providers/DiningPracticeStandards/.*

Pioneer Network also has a ''how to'' resource called the ''Dining Standards Toolkit'' that may assist LTC facilities in their efforts to understand and meet the updated requirements. In addition, CMS produced a video related to these standards. The video can also assist LTC facilities in their efforts to understand and meet the updated requirements. The video is available at *http://surveyortraining.cms.hhs.gov/pubs/VideoInformation.aspx?id=1101&cid=0CMSNEWDINPRSTAN.*

Comment: Some commenters felt that our proposed requirement that the facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e) was subjective and not specific enough. Some

commenters felt that the term ''sufficient'' was unclear and impossible to objectively measure. One commenter requested that we define ''support personnel'' or ''support staff''.

Response: Our proposal specifically requires that a facility have a dietitian, a food service manager in facilities that do not have a full-time dietitian, and enough support staff with the appropriate competencies and skills to carry out the functions of the food and nutrition service. Facilities have widely varying populations, and census. Thus, we would expect a facility to use the newly required facility assessment to determine both the competencies and skills that are required to effectively carry out the functions of the food and nutrition services, as well as the number of support staff that are needed. Given the potential diversity of each facility, we continue to believe that a ''one-size-fits-all'' approach to food and nutrition services serves neither the residents nor the facility. A facility should have some flexibility to determine how to best meet its resident's needs in the area. Furthermore, a facility should be able to articulate how it made its staffing decisions and how various factors, including the facility assessment and resident-specific needs, are incorporated into that decision making.

We note that the term ''sufficient support personnel'' is an existing term in the current requirements for long-term care facilities. It is defined in current sub-regulatory guidance as 'enough staff to prepare and serve palatable, attractive, nutritionally adequate meals at proper temperatures and appropriate times and support proper sanitary techniques being utilized.'' It would include any staff in addition to the qualified dietitian or other clinically qualified nutrition professional and the food service manager that are needed to carry out the functions of the food and nutrition service and meet the requirements of this section. We disagree that the term ''sufficient'' is unclear and impossible to objectively measure. ''Sufficient'' staff would be mean an adequate number, or enough staff, who have the skills and knowledge to safely and effectively deliver the care that residents need and that is the responsibility of the food and nutrition service. Direct observation and interview questions can be used to determine if residents are receiving the food and nutrition services they require, in accordance with his or her plan of care, in a safe, timely, and effective manner. Factors such as timely meal service, food that is served at an appropriate temperature and in an appetizing form, available assistance for residents who require assistance to eat a meal, as well as resident-specific issues such as unintended weight loss and dehydration may all be indicators considered when determining if a facility has sufficient staffing. We believe that surveyor training on these requirements and questions such as those identified above will allow surveyors to make evidence-based decisions about whether or not a facility has or does not have sufficient staffing.

Comment: One commenter suggested not referring to 'alternative' or 'substitute' meals, but instead refer to choices and options and ''at times of the resident's choosing.''

Response: We agree and have revised the language at § 483.60(d)(5).

Comment: One commenter recommended that we modify our proposal for therapeutic diets to allow the attending physician or that physician's covering physician to delegate the task a prescribing a resident's diet, including a therapeutic diet, to a registered or licensed dietitian to the extent allowed by state law.

Response: Please see our discussion regarding section § 483.30(f). We are retaining the existing regulatory language which states that the attending physician must prescribe a therapeutic diet and we are finalizing our proposal, with some modification, to allow the attending physician to delegate this task to a qualified dietitian or other clinically qualified nutrition professional. We note that the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician.

Comment: One commenter did not support our proposal to allow an attending physician to delegate the task of writing dietary orders to a qualified dietitian or other nutrition professional acting within the scope of state law. The commenter acknowledged that it has been a real challenge through the years of getting physicians to fulfill their responsibilities in this aspect of care but believed that there are alternatives to our proposal and that it is not in the interest of resident to put a blanket authorization in regulation with its potential for misuse to the detriment of the residents. Finally, the commenter stated that the development of protocols to allocate responsibility to those of other disciplines should be done on a facility level based on knowledge of staff capabilities and close oversight of who is allowed to write orders in consultation with a medical practitioner.

Response: As we discussed earlier, our proposal is intended to improve responsiveness to a resident's needs and is implemented at the discretion of the physician. It does not allow a physician to shift all authority to either a dietitian or a therapist, as the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician. As one commenter noted, our proposal provides for both oversight and accountability. Given the limited time that many commenters have stated physicians spend in the facility, we believe that in appropriate circumstances, this flexibility will benefit both the physician and the resident. Furthermore, nothing in this rule precludes a facility from implementing many of the alternatives suggested by the commenter, such as more detailed assessments of resident appetite and weight issues, better communications to the attending physicians, facility use of reliable and comprehensive references on nutrition, and facility adoption of protocols based on reputable references and resources. We agree that facilities should be knowledgeable of staff capabilities and would expect an attending physician who chooses to delegate responsibility for writing any order would also be knowledgeable about the capabilities of the staff to whom responsibility is being delegated, particularly since the attending physician remains accountable.

Comment: One commenter suggested we change the term ''skill sets'' to ''skills'' as the terms are synonymous.

Response: We thank the commenter for their suggestion, however, we have retained the language as proposed as we do not believe that this change would substantially improve the clarity or intent of the provision.

Comment: One commenter urged us to make a more straightforward statement in the final rule that each resident, unless medically contraindicated, must be afforded a choice of foods at all times. One commenter suggested we more specifically address pureed foods. Another suggested that we change the language at § 483.60(f)(3) that currently states that ''Suitable, nourishing meals and snacks must be available for residents who want to eat at non-traditional times or outside of scheduled meal times, in accordance with the plan of care'' to eliminate ''in accordance with the plan of care'', as resident requests to dine outside of mealtime should not be required to be

documented on the plan of care, unless nutrition is a concern and is being monitored for specific reasons. Other commenters objected to this requirement on the basis that it would require extended kitchen hours.

Response: We believe our proposal, as written, addresses the concerns implicated in the commenters' statements. We agree that a resident's request to eat outside of mealtime does not necessarily need to be documented in the plan of care, nor should a resident be able to eat outside of meal time only if it is required by the plan of care. However, where nutrition is a concern and being monitored for a specific reasons, or where there are dietary restrictions necessitated by a resident's medical condition(s), the provision of such snacks and meals must be consistent with the plan of care. We have modified the regulatory language to state ''Suitable, nourishing meals and snacks must be provided for residents who want to eat at non-traditional times or outside of scheduled meal times, consistent with the plan of care'' to focus on residents actually receiving these snacks or meal options, rather than focusing on the availability of such options. As discussed in the proposed rule, this requirement is not intended to require the availability of a 24-hour-a-day full service food operation (80 FR 42208), but rather accommodate residents who cannot or choose not to eat at a scheduled mealtime.

Comment: Some commenters supported our proposed revisions to the food and nutrition requirements. One commenter stated that they expect the proposed rules will improve the quality of life and health outcomes for residents in LTC facilities.

Response: We thank these commenters. The intent of our proposals is, ultimately, to improve the quality of life and the health outcomes for LTC facility residents. We understand that residents may have varying and unique dietary and hydration needs. We also appreciate the commenters support for our proposals that require that facilities incorporate resident preferences in decisions about food and beverages as well as the need to acknowledge cultural and ethnic diversity in menus and the requirement to provide meals at times in accordance with resident needs, preferences, requests, and the plan of care.

Comment: Some commenters objected to our requirement that menus reflect the religious, cultural, and ethnic needs of the residents, as well as input received from residents and resident groups. The commenters felt that this meant that every facility would have to meet all religious dietary requirements for multiple faiths and that this was not achievable. One commenter suggested that we add ''to the extent possible'' to the requirement.

Response: This requirement does not mandate that every facility be able to provide every possible religious, cultural, or ethnic diet. However, a facility should consider these factors with respect to the population it serves, as well as input from residents and resident groups, when developing its menus. We have clarified this provision to state that menus should ''reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups;'' and defer additional discussion to sub-regulatory guidance.

Comment: One commenter objected to the inclusion of the term ''industry standards'' with regard to menus. One suggested we retain only the term ''national guidelines.'' The commenter expressed concern that ''industry standards'' could allow for poor quality foods.

Response: We agree that including ''or industry standards'' could allow for menus that don't meet national guidelines and therefore have eliminated the term ''industry standards.''

Comment: One commenter suggested that in paragraph § 483.60(c)(1) after ''in accordance with established national guidelines or industry standards'' we add ''in accordance to the individual per his or her comprehensive assessment and care plan. The commenter is concerned that many kitchen staff mistakenly think that they must offer the dietary guideline amounts, ignoring a resident's preferences such as smaller portions, as bigger portions may overwhelm some individuals. Another commenter suggested we make proposed § 483.60(c)(7) stronger by revising it to read: '' The comprehensive assessment and care plan support resident choice and preference for larger or smaller portions''. The commenter asked that we make clearer that residents decide what they want to eat. They wanted to clarify that no resident should be made to eat or to believe that they should eat a certain amount of food, which is what happens when menus are built upon generic ''recommended dietary allowances.''

Response: We agree that an individual's preference for smaller portions or who are overwhelmed by large portions should have that preference or need accommodated. However, the section in question refers to the menu that is prepared for the facility as a whole, not how each meal is provided to the resident. We believe that the provisions as proposed require appropriate menu development at the facility level, but also clearly allow, and in fact require, that meals meet individual needs and accommodate resident preferences. Specifically, § 483.60(c)(7), as finalized, states that nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices and § 483.60(d)(4) requires that each resident receive food that accommodates resident allergies, intolerances, and preferences. We would defer additional specificity, such as choice of portion size, to sub-regulatory guidance.

Comment: Commenters requested that we eliminate paid feeding assistants. One commenter is concerned that feeding assistants have little training and are ill-equipped to help residents who may have swallowing difficulties or resist being fed. The commenter suggests such assistants need training and skills that CNAs have and that assigning such tasks to CNAs would promote continuity of care and support the CNA's relationship with the resident. Another commenter asked that we change the title to ''dining assistant.''

Response: We did not propose to eliminate the role of paid feeding assistants and do not have the benefit of public comment on such a proposal. The requirements for paid feeding assistants were issued in 2003 in response to demonstration programs that evaluated supplementing LTC facility staffing with this role in order to address a recognized problem that most LTC facility residents needing mealtime assistance did not receive enough feeding assistance to ensure adequate nutrition and hydration. A follow-up study by Abt Associates, Inc. in 2007 did not support concerns that paid feeding assistants would be poorly trained or that they would replace existing nurse aides or used for additional resident assistance. The study did raise a concern regarding facilities identification of residents who were assigned a paid feeding assistant. We proposed a requirement that the IDT identify residents who were appropriate for this program that assessment should be reflected in the comprehensive care plan. This would assist in ensuring that resident selection for paid feeding assistance is appropriate. We believe we would need to pursue notice and comment rule-making to eliminate this role. Further, we believe we need to further investigate the need to do so and

the implications of doing so. We will evaluate the concerns raised and consider this issue for inclusion in future rule-making.

Comment: Some commenters supported the proposed requirements' enhanced focus on resident preferences, assessment and care planning in this section, including incorporating resident preferences, recognizing residents' religious, ethnic, and cultural diversity, flexible meal times, the addition of 'drinks, including water and other liquids, and the inclusion of a member of food and nutrition services on the IDT. Another commenter strongly supported our proposed requirements in § 483.60(i)(1) to allow food to be obtained from local producers or grown on-site, subject to some safety requirements and to clarify that the requirements do not preclude residents from consuming foods not procured by the facility (that is, food brought in by visitors).

Response: We appreciate the commenters' support. We agree that these efforts will improve facility responsiveness to the unique needs and preferences of residents while ensuring residents a greater sense of participation in their care.

Comment: One commenter suggested that instead of requiring specific educational requirements for the director of food services or any other position, we require that a member of the food and nutrition services management team include a person credentialed in the manner we have proposed. The commenter stated that there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be competent within a long-term care environment. Another commenter suggested that our requirements for a food service manager were ''woefully inadequate'' specifically citing the fact that we included a degree in hospitality as an option.

Response: Effective management and oversight of the food and nutrition service is critical to the safety and well-being of all residents of a nursing facility. Therefore, it is important that there are standards for the individuals who will lead this service. However, we agree that there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be highly competent within a long-term care environment. It is for this reason that we have allowed sufficient time to meet the new requirements. With regard to our requirements for food service managers, we have modified the option of a degree in hospitality. Based on the comment that a degree in hospitality was a ''woefully inadequate'' qualification, we conducted additional research, and determined that not all hospitality degree programs specifically require food service management. However, based on our research, food service management/restaurant management is a common aspect of hospitality degree programs. Therefore, rather than eliminate a hospitality degree as an qualifying option for facilities, we have clarified to specify that, in order to qualify based on a degree in hospitality, the individual must have included food service management/restaurant management in their degree program.

Comment: Some commenters supported our proposed definition of 'qualified dietitian' but recommended refinements. Other commenters opposed our definition of 'qualified dietitian,' asserting that the proposed change would weaken professional standards and enable unqualified practitioners without the necessary training or skills to oversee facilities' food and nutrition services. They suggested that we define ''qualified dietitian'' consistent with the definition of ''registered dietitian or nutrition professional'' set out at section 1861(vv)(2) of the Act.

Response: We based our proposal for the definition of a ''qualified dietitian'' in part on our experience in allowing hospitals to grant specific nutritional ordering privileges to qualified professionals. We discussed our rationale in the final rule ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; published on May 12, 2014 (79 FR 27106).

Section 1861(v)(2) of the Act defines a ''registered dietitian or nutrition professional'' as an individual who holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose, who has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed; or, in the case of an individual in a state that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes. The definition of a ''registered dietitian or nutrition professional'' at § 410.134 is closely aligned with this statutory definition, adding only that, in a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the degree and practice requirements specified by the statute. Section 483.94(e) of our rules defines a qualified dietitian as ''an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.'' We note that, according to the Academy of Nutrition and Dietetics, the credential ''registered dietitian nutritionist'' (RDN) is synonymous with ''registered dietitian'' (RD) and the two credentials have identical meaning and legal trademark definitions.

We have reviewed state requirements for licensure or certification of dietitians and nutrition professionals and find those requirements, with a few exceptions, generally include, at a minimum, similar education and experience requirements to those forth by the statute and currently reflected in § 410.134. Many also require an examination and/or defer to the national examination provided by the Commission on Dietetic Registration for qualification as a Registered Dietitian. A few states do not require or offer licensure or certification. One state repealed such requirements in 2014. In those states, our proposed definition would require that qualified dietitians or nutrition professionals must be a RD in the state they are providing services. However, we agree that there could be states whose licensure requirements are less than the statutory requirement and we cannot predict future changes in state licensure requirements. Therefore, in order to better align our definition with section 1861(v)(2) of the Act, we have removed our proposed definition and provide that a qualified dietitian or other clinically qualified nutrition professional is one who: Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; has completed at least 900 hours of supervised dietetics practice under the

supervision of a registered dietitian or nutrition professional; and is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or has a bachelors' degree or higher and has completed at least 900 hours of dietetics practice.

Comment: Some commenters assert that 5 years is too long to allow for facilities to come into compliance with the proposed qualifications for dietitians and food service managers. Some commenters suggest 2 years as an alternative.

Response: We appreciate the commenters concerns and considered shorter timeframes. However, as another commenter noted, there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be highly competent within a long-term care environment. We do not want to penalize such professionals and want to ensure that they have sufficient time to meet the new requirements and remain an asset to their facility.

Comment: Some commenters objected to the alternative qualifications for a food service manager and suggest that the food service manager must be a certified dietary manager who has obtained a ServSafe® certification. A number of commenters expressed concern about the existing supply of certified dietary managers. These commenters recommended we allow 6 to 18 months after the effective date of this final rule for facilities to hire new food service managers and give them time to complete the requirements to become a certified dietary managers.

Response: We note that there are currently no regulatory requirements for a food service manager. The ServSafe® manager certification requires training in the importance of food safety, good personal hygiene, time and temperature control, preventing cross-contamination, cleaning and sanitizing, safe food preparation, receiving and storing food, methods of thawing, cooking, cooling and reheating food, HACCP (Hazard Analysis and Critical Control Points), food safety regulations, and more. These are important topics. However, while ServSafe® manager certification is one way to ensure that food service managers are current in this knowledge, it is not the only way to ensure this. We have chosen to allow some flexibility in this regard. Given commenters' concerns regarding a potential workforce shortage of certified dietary managers, we agree it is reasonable to allow facilities 12 months from the effective date of this rule for a food service manager hired after the effective date of this rule to meet the updated qualifications.

Comment: We received a number of comments both supporting and objecting to our proposal to eliminate the requirement that there be no more than 14 hours between meals. Those who object felt that our objective was not person-centered care, as we stated in the preamble, but rather an intent to limit the existing regulatory requirement that facilities ensure that appropriate food is available and provided to residents at reasonable times. These commenters saw no reason not to retain the current requirement and recommended doing so. Other commenters felt that our proposal would allow facilities to tailor their food service programs to the needs and desires of its residents and patients and would improve the resident's environment and quality of life.

Response: The intent of our proposal was, as some commenters noted, to give facilities some flexibility and to focus their efforts on meeting the residents' needs and preferences. The proposal required that the facility provide three meals a day at ''regular times comparable to the community or in accordance with the resident needs, preferences, requests, and plan of care'' and that suitable and nourishing alternative meals and snack *must* (emphasis added) be available for residents who want to eat at non-traditional times or outside of scheduled meal service times. We believe these requirements, in combination with other requirements, including the requirements for food and drink in paragraph (d), ensure that each resident will receive adequate nutrition and will have in say in both what he or she eats and when. However, the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span, does not conflict with the proposed requirement and may prevent diminished availability of meal service. Therefore, we will not finalize our proposal to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

Comment: Some commenters objected to our requirement that facilities establish a policy regarding use and storage of foods brought to residents by visitors to ensure safe and sanitary handling. These commenters felt they were not capable of policing this and that it was inappropriate to ask them to, but at the same time felt that foods from visitors were an enhancement to resident enjoyment.

Response: We were deliberately flexible in establishing this requirement, to allow facilities to determine how to best balance resident enjoyment of such treats and food safety. For example, some facilities may have the capacity to provide refrigeration space for residents, while others will not. We continue to believe that having a policy which residents and visitors are aware of is an important safeguard.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified our definition of ''qualified dietitian or other clinically qualified nutrition professional'' at § 483.60(a)(1) to more closely align with statutory requirements.
- Director of Food and Nutrition Services: We have modified § 483.60(a)(2)(i)(D) to specify that the hospitality degree must include food service or restaurant management.
- Menus and Nutritional Adequacy: We have deleted the term ''industry standards'' from our proposal at § 483.60(c)(1) that menus must meet the nutritional needs of residents in accordance with established national guidelines. We also clarified that menus must reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups.
- Food and Drink: At 483.60(d)(5), we have replaced the terms ''substitutes'' and ''alternative'' with the terms ''options'' and ''different meal choice.''
- We have withdrawn our proposal at (f)(2) to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

S. Specialized Rehabilitative Services (§ 483.65)

Current regulations at § 483.45 set forth the services that a facility must provide if a resident needs specialized rehabilitative services including, but not

limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for a mental disorder. Following the reorganization of part 483 subpart B, we proposed to relocate these existing provisions to § 483.65 with minor revisions. We proposed at re-designated § 483.65(a) to specifically add respiratory therapy to the list of specialized rehabilitative services. The addition of this service explicitly requires facilities to provide or obtain these services when necessary and meet the needs of residents facing respiratory issues. However, this addition did not change coverage policy regarding respiratory therapy. At § 483.65(a)(2), we proposed to clarify that when it is necessary for facilities to obtain these services from an outside source, the provider would have to be a certified Medicare and/or Medicaid provider.

Secondly, we proposed to clarify the meaning of specialized rehabilitative services in relation to PASARR. We proposed to add in § 483.65 a cross reference to the PASARR regulations at § 483.120(c) which set out the mental health or intellectual disability services a nursing facility must provide to all residents who need these services. In addition, we proposed to correct a typographical error deleting the redundant ''mental health'' before ''rehabilitative services for a mental disorder and intellectual disability''.

Comment: Many commenters supported the inclusion of respiratory therapy in the list of specialized rehabilitative services. One commenter suggested that recreational therapy also be added since recreational therapy is recorded in the MDS 3.0 for LTC facilities under Section O.

Response: We appreciate the feedback and support from commenters. We have chosen not to add recreational therapy to the list of specialized rehabilitative services at § 483.65 because at this time we do not believe that we have the evidence as to the efficacy of such therapy to support the addition.

Comment: One commenter indicated that it is unclear whether the proposed rule requires that respiratory therapy services be provided by a respiratory therapist. The commenter notes that it would be nearly impossible to find enough respiratory therapists to provide the services and noted further that a nurse with appropriate training could provide necessary respiratory services in most instances. Commenters requested that a regulatory definition of ''respiratory therapy'' and a clear discussion of the scope of respiratory therapy services that must be provided be included in the final rule. In addition, commenters noted that the final rule should include a discussion of the qualifications necessary for individuals to furnish these services to help providers better understand how to meet these requirements.

Response: All specialized rehabilitative services are considered facility services and are included within the scope of facility services. Therefore, the facility must provide the necessary respiratory therapy services for all residents who need them, so that the needs of the resident are met and support the resident in attaining or maintaining their highest practicable physical, mental, and psychosocial well-being. In addition, the regulation requires that these services be provided in accordance with the resident's comprehensive assessment and plan of care. Regulations at § 483.70(f) discuss staff qualifications and specify that the facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of the requirements for LTC facilities. This would include those services related to specialized rehabilitative services, including respiratory therapy. In addition, the regulations at § 483.70(f) require that professional staff must be licensed, certified, or registered in accordance with applicable state laws.

Comment: One commenter indicated concern regarding the difficulty smaller and more rural facilities may face when providing very complex respiratory therapy services such as mechanical ventilation. The commenter noted that it would be reasonable to permit facilities some flexibility in how the needs of these residents are met and requested that we include provisions describing what complex respiratory services could be excluded from those services the facility must provide. The commenter noted that rehabilitation agencies provide services that may be furnished in a home environment that is similar to a SNF, such as an assisted living facility or independent senior living residence and recommended that the regulations be revised to allow the appropriate flexibility for SNFs that is consistent with that permitted in other Medicare outpatient therapy provider settings.

Response: We appreciate the commenter's feedback and understand that there are challenges that smaller and rural facilities may face when trying to obtain access to care and services for their residents. However, facilities must be able to provide, directly or under arrangement, the necessary care that their residents require. We urge facilities to use the facility assessment that was proposed at § 483.70(e) as a tool for appropriately assessing the resources necessary for providing care to its residents. Facilities should use this assessment to make decisions about their direct care staff needs as well as their capabilities to provide services to the residents in their facility.

Comment: One commenter disagreed with our proposal to clarify that when it was necessary to obtain specialized rehabilitative services from an outside source, the provider would have to be a certified Medicare and/or Medicaid provider. The commenter noted that this revision limits access to providers and recommends that facilities continue to be permitted to obtain necessary services from a qualified therapy professional that is appropriately licensed or certified to practice in the state in which services are being furnished. The commenter recommended that services obtained from an outside resource should only be restricted to a provider who was not excluded from federally funded health care programs including Medicare and/or Medicaid.

Response: We appreciate the commenter's feedback and have given much consideration to the implications that this revision may have on access to providers of specialized rehabilitative services. Our goal is to ensure that all LTC residents receive services from qualified professionals. Therefore, in an effort to balance the need to assure the safety of LTC residents against the concerns of facilities regarding obtaining access to providers, we have withdrawn our proposal at § 483.65(a)(2) to require that an outside resource must be a Medicare or Medicaid provider. Instead we are revising the requirement to indicate that services obtained from an outside resource must come from a provider that is not excluded from any federally funded health care program. We believe that this revision supports our intent to assure that LTC facility residents receive services from outside resources that are both professional and safe, while maintaining the access to providers.

Comment: Some commenters indicated that the use of the term ''specialized rehabilitative services'' should be revised to ''rehabilitative services and devices'' to be consistent with a CMS regulation entitled, ''Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016'' (80 FR 75487). Commenters noted further that the final rule should adopt a definition of ''rehabilitative services'' that includes explicit recognition and coverage of devices. Commenters noted that the

definition of ''rehabilitative devices'' should also include durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition, commenters recommended that rehabilitative devices should be covered whether or not they are considered part of the SNF per diem rate or separately billable to the Medicare program.

Response: We disagree with commenters and believe that the term ''specialized rehabilitative services'' is appropriately used in the LTC setting. Sections 1819(b)(4)(A) and 1919(b)(4)(A) of the Act specifically use the term ''specialized rehabilitative services'' when discussing the provision of services that a facility must provide, directly or under arrangement, to the extent needed by residents to fulfill all plans of care. The CMS regulation discussed by commenters (''Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016'' (80 FR 75487)) applies to private insurance under the Affordable Care Act and does not have an impact on long-term care facilities that participate in the Medicare and Medicaid program. In addition, the coverage of rehabilitative devices under the Medicare program falls outside the scope of this regulation.

Comment: A few commenters also recommended that the regulation be revised to ensure compliance with the decision in *Jimmo* v. *Sebelius,* which indicated that Medicare coverage for skilled services should not be denied based on the absence of potential for improvement or restoration. Commenters indicated that residents should not have to show improvement for rehabilitative services to be determined as reasonable and necessary.

Response: We thank the commenters for highlighting the importance of the decision in *Jimmo* v. *Sebelius.* However, the *Jimmo* v. *Sebelius* settlement agreement did not modify or expand the existing eligibility requirements for receiving Medicare coverage and does not fall into the scope of this regulation. We note that CMS committed to conducting a number of activities in response to the settlement agreement to ensure that the existing Medicare policy is clear and that Medicare claims are adjudicated consistently and appropriately. Specifically, CMS planned to engage in the review of claims determinations, update program manuals, and educate contractors, adjudicators, and providers and suppliers on the policy clarifications. Readers may refer to the CMS Web site at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/SNFPPS/downloads/jimmo-factsheet.pdf* for a fact sheet regarding the *Jimmo* v. *Sebelius* settlement agreement.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- At § 483.65(a)(2), we are removing the requirement for outside resources to be Medicare and/or Medicaid providers of specialized rehabilitative services. We have clarified that the outside resource must be a provider of specialized rehabilitative services that is not excluded from participating in any federal or state health care programs pursuant to sections 1128 and 1156 of the Act.

T. Outpatient Rehabilitative Services (§ 483.67)

We proposed to add a new § 483.67 ''Outpatient Rehabilitative Services'' to address facilities that choose to provide outpatient rehabilitative therapy services to individuals that do not reside in the facility. Currently, the provision of outpatient rehabilitative services for non-residents is not addressed by the requirements for LTC care facilities. We noted that § 483.65 ''Specialized Rehabilitative Services'' sets forth the requirements that a facility must meet when providing rehabilitative therapy services to residents who reside in their facility.

We proposed to require facilities that provide outpatient rehabilitative therapy services to meet requirements similar to those already established for hospitals. Specifically, we proposed to require in new § 483.67 that if the facility provides outpatient rehabilitation, physical therapy, occupational therapy, audiology, or speech-language pathology services, the services must meet the needs of the patients in accordance with acceptable standards of practice and the facility must meet certain requirements. At § 483.67(a), we proposed that the organization of the service must be appropriate to the scope of the services offered. At § 483.67(b), we proposed to require that the facility assign one or more individuals to be responsible for outpatient rehabilitative services and that the individual responsible for the outpatient rehabilitative services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services. We also proposed to require that the facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered. In addition, we proposed to require that physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter. At § 483.68(c), we proposed to require that services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law and that all rehabilitation services orders and progress notes must be documented in the patient's clinical record in accordance with the requirements at § 483.70(i). Finally, we proposed to require that the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

Comment: The majority of commenters indicated support for the addition of the requirements regarding facilities that provide outpatient rehabilitative services. Commenters noted that there has been inconsistent interpretation regarding how SNFs can furnish outpatient therapy services to non-residents and that steps towards standardization are needed. While a few of the commenters indicated that the new section provides adequate guidance for those facilities offering these services, other commenters raised concerns that the proposed requirements need further clarification and revision.

Specifically, one commenter raised the issue of SNFs that provide outpatient rehabilitative services to non-residents at a location outside of the facility. The commenter requested that the regulations address SNFs that may furnish outpatient rehabilitative services in locations other than the facility and allow flexibility in how these services are provided. The commenter urged CMS to revise the regulations so that they are consistent with requirements imposed for other Medicare outpatient therapy providers. The commenter indicated that the outpatient therapy services furnished by SNFs resemble the delivery of services furnished through outpatient rehabilitation providers described under 42 CFR part 485 subpart H (referred to in the comment as rehabilitation agencies) and not those services furnished through outpatient hospital departments. The commenter noted that unlike a hospital, rehabilitation agencies may also provide outpatient therapy services to individuals in a home environment, such as to residents of independent senior living and assisted living

residents. In addition, the commenter noted a CMS memo from April 3, 2015 entitled ''Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services and Off-Premises Activities'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-33.pdf*). The commenter requested that the provisions addressed in this memo regarding off-premise treatment activities be added as requirements for SNFs.

A few commenters also recommended that the requirements be revised to ensure compliance with the decision in *Jimmo* v. *Sebelius,* which indicated that Medicare coverage for skilled services should not be denied based on the absence of potential for improvement or restoration. Commenters indicated that residents should not have to show improvement for rehabilitative services to be determined as reasonable and necessary. Also, a commenter raised concerns regarding inconsistences between the proposed requirements and Medicare Part B outpatient therapy payment policy. Lastly, commenters requested that the regulatory section be updated to replace the term ''patient'' with ''resident''.

Response: We appreciate the in depth feedback from commenters. Through our proposal, we intended to establish requirements for outpatient rehabilitative services provided to non-residents in the LTC facility to ensure that these services meet health and safety standards. We were informed that a number of facilities provide rehabilitative services on an outpatient basis and that these services may be paid for under Medicare Part B. We want to ensure that our requirements are fully and clearly developed in an effort to provide clarity to facilities and safety to those individuals that are receiving services. After carefully considering all of the comments we received, reviewing the comprehensive regulations for outpatient therapy providers found in part 485, and the CMS guidance regarding off-premise treatment activities recommended by commenters (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-33.pdf*); we believe that the practice of some LTC facilities providing outpatient rehabilitative services presents several additional complex issues that were not carefully and thoroughly considered during the development of the proposed regulations. Therefore, we have decided against finalizing the proposed requirements for outpatient rehabilitative services. We believe that it is necessary to study the issue further and consider proposals for future rulemaking.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modification:

- We have withdrawn this proposed section in its entirety.

U. Administration (§ 483.70)

Relocation of Existing Requirements

We proposed to re-designate current § 483.75 ''Administration'' as § 483.70. At § 483.75(c), we proposed to replace the term ''handicap'' with the term ''disability''and to add a reference to the HIPAA Privacy, Security, and Breach Notification Rules, 45 CFR parts 160 and 164. In addition, we proposed to clarify that violations of other HHS regulations, as determined by the agency or entity with enforcement authority for those regulations, may result in a finding by CMS of non-compliance with the requirements of § 483.70(c).

We proposed to re-designate and revise existing § 483.75(e) and (f), provisions regarding nurse aides, to § 483.35 ''Nursing Services'' or § 483.95 ''Training'', as discussed under these sections.

We proposed to create new section § 483.50 ''Laboratory, radiology, and other diagnostic services'' and relocate and revise existing paragraphs, § 483.75(j) ''laboratory services'' and § 483.75(k) ''radiology and other diagnostic services'', to the new section. In addition, we proposed to retain the provisions in existing § 483.75(g), (h) and (i) unchanged and re-designate them as proposed § 483.70 (f), (g), and (h).

We did not receive any comments in response to these proposals and are finalizing as proposed except that we have added a reference to 45 CFR part 92 in the list of regulations that facilities are required to comply with, based on a comment received with regards to § 483.12.

Governing Body § 483.70(d)

At § 483.70(d)(2)(i) we proposed to delete the phrase ''where licensing is required'' since all states participating in the Medicaid program are required to license nursing home administrators under section 1908 of the Act. We proposed to add a new § 483.70(d)(2)(iii) to specify that the LTC facility administrator would report to and be accountable to the governing body. We also proposed to add a new § 483.70(d)(3) to specify that the governing body is responsible and accountable for the QAPI program, in accordance with proposed § 483.75(f).

Comment: One commenter pointed out that deleting the phrase ''where licensing is required'' could result in confusion in states where state law allows administrators of hospitals which have a distinct part SNF not to be certified as LTC facility administrators.

Response: We agree and withdraw this proposal.

Comment: Some commenters supported the proposed changes to § 483.70(d)(2)(iii), which would require that the LTC facility administrator report to and be accountable to the governing body.

Response: We thank the commenters. We believe this change will ultimately benefit LTC facility residents.

Comment: One commenter was concerned about the proposed requirement at § 483.70(d)(2)(iii) for the LTC facility administrator to report to and be accountable to the governing body. The commenter stated that, while they understand and appreciate the need for the governing body to be kept apprised of the operations and management of the facility, they do not support a regulatory requirement prescribing that the facility administrator report to and be directly accountable to the governing body. The commenter stated that many not-for-profit organizations have management structures that include a Chief Executive Officer (CEO) who is not the administrator of record of the LTC facility. Under the bylaws and governance structure of these organizations, the CEO is directly accountable to the board of directors and responsible for hiring and supervising the facility administrator and other executive staff. Requiring the administrator to report to and be directly accountable to the governing body in these circumstances would supplant the governance policies of these organizations and undermine the relationship of the CEO to the board of directors. The commenter recommended that this requirement be eliminated in its entirety. Alternatively, the commenter suggested the requirement could be modified to require that the organization's senior management keep the governing body apprised of the operations and management of the facility, while leaving it up to the organization to designate the individual

who would be responsible for this function.

Response: As the commenter noted, we believe that it is important for the governing body to be kept apprised of the operations and management of the facility. Under current regulation, the governing body is already responsible for appointing the administrator who is responsible for the operations and management of the facility. The proposed provision would add that the administrator reports to and is accountable to the governing body. The new provision does not specify ''directly'' and thus we believe that a governing body may appoint a designee, such as a CEO, to directly interface with an Administrator. However, the use of a designee does not change the Administrator's accountability to the governing body nor the governing body's responsibility to know and respond to concerns with the operation and management of the facility.

Comment: One commenter stated that they appreciate that CMS would make the administrator report to and accountable to the governing body. They note that while this may be implied, the proposed specificity clarifies this point. Given the governing body's responsibility for implementing the management and operations of the facility, the commenter agrees with CMS that the administrator must keep the governing body informed and knowledgeable about these issues. The commenter also supports the governing body also being responsible and accountable for the facility's QAPI. This program cannot be successful unless the facility leadership is involved.

Response: We agree. As noted above, we believe it is important that the governing body be kept apprised of the operations and management of the facility. Furthermore, should the governing body appoint an intermediary such as a CEO, the use of such an intermediary does not change the Administrator's accountability to the governing body nor the governing body's responsibility to know and respond to concerns with the operation and management of the facility.

Facility Assessment (§ 483.70(e))

We proposed a new § 483.70(e) to establish a new requirement for an annual facility assessment. We proposed to require that the facility assessment address or include:

- The facility's resident population, including the number of residents, the facility's resident capacity, the care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, and overall acuity that are present within that population.
- The staff competencies that are necessary to provide the level and types of care needed for the resident population.
- The physical environment, equipment, and services that are necessary to care for this population.
- Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.
- The facility's resources, including but not limited to buildings and other physical structures and vehicles; medical and non-medical equipment.
- The services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies.
- Personnel, including managers, employed and contracted staff, and volunteers, as well as their education and/or training and any competencies related to resident care.
- Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility both during normal operations and emergencies.
- Health information technology resources, such as systems for electronically managing patient medical records and electronically sharing information with other organizations.

General Comments

Comment: Some commenters did not believe that the proposed requirement for a facility assessment would be a significant change from what is currently required. Commenters pointed to language in the proposed rule, where we first said, that the requirement for a facility assessment was ''a central feature'' of our revisions and that ''[t]his is similar to existing common business practices for strategic planning and capital budget planning'' (80 FR 42210). Commenters said that authorizing a practice that is already common does not appear to be a significant change. The current requirements already require resident-centered and specific care plans designed to attain and maintain the resident's highest practicable physical, mental, and psychosocial well-being. LTC facilities already use multiple sources of data, including the items listed in the proposed rule, in various ways to make operational decisions, including the number of staff and skills that staff need to provide care to the residents. Some commenters also noted that the current requirement to determine staffing levels was already producing serious staffing and quality deficiencies and did not see where the proposed changes would make any appreciable difference. They also said the reason for this assessment was completely unclear.

Response: Based on our experience with LTC facilities, we believe that there is already some assessment of the resident population and the resources that would be required to care for that population. However, we do not believe that all facilities perform as thorough an assessment of their resident population or the facility's resources as is required by § 483.70(e). In addition, we do not believe that most facilities have a formal process that is documented. We believe that the requirement for a facility assessment that must address the factors identified in § 483.70(e)(1) through (3) will enable each LTC facility to thoroughly assess their resident population and the resources that are needed to provide the care they need. It will also enable the facility to determine the resources it has so that it can determine what resources it needs to competently care for its resident population. By having the facility assessment documented, it will also provide a record for staff and management in the future to understand the reasoning for decisions that were made on staffing and other resources. It will also provide a reference point for assessment when deficiencies are noted or when adverse events occur.

Comment: Some commenters were very supportive of the requirement for a facility assessment, but wanted us to also require that self-assessment plans include individual crisis plans for residents who may develop dementia-related or other behavioral crisis.

Response: We understand the commenters concern for residents who have or may develop dementia-related or other behavioral crisis. As proposed and now finalized in this rule, § 483.70(e) requires that facilities must, among other things, conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies and this assessment must address or include the care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity; and other pertinent facts that are present within that population. Hence, LTC facilities must already consider the care that is needed for those residents who already have dementia-related or other behavioral crises or could develop these during an emergency. We have not required a specific methodology for LTC facilities to perform their facility assessments because we believe that

facilities need the flexibility to decide how they will conduct their assessments. Thus, we will not require that individual crisis plans be included; however, each facility must address the needs of all residents, including those who have or may develop dementia-related or other behavioral crises both during day-to-day operations and emergencies.

Facility Assessment Methodology

Comment: Some commenters were supportive of LTC facilities conducting their own facility assessment and taking into consideration the factors set out in the proposed rule at § 483.70(e). However, they were concerned about the facility being able to rely on its own assessment without there being any enforcement mechanisms or safeguards to ensure that the facility was objectively assessing its residents' needs, acuity, and other important factors and not relying unduly on other factors, such as costs or convenience. Some commenters were concerned that LTC facilities would simply produce assessments that indicated that their current staffing and other resources were sufficient to care for their resident population. Commenters recommended that facility assessments be validated in some manner.

Response: We understand the commenters' concerns; however, we believe that in complying with the requirements finalized in this rule as set forth in § 483.70(e), LTC facilities will have to conduct and document a thorough assessment and analysis of their resident population, staff and staff competencies, and resources to determine not only the resources they currently have but also the resources they need to obtain in order to care for their resident population competently. We will also be developing sub-regulatory guidance that will provide more information on how to comply with this requirement. If any LTC facility simply writes up a facility assessment to justify the resources it currently has, we believe that will be evident in the facility assessment, as well as in their performance on surveys.

Comment: Some commenters were concerned about having the facility assessment developed by the LTC facility without requiring input from other sources. They recommended that the facility be required to seek and use input from the state's Office of the Long-Term Ombudsman, the resident and family groups, and family caretakers when conducting its assessment. However, other commenters believed that the facility assessment should be considered proprietary and that the facilities should not be required to either include input from sources outside the facility or share the assessment with them.

Response: While we encourage LTC facilities to seek out and consider input from multiple sources, including residents, residents' representatives, families, and advocates, including the state Office of the Long Term Care Ombudsman, we disagree with the commenters that this should be required. As stated in the proposed rule, we encourage LTC facilities to seek input from multiple sources; however, ''[w]e believe the facility should have the flexibility to determine when and from whom a facility would seek input and how to incorporate that information into their assessment'' (80 FR 42210 through 42211). We believe that each facility needs the flexibility to decide the best way to comply with this requirement. This is also the reason we have not required any specific methodology for facilities to use for the facility assessment.

Comment: Some commenters believed that the level of detail in facility assessment requirement was unreasonable, complex, and would be extremely burdensome for the LTC facilities. However, other commenters were concerned about the lack of specificity for the facility assessment requirement. They said it was unclear what these assessments would look like or which staff members should be involved. Some commenters noted that there was insufficient information in the preamble and the regulatory text to evaluate the requirement for a facility assessment. Commenters were particularly concerned that this inevitable lack of consistency in methodology would result in the results not being comparable. Thus, the facility assessments would not provide any valid comparisons or provide any precedent over time sufficient to be beneficial for LTC facilities, advocates, regulators, surveyors, or researchers. Commenters also questioned whether these assessments could fail to comport with the OBRA '87 requirement that every facility have adequate staff in place to ensure that residents can achieve their maximum well-being.

Response: We understand that the commenters have concerns and questions about what would be needed to comply with the requirement for a facility assessment. In proposed § 483.70(e), we only included the elements that we believe are essential for a facility to assess and analyze its resident population and resources so that it can competently determine the resources it needs to care for its resident population. As we said in the proposed rule, ''[t]his facility-wide assessment would determine what resources a facility would need to care for its residents competently during both day-to-day operations and emergencies'' (80 FR 42210). Thus, we believe that the basic elements for the assessment are included and do not believe that the requirements are unreasonable, complex, and would be extremely burdensome. As we indicated earlier, we believe that facilities are already performing some type of assessment, although it may not be as formal or documented. In addition, after this final rule is effective, additional sub-regulatory guidance will be published or disseminated to provide further detail on how to comply with these requirements.

We acknowledge that there will likely be some variation in how LTC facilities will conduct and document their facility assessments. However, due to the significant variations in the types of LTC facilities, resident populations, and resources among the LTC facility facilities, we believe that the facilities need the flexibility to determine the best way for each facility to comply with this requirement. As to consistency among the facility assessments, we believe that the accuracy of the assessments is more important. However, over time we believe that some consistency will likely develop due to facilities sharing what has worked best for them with other facilities and their associations. In addition, if a facility complies with the requirements for the facility assessment finalized in this rule, we believe that facilities will be able to determine what constitutes sufficient staff for their facility, which would be in compliance with the requirement in OBRA '87 for sufficient staffing.

Annual and Other Updates

Comment: Some commenters were concerned that facilities may potentially need to update their assessments frequently, such as every time their resident-mix changes, they hire new staff or a DoN, conduct any remodeling, etc. This continuous, or at least frequent, need to update the facility assessment could distract LTC facilities from improving resident care.

Response: We do not believe that the facility assessment will need to be updated as frequently as the commenters suggest. We understand that the resident-mix may change frequently. However, the care that needs to be provided for the resident populations should not change that frequently. Once the facility completes its assessment, changes in its resident

population should not necessitate a change in the facility assessment unless the facility begins admitting residents that require substantially different care. For example, when a facility does its initial assessment, it might not have any morbidly obese residents who require special bariatric equipment, such as a bariatric wheelchair and walker. However, in the future, if the facility wants to admit morbidly obese residents who require that equipment, it would need to identify the care needs for morbidly obese residents, update the facility assessment, ensure that its staff have the relevant competencies, and obtain the other required resources. As long as the facility assessment encompasses the care and resources needed by the residents, admitting new residents with the same needs should not require an update of the facility assessment. Likewise, hiring new staff or a DoN or even remodeling should not require an update of the facility assessment, unless these are actions that the facility assessment indicated the facility needed to do. In that case, it should only require notation that the facility has taken the actions to satisfy a need the facility assessment identified.

Comment: Some commenters questioned the requirement to perform the facility assessment annually. They said that appropriate staffing levels and the competencies that are required to care for their resident population change much more frequently than annually. Commenters said that the annual assessment must be able to establish that its staffing will remain adequate throughout the year, both with regard to levels of total nurse staffing, and with respect to the responsibility that certain types of staff, for example, registered nurses, licensed practical nurse, have in overseeing the medical management of residents with regard to medications, falls prevention, development of pressure ulcers, readmission to hospitals, and other key areas.

Response: We believe that an annual assessment is needed to ensure that there have not been any substantial changes that will require the facility to update its facility assessment. The annual assessment is a minimum requirement. LTC facilities should update their facility assessment whenever they believe it is appropriate.

Number of Assessments

Comment: Some commenters stated that a single facility assessment was insufficient. Some commenters said that the facility assessment requirement, as a single process, did not appear to serve long-range planning needs and, simultaneously, the changing day-to-day needs of a facility for staffing and other services, such as food and nutrition, rehabilitation, and housekeeping. Some commenters argued for two different assessments. One facility assessment would be limited to the day-to-day needs for the facility and another that would address emergency planning, strategic planning, and capital budget planning. Other commenters offered specific language for this type of requirement, with separate subsections: One for an annual strategic planning and capital budget assessment and another for a bi-weekly staffing and day-to-day operations assessment. For the bi-weekly staff and day-to-day operation assessment, commenters also recommended the individuals they believed should be involved in that assessment and that this assessment must also address emergencies.

Response: The requirement for a facility assessment as finalized in this rule and set forth in § 483.70(e) is a minimum requirement. If facilities choose to conduct another assessment or expand the facility assessment to include long-range planning needs or any other needs, it is free to do so as long as it complies with the minimum requirements in this final rule. We have not required the involvement of specific LTC facility personnel because we believe that the facility should have the flexibility to determine the appropriate individuals who should be involved in the facility assessment.

Use of Facility Assessment

Comment: Some commenters stated that each LTC facility is a unique organization with its own values, goals, experiences, and other factors that drive how it operates. The commenters were concerned that the requirement for the facility assessment could result in organizational decisions and approaches being specifically directed or managed by CMS, which is contrary to the spirit of QAPI whereby the organizations operations should be shaped by the staff, residents, governing body, and other parties. However, other commenters wanted the facility assessment audited by a facility surveyor and that the surveyor be empowered to require, under threat of graduated monetary penalties, that the facility provide additional nursing resources if the surveyor disagrees with the facility's assessment.

Response: The requirement for the facility assessment is intended to ensure that LTC facilities have appropriately assessed their resident population and determined the resources, including staff and their competencies, to competently care for their residents. The facility assessment will be performed and documented by the facility and not by CMS or any other entity. LTC facilities must comply with the long term care requirements; however, we have endeavored to allow for as much flexibility as possible for facilities to decide the best way for their facility to comply with these requirements. We also believe that the facility assessment could be very useful tool for QAPI, especially when assessing the facility's performance on the elements they are required to include in the assessment.

Implementation

Comment: Some commenters said that there was no discussion on implementation of the findings in the facility assessment. They recommended including language that requires the facility to implement the competent staffing and resources determined necessary to care for the residents based on the results of the facility assessment.

Response: There are many sections in this final rule, as in the proposed rule, that requires that the facility assessment be used to determine the resources the facility needs to devote to certain activities. For example, § 483.35 requires that the facility have the appropriate staff with the appropriate competencies and skill sets for the resident population in accordance with the facility assessment. Section § 483.40(a) requires that the facility have sufficient direct care staff with the appropriate competencies and skills sets in behavioral health for the residents in accordance with the facility assessment. Facilities must also establish and maintain their infection prevention and control programs based upon the facility assessment as set forth in § 483.80(a)(1). In addition, we encourage facilities to use their facility assessment in any other activities that affect their resident population. We believe these requirements are sufficient to require facilities to use their facility assessments so we will not include the recommended specific language.

Alternatives

Comment: Some commenters recommended that the proposal for the facility assessment not be finalized and that CMS form a stakeholder workgroup that could explore the potential use of ''facility assessments'' and unintended consequences or outcomes, as well as possible alternate approaches. Commenters wanted CMS to provide clarification on what it envisions for a facility assessment; provide evidence for the value of proposing a requirement for this facility assessment; and provide

evidence-based models of facility assessment and process. Other commenters questioned what evidence we had that supported the validity of this requirement.

Response: As discussed above, we believe that LTC facilities already perform some type of assessment to determine staffing and other resources they will need to care for their resident population. For example, previous § 483.30 ''Nursing services,'' required facilities to provide ''sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.'' Also, previous § 483.15 ''Quality of life,'' required facilities to ''care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.'' The Veterans Administration is also using facility assessments in its strategy to improve its health care delivery system (''Restoring Trust in VA Health Care,'' 271 New Eng. J. Med. 295 (2014), accessed on Westlaw (2014 WLNR 20261329) on July 26, 2016). We believe that these requirements are necessary to ensure that the facility competently cares for its resident population by appropriately assessing its resident population and resources. The requirement includes specific elements that each facility must address that relate to its resident population, staff, and the resources the facility needs to care for its residents. It provides for not only a process but also provides a valuable tool for facilities to use for planning for and improving care. We do not believe that a stakeholder group is necessary prior to implementing the requirement for a facility assessment; however, we are always willing to review any information or comments that any member of the public wishes to send to us and will consider that information if there is any relevant future rulemaking.

Comment: Some commenters did not want the requirement for a facility assessment finalized because they believed that the outcomes for residents under the existing requirements should stand as evidence of the adequacy of the facility's assessment. These commenters questioned the need to require LTC facilities to spend precious time documenting a facility-wide assessment that surveyors will use to interpret whether the facility has sufficient staff. The more appropriate way to assess allocation of resources is to assess whether or how the facility has met the individual needs of each resident rather than require another documentation endeavor.

Response: The requirement for a facility assessment addresses different issues that the requirements for person-centered care for residents. In the facility assessment, LTC facilities should be proactive in assessing and analyzing the needs for the entire resident population. Individual care plans would certainly be a valuable resource in performing the facility assessment; however, the care plan would address the specific needs for a single resident. The facility assessment must address the care needed for all of the residents, as well as the resources needed to provide that care competently.

Comment: Commenters urged that CMS examine whether the current methodology for the five-star system, which calculates expected staffing based on RUG values along with reported staffing levels, could be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. An adaptation of this system must also be designed to incorporate the more robust payroll-based staffing data that will be in place as a requirement for all certified SNFs and NFs by July 2016.

Response: As discussed above, we will consider the commenters recommendation to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. In addition, we will also be reviewing the payroll-based staffing data that we will be receiving starting this year. However, proposals to use either of the above suggested methods would have to be developed. We will consider these recommendations if there is future rulemaking concerning the facility assessment or staffing.

Surveys/Surveyors

Comment: Other commenters were concerned about how the facility's management might use the facility assessment or how surveyors would use the facility assessment in assessing a facility's compliance with various requirements. The general requirement for a facility assessment invites a tremendous amount of subjectivity into the survey process when surveyors already have requirements and other sub-regulatory guidance to determine whether there is non-compliance during a survey.

Response: We understand the commenters' concern about how the facility assessment will be used by the facility and the surveyors. Facilities are required to use the facility assessment in determining how they need to comply with several requirements in this rule. However, facilities may also choose to use their assessments for other purposes. Concerning the surveyors, further guidance will be published or disseminated by CMS after this rule is published to provide additional information on what constitutes compliance with the requirements set forth in this final rule.

Medical Records (§ 483.70(i))

We proposed to re-designate existing § 483.75(l) as § 483.70(i) and to amend it to better conform to the requirements of the HIPAA Privacy, Security, and Breach Notification rules at 45 CFR parts 160 and 164. We also proposed minor revisions in it to clarify that the medical record must contain the resident's comprehensive plan of care and physician's and other licensed professional's progress notes. We noted in the proposed rule that existing paragraph (m) will be removed and revised pursuant to a separate proposed rule, ''Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (78 FR 79081, December 27, 2013).

Comment: One commenter was concerned about proposed § 483.70(e)(2)(i) using the term ''medical records,'' rather than the term in the current § 483.75(l), which is ''clinical records.'' The commenter stated that the term ''clinical records'' appears to be broader than ''medical records'' and states that CMS offered no reason for the change. The commenter suggested CMS retain the current term ''clinical records.''

Response: We believe the commenter is referring to proposed § 483.70(i), which addresses medical records rather than § 483.70(e), which addresses facility assessment. In the preamble to the proposed rule, we noted that we proposed to establish requirements that mirror some of those found in the HIPAA Privacy Rule (45 CFR part 160, and subparts A and E of part 164). We did not specifically state that our change to the term 'medical record' was related to achieving consistency with the HIPAA rules, but that was the impetus for the change. The HIPAA rules in 45 CFR part 164 use the term 'medical record' rather than 'clinical record'. We regard the terms as synonymous.

Comment: One commenter suggested that we further clarify that the

comprehensive care plan and services provided includes records documenting activities of daily living care and services, bathing and skin inspections, and nutrition and fluid intake and output records.

Response: We thank the commenter for their suggestion. We proposed that the medical record must include, in addition to the comprehensive care plan and services provided and other existing requirements, the reports of diagnostic testing and the progress notes of licensed personnel. We expect that this will address some of the commenters concern. However, we will consider further expanding this requirement in future rule-making, which would give us the opportunity to obtain further feedback on this issue.

Comment: CMS proposed to incorporate, without change, the current requirements for medical directors, current § 483.75(i). The commenter was concerned that, too often, the medical director also serves as the attending physician for most of the facility's residents. The dual roles of medical director and attending physician make it impossible for the medical director to perform the medical director's specific regulatory functions—implementing resident care policies and coordinating medical care in the facility. The medical director cannot ''oversee'' the care he or she is providing to residents as attending physician. The commenter encouraged CMS to address this issue in final regulations. The commenter stated that, although there may be a need, in some limited instances, for medical directors to serve as residents' attending physicians, CMS needs to strengthen the regulatory standards for medical direction so that medical directors can, in fact, perform their critical management functions. The commenter suggested that, for example, CMS could mandate specific minimum numbers of hours per week or per month for medical direction functions; require certification for medical directors; limit medical directors from serving as medical director in more than two facilities; and prohibit medical directors from serving as the residents' attending physicians (with a limited exceptions process).

Response: We thank the commenter for these suggestions. As noted by the commenter, we did not propose any changes to this provision, but are re-designating it as § 483.70(h). We defer to sub-regulatory guidance for further discussion of the medical director's specific functions pertaining to resident care policies and coordinating medical care in the facility. In addition, while we are not addressing them in this final rule, we will continue to evaluate both the situation where the medical director is fulfilling the attending physician role and the oversight role and the need for additional standards for medical direction. We will consider addressing these concerns in future rule-making.

Transfer Agreement (§ 483.70(j))

In § 483.70(j), ''Transfer Agreement, ''we proposed to modify the current language at § 483.75(n) to allow a practitioner other than the attending physician to determine that a hospital transfer is medically appropriate in an emergency situation, consistent with state law and facility policy. We further proposed to specify here that the information exchange required by existing paragraph § 483.75(n)(1)(ii) be modified to require that the exchanged information include, at a minimum, the information we proposed to require under new paragraph § 483.15(b)(2)(iii)(B). We proposed to incorporate existing § 483.75(o), assessment and quality assurance, into proposed § 483.75(c).

Comment: Some commenters indicated support for our proposal to allow a practitioner other than the attending physician to determine that a hospital transfer is medically appropriate in an emergency situation, consistent with state law and facility policy.

Response: We thank the commenters. We believe this change will ultimately benefit LTC facility residents.

Discussion of § 483.70(l), (m), and (o)

Provisions on disclosure of ownership, facility closure-administrator, facility closure, and hospice services were proposed to be re-designated as paragraphs § 483.70(k), (l), (m), and (o) respectively, and the cross-reference in (m) updated, but otherwise unchanged. We proposed to address training of paid feeding assistants in § 483.95 ''Training requirements.''

Comment: One commenter stated that they believe that § 483.70(l) is an adequate statement of a requirement for facilities to be judicious about hospitalizing and re-hospitalizing people. The commenter further stated that the additional structural requirements proposed elsewhere in the proposed regulations related to hospital transfers are warranted or that they will somehow correct what are essentially process problems due to diverse causes.

Response: We address the commenters concerns about additional structural requirements related to transfer in our response to comments on proposed § 483.15. Section 483.70(l) applies to requirements for the facility administrator in the event of a facility closure.

Comment: A few commenters recommended we add notice and timing requirements related to facility closure, including notice to facility staff and any union representation.

Response: Timing and notice requirements for facility closures are specified in final § 483.70(l). We did not propose any changes, other than re-designation, to the requirements associated with facility closure. We will consider the commenters' suggestions for future rule-making.

Comment: One commenter was concerned that § 483.70(o)(1)(ii) enabled LTC facilities to ''not arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice.'' The commenter stated that they understand that a resident cannot use both the SNF and hospice benefits at once and that SNF discharge may be needed for a resident to access hospice. However, the commenter feels this situation does not seem to be the intent of the requirement. Moreover, the commenter is concerned that, although a facility may assist the resident in transferring to a facility that will arrange for the provision of hospice services, as stated in the requirement, such a transfer disrupts a resident's care at a critical juncture. Care cannot be person centered, and a LTC facility cannot be considered a resident's home, if the resident is not able to access the services of a Medicare-certified hospice. The commenter urges CMS to delete subsection (o)(1)(ii).

Response: We respectfully decline. While we understand the commenter's concern, such a change is outside the scope of this final rule, as we did not propose any changes to our hospice provisions and have not had the opportunity to obtain public feedback on this issue. We would need to carefully consider the implications for both hospice providers and long-term care facilities of mandating, without exception, that long-term care facilities contract for hospice services. There may be instances where an appropriate hospice provider is not available to the facility or there are other reasons that the facility is unable or unwilling to enter into a contractual relationship with a hospice provider or the hospice provider is unwilling or unable to enter into a contract with the facility. We would need to consider these issues carefully before mandating that nursing facilities contract for hospice services.

Binding Arbitration Agreements (§ 483.70(n))

We proposed in § 483.70(n) to require facilities that ask residents to accept binding arbitration to resolve disputes between the facility and the resident to meet certain criteria. We proposed that the facility be required to explain the agreement to the resident in a form, manner and language that he or she understands and have the resident acknowledge that he or she understands the agreement. The agreement could not contain any language that prohibited or discouraged the resident or any other person from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, or representatives of the Office of the State Long-Term Care Ombudsman, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action, in accordance with proposed § 483.11(i). If a facility utilized an arbitration agreement, such facility would be required to inform the resident, at a minimum, that the resident was waiving his or her right to judicial relief for any potential cause of action covered by the agreement. The agreement could only be entered into by the resident voluntarily and would have to provide for the selection of a neutral arbitrator and a venue convenient to both parties, the resident and the facility. We indicated in the proposed rule that any agreement for binding arbitration could not be contained within any other agreement or paperwork addressing any other issues. It would have to be a separate agreement in which the resident made an affirmative choice to either accept or reject binding arbitration for disputes between the resident and the facility. We also proposed to specify that the guardians or representatives could not consent to an agreement for binding arbitration on the resident's behalf unless that individual was allowed to do so under state law, all of the other requirements in this section were met, and the individual acting on behalf of the resident had no financial interest in the facility. In addition, in the proposed rule, we solicited comments on whether binding arbitration agreements should be prohibited entirely.

We received a significant number of public comments concerning this proposal. The commenters from the LTC facility industry overwhelmingly wanted us to withdraw our proposal. Other commenters, including members of the public, advocates, and members of the legal community, predominantly wanted a prohibition on ''pre-dispute'' arbitration agreements (that is, agreements made before any dispute had arisen). Some commenters believed that arbitration should not be allowed in LTC facilities under any circumstances. We also received numerous items of congressional correspondence concerning arbitration agreements. One letter signed by 34 senators urged CMS to ban pre-dispute arbitration clauses; another letter from three members of the House of Representatives argued that CMS lacked the authority to ban these agreements and, even CMS did have the authority, the agency should not prohibit them. Another senator urged us to seriously consider the concerns surrounding pre-dispute arbitration agreements and their consequences to residents. The senator noted that individuals seeking long-term care, many of whom are elderly or disabled, are basing their decisions on the cost of care and proximity to their loved ones, and that it would be difficult for these individuals to fully understand the gravity of contract terms and their legal rights to concerning potential future disputes between themselves and the facilities. This senator also noted that due to the limited grounds for appeal, it was imperative that both parties understand the terms of the agreement, especially in the long-term care setting, where individuals and their families are making choices that profoundly impact the health and safety of their loved ones.

In addition, we received a letter signed by 16 state attorneys-general stating that pre-dispute arbitration agreements were harmful to residents in LTC facilities and should be prohibited. Other commenters were concerned about particular aspects surrounding arbitration, such as: The conflict of interest in having the LTC facility explain and ask the resident to sign the agreement; the coercive nature of having the resident sign the agreement during the admission process, before any dispute has arisen; the arbitration process not actually being conducted by a neutral arbitrator or in a neutral environment; the costs of arbitration to the residents; and the secrecy of the entire arbitration process. Other commenters were not only against our proposed requirements but opposed any regulation concerning arbitration, including a ban on arbitration agreements. A summary of the comments and our responses are set forth below. We have grouped the discussion into issue areas raised by commenters.

Statutory Authority To Regulate Arbitration Agreements

Comment: Some commenters argued that the federal government, through the Federal Arbitration Act (FAA) (9 U.S.C.A. § 1 *et seq.*) favors arbitration and requires that arbitration agreements be enforced unless there are grounds that exist at law or in equity for the revocation of any contract, such as enforcing the agreement would be unconscionable (9 U.S.C.A. § 2). They also pointed out that both Congress and the courts have repeatedly refused to regulate arbitration agreements between LTC facilities and their residents. They noted that Congress had failed to pass five different bills to regulate arbitration agreements in LTC facilities during [time period].[1] Commenters also cited the Supreme Court's per curiam ruling in *Marmet Health Care Center, Inc.* v. *Brown* (132 S.Ct.1201, 1203 (2012)), which addressed on appeal a decision of the Supreme Court of Appeals of West Virginia. The West Virginia court had held that all predispute arbitration agreements pertaining to claims alleging personal injury or wrongful death were unenforceable in accordance with West Virginia's public policy. The Supreme Court reversed the decision, holding that ''[w]hen state law prohibits outright the arbitration of a particular type of claim, the analysis is straightforward: The conflicting rule is displaced by the FAA.'' *Id.* at 1203 (quotations omitted).

The commenters also pointed to cases in which courts rejected various federal agencies' attempts to prohibit the enforcement of arbitration agreements. The commenters argued that when Congress intends to give an agency authority to prohibit or impose conditions on the use of arbitration agreements it does so with unambiguous statutory language, and it did not do so in the Social Security Act. They also argued that there was no language in the Act that gave the Secretary statutory authority to interfere in commerce, and that Congress had in face expressed its opposition to such actions in creating the International Court of Arbitration of the International Chambers of Commerce (ICC) and the Federal Trade Commission (FTC). They argued that prohibiting the use of or regulating arbitration was contrary to legal policy and tradition favoring contract formation.

[1] *See* Fairness in Nursing Home Arbitration Act of 2012, H.R. 6351, 112th Cong.; Fairness in Nursing Home Arbitration Act of 2009, H.R. 1237, 111th Cong.; Fairness in Nursing Home Arbitration Act, S. 512, 111th Cong.(2009); Fairness in Nursing Home Arbitration Act of 2008, H.R. 6126, 110th Cong.; Fairness in Nursing Home Arbitration Act, S. 2838, 110th Cong. (2008).

In addition, they claimed that a previous survey and certification memorandum issued by CMS acknowledged that these agreements were between the facility and resident. They noted that former HHS Secretary Mike Leavitt had sent a letter dated July 29, 2008 addressed to the House Judiciary Committee, a letter that officially opposed the ''Fairness in Nursing Home Arbitration Act of 2008'' that would have amended the FAA to render pre-dispute binding arbitration agreements between LTC facilities and their residents unenforceable.

Some commenters pointed out that, in addition to the FAA, courts have upheld arbitration in many industries, and that many contracts in the health care field including but not limited to admissions contracts for LTC facilities, are on a take-it-or-leave it basis. Others argued that arbitration had been successfully used in LTC facilities for years and that further regulation was not necessary.

Response: We disagree with the commenters' assertions that CMS lacks authority to issue regulations concerning arbitration agreements contained in LTC facility admissions contracts.

First, we note that the plain language of the FAA applies only to existing arbitration agreements voluntarily made between private parties; it does not compel or require the use of arbitration between private parties.[2] Because it does not prescribe circumstances in which arbitration agreements must be used, it does not impinge on federal agencies' rights to issue regulations regulating the conditions of adoption of such agreements, assuming that the Secretary otherwise has proper statutory authority. Consequently, we believe that the proper focus of this discussion is only on whether these rules have been properly issued under the Act and the procedural requirements of the Administrative Procedure Act. The proposed and final regulation would have no legal effect on the enforceability of existing pre-dispute arbitration agreements between LTC facilities and patients, and therefore we believe that the terms of the FAA are not implicated. ''('' [W]hen two statutes are capable of co-existence . . . it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'' (citation omitted)).'' *Morris* v. *Ernst & Young LLP,* ____ F.3d ____ (9th Cir., August 22, 2016) (2016 WL 4433080 at *8).

We are finalizing this rule, which will prohibit facilities' use of pre-dispute arbitration agreements, as a requirement for participation in the Medicare and Medicaid programs. Under sections 1102(a) and 1871 of the Social Security Act, the Secretary of Health and Human Services Section is authorized to issue such rules as may be necessary to the efficient administration of the functions of the Department. Section 1866 of the Act requires all Medicare providers and suppliers to agree to certain conditions in order to participate in the Medicare program. Likewise, section 1902(a)(27) of the Act requires that Medicaid providers meet all the requirements set out in the Medicaid provider agreement; and section 1902(a)(28) of the Act requires that States ensure that Medicaid nursing facilities meet all provisions of section 1919(b)–(d) of the Act (governing requirements for Medicaid nursing facilities).

The Department regularly requires providers and suppliers of health care items and services to forgo certain rights they might otherwise have with respect to Medicare and Medicaid patients, such as the right to pursue the patient for payment when the patient has no way of knowing that services are not covered by Medicare (See Section 1879 of the Act); requirements that LTC facilities give Medicare beneficiaries written advanced notifications of non-covered services (See Skilled Nursing Facility Advance Beneficiary Notice (SNFABN) Form CMS–10055, accessed at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS019508.html*, on September 19, 2016), limitation on the rights of insurers to market alternative products while potential Medicare advantage customers are placed on hold (or to upsell products to Medicare Advantage and Medicare Prescription Drug Plans (See Medicare Marketing Guidelines, accessed at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf*, on September 19, 2016), specific limitations on the rights to provide patients with promotional information, including a prohibition on marketing Medicare Advantage and Part D insurance plans to Medicare beneficiaries residing in long-term care facilities (including LTC facilities, assisted living facilities, board and care homes, etc.) without first receiving a specific request from the beneficiary (See Medicare Marketing Guidelines issued June 10, 2016, located at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf*, accessed on September 19, 2016), and so on. These rules mandating that suppliers of health care items and services forgo contractual and other commercial rights they might otherwise have with respect to Medicare and Medicaid patients, evince a Congressional and administrative understanding that business arrangements with Medicare and Medicaid patients are not typical commercial contracts where both parties engage in arms-length bargaining. Given the unique circumstances of the LTC admissions process, coupled with the clear interest that Medicare and Medicaid have in protecting beneficiaries, a prohibition on the use of pre-dispute arbitration agreements is not by its nature outside the permissible realm of conditions a facility must meet if it wishes to receive payment under the Medicare and Medicaid programs.

In addition to the statutory authority of the Secretary to set general practice parameters for payment under Medicare and Medicaid, the Secretary, under the explicit authority of Congress, is charged with protecting the health, safety and welfare of LTC facility residents pursuant to specifically enumerated standards set out in sections 1819 and 1919 of the Act. In addition, Congress granted the Secretary explicit authority under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require LTC facilities to ''meet such other requirements relating to the health, safety, and well-being[3] of residents or relating to the physical facilities thereof as the Secretary may find necessary.'' As set out below, there is significant evidence that pre-dispute arbitration agreements have a deleterious impact on the quality of care for Medicare and Medicaid patients, which clearly warrants our regulatory response.

In addition, sections 1819(c)(1)(A) and 1919(c)(1)(A) of the Act create a host of specified rights for LTC facility residents, including, but not limited to, free choice, confidentiality, privacy, and the expression of grievances. These sections also include a broad grant authorizing the Secretary to establish ''any other right'' (sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act) as she may deem necessary. Based on the comments received in

[2] The applicable provision of the FAA reads, in its entirety: ''A written provision in any maritime transaction or a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.'' 9 U.S.C. 2.

[3] We note that section 1919(d)(4)(B) of the Act omits ''well-being''.

response to this rulemaking, we are convinced that requiring residents to sign pre-dispute arbitration agreements is fundamentally unfair because, among other things, it is almost impossible for residents or their decision-makers to give fully informed and voluntary consent to arbitration before a dispute has arisen. We believe that LTC residents should have a right to access the court system if a dispute with a facility arises, and that any agreement to arbitrate a claim should be knowing and voluntary.

With respect to the Supreme Court's opinion in *Marmet,* we believe the decision to be inapposite, because the matter under consideration involves the enforceability of an already-existing pre-dispute arbitration clause. As noted above, the rule we are issuing does not affect already-existing arbitration clauses, but prohibits Medicare-and Medicaid-participating LTC facilities from using them in the future, as a condition of participating in these programs. While we share the same public policy concerns about already-existing arbitration agreements, we are only addressing agreements reached after the effective date of this rule. Likewise, *Compucredit Corp.* v. *Greenwood,* 565 U.S. ____ 132 S.Ct. 665 (2012), a case involving consumer credit, considered whether a provision of the Credit Repair Organizations Act (15 U.S.C. 1679c(a)) (CROA) created a right to sue which would have the effect of rendering any arbitration clause unenforceable. The Supreme Court's opinion held that the statutory language of CROA failed to create an explicit right to have recourse to the courts that superseded the public policy concerns of the FAA. Because the case involved the interpretation of CROA's language, we do not believe it to create any meaningful restriction on the Secretary's statutory authority to prohibit facilities' future use of pre-dispute arbitration clauses as a condition of participation in Medicare and Medicaid.

Concerning the survey and certification letter previously published by CMS, we do not believe the requirements in this final rule contradict that letter. Any agreement for binding arbitration is clearly between a facility and a resident, and this rule does not in any way prohibit the use of post-dispute arbitration agreements. The requirements in this final rule only ensure that the residents receive basic protections in signing an agreement for arbitration. Since facilities will only be able to approach residents to request them to sign an agreement for binding arbitration after a dispute has arisen, residents and their representatives will have the information necessary to make an informed decision, and should also be able to negotiate specific terms. Former HHS Secretary Leavitt's letter, dated July 29, 2008 addressed to the House Judiciary Committee, officially opposedthe Fainess in Nursing Home Arbitration Act of 2008, which would have amended the FAA to render pre-dispute binding arbitration agreements between LTC facilities and their residents unenforceable. Again, we see no contradiction between the Secretary's letter and this final rule. The requirements in this rule do not prohibit arbitration between facilities and residents. After a dispute arises, facilities and residents could enter into agreements for binding arbitration and settle a dispute in arbitration. Our rule also does not affect any arbitration agreements signed before the effective date of the rule. Moreover, it does not purport to preempt or otherwise supersede arbitration agreements made after the effective date. We have only prohibited pre-dispute binding arbitration agreements between facilities and residents as a condition of participation in Medicare and Medicaid. If a facility wishes to continue to utilize pre-dispute agreements, it is free to continue in business without Medicare or Medicaid residents.

We agree with the commenters that arbitration is clearly favored in the Federal courts and has been used in many industries, including the healthcare industry, successfully for years. As discussed in detail below, however, some of the key organizations whose members conduct nursing home arbitrations (including the American Bar Association, the American Health Lawyers Association, and the American Arbitration Association) have expressed concerns about the fairness of pre-dispute arbitration clauses in the LTC context. Thus, while the FAA contains a policy encouraging arbitration, it also recognizes that there may be situations where enforcing an arbitration agreement is improper. For example, the FAA's saving clause permits agreements to arbitrate to be invalidated by certain defenses, such as ''fraud, duress, or unconscionability,'' but not by defenses that apply only to arbitration.

We recognize that an argument could be made that Medicare and Medicaid beneficiaries can assert in Court the FAA's saving clause if they believe that a pre-dispute arbitration agreement should not be enforced. However, the comments we have received have confirmed our conclusion that predispute arbitration clauses are, by their very nature, unconscionable. As one commenter noted, it is virtually impossible for a resident or their surrogate decision-maker to give fully informed or voluntary consent to such arbitration provisions. That same commenter also noted that refusing to agree to the arbitration clause, in most cases, means that care will be denied. Furthermore, Medicare and Medicaid beneficiaries are aged or disabled and ill. Many beneficiaries lack the resources to litigate a malpractice claim, much less an initial claim seeking to invalidate an arbitration clause. Rather than requiring Medicare and Medicaid beneficiaries to incur the additional fees, expense, and delay that would be the direct cost of opposing a motion to enforce arbitration, we have concluded that this is precisely the type of situation envisioned by the Congressional grant of authority contained in sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act authorizing the Secretary to establish ''such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.''

There is a significant differential in bargaining power between LTC facility residents and LTC facilities. LTC agreements are often made when the would-be resident is physically and possibly mentally impaired, and is encountering such a facility for the first time. In many cases, geographic and financial restrictions severely limit the choices available to a LTC resident and his/her family. LTC facilities are also, in many cases, the resident's residence. These facilities not only provide skilled nursing care, but also everything else a resident needs. Many of these residents may reside there for a prolonged period of time, some for the rest of their lives. Because of the wide array of services provided and the length of time the resident and his/her family may have interactions with the LTC facility, disputes over medical treatment, personal safety, treatment of residents, and quality of services provided are likely to occur. Given the unique circumstances of LTC facilities, we have concluded that it is unconscionable for LTC facilities to demand, as a condition of admission, that residents or their representatives sign a pre-dispute agreement for binding arbitration that covers any type of disputes between the parties for the duration of the resident's entire stay, which could be for many years.

Comment: Some commenters stated that the proposed requirements concerning arbitration agreements violate the Non-Delegation and the Separation of Powers Doctrines (*See* Black's Law Dictionary, 7th ed., West

Group, MN (1999)). The Delegation Doctrine states that an agency may only act within the authority granted to it by Congress in the enacting legislation. The Separations of Powers Doctrine states that governmental authority is divided between the three branches of government—the legislative, executive, and judicial—each has its own duties and the other branches should not encroach on its duties. According to these commenters, CMS, is quasi-executive and quasi-legislative. It is not part of the judicial branch and has no authority to act in a quasi-judicial function. They argue that the attempt to regulate arbitration amounts to interference in private contracts, which is contrary to legal policy and tradition favoring contract formation.

Response: As discussed above, the Secretary has statutory authority to promulgate regulations for the residents' health, safety, and well-being and administer the programs under the Act. In addition, the Secretary has the authority to create specified rights for LTC facility residents, including, but not limited to, free choice, confidentiality, privacy, and grievances. Sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act also grant the Secretary authority to establish any other rights for residents. Thus, the Secretary, in this final rule, is acting well within her statutory authority, particularly given the concerns raised by commenters over the unfairness of pre-dispute arbitration and the harm these agreements cause LTC facility residents. In addition, these requirements do not decide the validity of existing arbitration agreements, but establish protections for LTC facility residents prospectively by prohibiting pre-dispute binding arbitration agreements and establishing requirements for post-dispute agreements entered into after the provision's effective date. Insofar as the commenters are going beyond this to question the Secretary's right to issue legislative rules in general, we believe the Secretary's authority under the Social Security Act, authorizing her to promulgate legislative rules under the Administrative Procedure Act (5 U.S.C. 553) that protect the well-being of Medicare and Medicaid beneficiaries, is a matter of settled law.

Residents' Health, Safety, and Well-Being

Comment: Some commenters acknowledged that the Secretary had authority to promulgate regulations for the health and safety of LTC facility residents; however, they indicated that our concerns about these agreements being detrimental to the residents' health and safety were theoretical and the proposals were not ''necessary.'' They also indicated that they were not aware of any incidents in which residents or their families were precluded from expressing quality-of-care concerns with governmental officials. In contrast, other commenters stated that they believed that some facilities use pre-dispute binding arbitration agreements to avoid responsibility for providing poor or substandard care to their residents. Some commenters believed that residents who did not sign pre-dispute binding arbitration agreements received better care than the residents who did sign these agreements. Many commenters expressed their belief that the proposed requirements did not go far enough to protect residents' rights. Most of these commenters wanted to ban arbitration agreements, especially pre-dispute arbitration agreements. However, some of the commenters said that post-dispute binding arbitration agreements should be allowed.

Response: In addition to reviewing the comments received, we conducted a literature review and also reviewed court opinions involving arbitration in LTC facilities. Many the articles we reviewed provided evidence that pre-dispute arbitration agreements were detrimental to the health and safety of LTC facility residents (*See, e.g.,* Tripp, Lisa, ''A Senior Moment: The Executive Branch Solution to the Problem of Binding Arbitration Agreements in LTC facilities Admission Contracts'', *Campbell Law Review Sym. 2009,* 31 Campbell L.Rev. 157 (2009); Tripp, Lisa, ''Arbitration Agreements Used by LTC facilities: An Empirical Study and Critique of AT&T Mobility v. Concepcion'', 35 *Am. J. Trial Advoc. 87* (2011); and Bagby, K. and Souza, S., ''Ending Unfair Arbitration: Fighting Against the Enforcement of Arbitration Agreements in Long-Term Care Contracts'', 29 *J. Contemp. Health L. & Pol'y (2013)*). These articles discuss, among other things, the unequal bargaining power between the resident and the LTC facilities; inadequate explanations of the arbitration agreement; the inappropriateness of presenting the agreement upon admission, an extremely stressful time for the residents and their families; negative incentives on staffing and care as a result of not having the threat of a substantial jury verdict for sub-standard care; and the unfairness of the arbitration process for the resident. Bagby and Souza note that ''oftentimes, only after a nursing facility's negligence has caused a resident severe injury or death, does the resident or family member discover that, upon admission to the nursing facility or during their stay, the resident became bound to settle disputes in arbitration, ostensibly giving up the resident's constitutional right to a jury trial.'' (29 J. Contemp. Health L. & Pol'y 183). Tripp notes that ''residents of nursing homes are frail and elderly people who are completely dependent on the facility and its employees for their safety and health. Thus, many residents and their families would not oppose the arbitration provision because they are fearful of antagonizing the facility'' (31 Campbell L.Rev. 157, p. 5). Tripp further notes that, ''with so many operators selecting pre-dispute binding arbitration, this may have the effect of forcing some vulnerable elders suffering serious injury or even death to adjudicate their claims outside of the public court system with all of its safeguards, and into private arbitration without those protections'' (35 AM. J. Trial Advoc. 89).

Additionally, a number of commenters stated that arbitration clauses have a detrimental effect on patient safety. One commenter, a healthcare provider who had previously treated LTC facility residents, stated that they had personally witnessed resident neglect and attributed it to facilities believing that they were immune to any legal consequences for their mistreatment because of the likelihood that they would prevail in binding arbitration. Another commenter, a large association of lawyers, asserted that permitting pre-dispute arbitration clauses creates an unnecessary shield that protects facilities. Other commenters stated that binding arbitration clauses generally cover all claims, including claims involving serious bodily harm and death, and allow facilities to escape accountability for neglect and abuse. We believe we have ample basis between the published research and the statements of commenters to support the connection between the use of pre-dispute arbitration clauses and the health and safety of LTC facility residents.

Comment: Some commenters stated that proposed § 483.70(n)(4), regarding communication with outside parties, was unnecessary because proposed § 483.11(i) contained similar provisions. Proposed section 483.70(n)(4) would require that the binding arbitration agreement could not contain any language that prohibited or discouraged the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other

federal and state health department employees; and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

Response: Although the two requirements are similar, they are not identical. Proposed § 483.11(i), which is being moved but otherwise finalized as proposed, states that facilities must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal and state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and the protection and advocacy system, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action. However, § 483.70(n)(4) specifically addresses the arbitration agreement and applies both to the resident and anyone else who would like to, or chooses to, communicate with outside authorities. We wished to ensure that pre-dispute arbitration agreements could not be used to in any way prohibit or discourage anyone from contacting or communicating with outside authorities, while § 483.10(k) simply addresses the resident's right to contact outside entities. We believe both requirements are necessary to protect residents' rights and have finalized both of these requirements in this rule.

Arbitration as an Appropriate Forum

Comment: Some commenters believed that the proposed rule suggested that the arbitration proposals were being proposed due to recent changes in the business practices of LTC facilities, especially an increased prevalence of binding arbitration agreements in these facilities. These commenters stated that LTC facilities have been using these agreements for many years. These commenters also noted that residents can still obtain judicial review of an arbitration decision if the agreement was entered into as a result of corruption, fraud, or undue means or that an arbitrator was guilty of misconduct or exceeded his or her powers. They also pointed out that these agreements only establish the forum in which legal claims will be heard and not that residents are denied an opportunity to bring them. However, other commenters pointed out that the differences between arbitration and litigation did result in disadvantages to residents in addition to the lack of judicial review, such as, lack of choice of arbitrators, the venue for the arbitration, and limitations on discovery and damages, such as punitive damages, which might have been available if the dispute were settled in a court. Another commenter, a national association whose members included several groups dedicated to the protection of senior citizens and consumer rights, argued that these pre-dispute binding arbitration agreements and the associated disadvantages they have for residents actually deter many residents from pursuing claims and result in claim suppression.

Response: Although arbitration has been an alternative dispute resolution strategy that has been in use for many years, based upon the comments we have received, as well as our literature review, it appears to us that the use of arbitration agreements has increased in LTC facilities in recent years (Tripp, Lisa. ''A Senior Moment: The Executive Branch Solution to the Problem of Binding Arbitration Agreements in LTC facilities Admission Contracts.'' *Campbell Law Review Sym. 2009* 31 Campbell L. Rev. 157 (2009); and Schleppenback, John R., ''Something Old, Something New: Recent Developments in the Enforceability of Agreements to Arbitrate Disputes Between LTC facilities and Their Residents'', 22 Elder L.J. 141 (2014)). A number of commenters to this rulemaking also stated that there has been a marked increase in the use of binding arbitration agreements by LTC facilities in recent years. For example, one commenter, a large organization of attorneys, referenced a *Wall Street Journal* article that noted that LTC facilities became some of the biggest converts to binding arbitration after sustaining some very large jury awards in the 1990s (Nathan Koppel, ''LTC facilities, in Bid to Cut Costs, Prod Patients to Forgo Lawsuits'' *Wall Street Journal,* April 11, 2008, available at *http://www.wsj.com/articles/SB120786025242805879*, accessed August 3, 2016). The *Wall Street Journal* article also stated that attorneys that litigate on both sides of LTC facility-resident disputes agreed that arbitration in LTC facilities was quickly becoming the rule rather than the exception in these cases.

We disagree with the commenters who suggest that arbitration is merely a change of the forum and therefore, inconsequential. Arbitration changes the manner in which a dispute will be resolved by, among other things, waiving the right to a jury trial, and providing only limited grounds to appeal the arbitrator's decision. Some commenters noted that arbitration can be very expensive for the resident, with some agreements requiring the resident to bear some of the costs of the arbitration, and the limited discovery generally allowed puts the resident at a distinct disadvantage. However, due to contingency agreements with attorneys and the public funding of the court system, residents have a possibility of litigating a dispute with the LTC facility for little or no money. As noted, by entering into an arbitration agreement, both parties are waiving their right to a jury trial. There is no public forum and the arbitrator's decision will not usually be publically available, whereas a court decision would be a matter of public record. We believe that a public knowledge about a dispute and a public record of a decision are vitally important for checking the worst abuses of non-compliant LTC facilities.

We also disagree with the implication that judicial review of an arbitrator's decision is adequate protection for beneficiaries. A resident cannot usually challenge an arbitrator's decision even if it is based on a mistake in the applicable law for the issue in dispute. In addition, even when there are grounds under the applicable state law to overturn the arbitrator's decision, this requires additional judicial proceedings, which adds additional time and expense to the litigation.

We are also concerned about the possibility of claim suppression. If a resident or their representative does not believe that arbitration is a fair process, they may not pursue a claim despite its merit; the secretive nature of the process and decision only adds to the public perception that the forum may be biased against the resident. However, we believe that the requirements being finalized in this rule should mitigate some of commenters' concerns about claim suppression.

Comment: One commenter pointed out that other Medicare and Medicaid healthcare providers use arbitration agreements. This commenter also stated that there was no factual or legal justification for imposing requirements for arbitration agreements on LTC facilities and not on these other providers.

Response: We believe that the concerns about pre-dispute binding arbitration are applicable to any resident that signs one as a condition of receiving services, regardless of provider or supplier type. However, we have decided to make LTC facilities our first priority because many of the residents spend an extended period of time in these facilities, and as noted, these facilities often serve as the resident's residence. A number of commenters agreed with our conclusions. Whether arbitration

agreements should be prohibited for other providers and supplier types is beyond the scope of this rule. However, we will retain this comment for review in case there is future rulemaking in this area.

Comment: One commenter made a Freedom of Information Act (FOIA) request asking for the comments that raised our concerns about arbitration agreements in LTC facilities. They noted that CMS' response was that there was only one document and that was a three-year old letter that had been submitted by a national organization for trial attorneys. The commenter stated that the letter contained an inaccurate portrayal of the use of arbitration agreements in LTC facilities.

Response: We understand that the commenter may have different views from those expressed in the letter that raised the issue of arbitration agreements in LTC facilities. However, our proposed requirements for arbitration agreements were not based solely upon that letter. We performed a literature search and reviewed judicial decisions that involved arbitration agreements in LTC facilities. We also received input from healthcare providers with experience working in or surveying LTC facilities. Thus, our proposed requirements were based upon multiple sources of information, not just the letter described by the commenter. Moreover, as noted, we have received nearly a thousand comments on our proposal and reviewed substantial amounts of information supporting many different points of view.

Comment: Many commenters argued that arbitration was beneficial for residents and their families as well as facilities. Disputes could be resolved more quickly and with less animosity and expense than litigation. Some commenters also argued that prohibiting these agreements would only benefit lawyers, result in protracted litigation, increase costs to the facilities, and increase the burden on an already overwhelmed court system. This would also result in resources for resident care being diverted for litigation. Other commenters argued that prohibiting arbitration could be detrimental to residents. If a dispute was not worth a sufficient amount of money, the resident or their representative might not be able to obtain a lawyer, which could result in the resident not being able to address the dispute with the facility. Some commenters discussed how arbitration agreements may include a prohibition against the individual pursing a class action. A class action arbitration or lawsuit may be the only opportunity an individual may realistically have to pursue their claim. If they could not join a class action, they could be effectively denied any avenue of redress for the dispute. Other commenters were concerned that we had not sufficiently assessed not only the costs of these proposals but also the real life, practical implications of these proposals within the long-term care community and the daily practice within this community. Other commenters disagreed with these arguments. Some argued that there could still be protracted litigation even within the context of pre-dispute arbitration agreements; and noted that arbitration could be very expensive for the resident.

Response: There are both advantages and disadvantages associated with both pre-dispute arbitration agreements and arbitration itself. As finalized in this rule, residents and their representatives have the option of signing an agreement for binding arbitration with the facility after a dispute arises. In addition, residents can also use the facility's grievance process, as set forth at § 483.10(j). However, arbitration agreements, particularly pre-dispute agreements provided to residents on a ''take-it-or-leave-it'' basis, present opportunities for facilities to include terms that undercut commenters' contention that arbitration is a neutral process that works to the benefit of both parties. A report of the American Bar Association noted, ''[c]lauses frequently specify that the provider can select the arbitration service and the location of the arbitration. Some include caps on damages, even for tragic and possibly preventable deaths. Moreover, some clauses or arbitration procedures restrict the discovery process–limiting the number of investigative interviews or the exchange of documents. 'This could prevent an aggrieved consumer's lawyer from deposing all possible employees who might have witnessed an incident at a nursing home and gaining access to relevant records,' whereas the facility has the records and personnel at its disposal (Sturgeon, J., ''Nursing Homes Use Arbitration As a Shield,'' The Roanoke Times, Aug. 24, 2006). The resident may have to pay substantial fees for the arbitration.'' (American Bar Association, Commission on Law and Aging, Policy on LTC facility Arbitration Agreements 111B, page 4, February 16, 2009, at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on September 15, 2016). By contrast, this final rule will allow residents to avail themselves of the benefits of arbitration once a dispute has arisen and the resident and/or his/her representatives can determine whether it may be an advantageous forum for them.

Concerning class actions, we share the commenters' concerns about residents possibly not being able to pursue their claims. However, since we did not propose to address matters relating to class actions in our proposed rule, we are unable to address them in this final rule. We also note that to date, litigation against LTC facilities has involved primarily malpractice claims, which tend to be individual-specific. Because class actions against LTC facilities remain rare, we believe that it is not yet clear that there is a problem that would require additional regulation. We will retain these comments and concerns about protection of class-action litigation and consider for future rulemaking.

Comment: Some commenters pointed out the lawyers in their areas are already aggressively advertising for LTC facility litigation. Another commenter noted that some residents and/or their families are already dispositionally angry before they even arrive at the facility and may find fault with the facility despite the provision of quality care. Other commenters noted that depending upon the jurisdiction and the aggressiveness of the attorney, jury verdicts could be excessive; however, an arbitrator who is an impartial and experienced profession should be able to look at the dispute and make a rational decision. Some commenters noted that an important factor in determining liability insurance premiums was whether a facility used pre-dispute arbitration agreements and that prohibiting these agreements could result in a substantial increase in LTC facilities' insurance premiums. Other commenters expressed their concern that prohibiting pre-dispute binding arbitration agreements could result in a substantial increase in the cost of business without any commensurate quality in care. It would increase the amount of frivolous lawsuits because arbitration was effective in deterring those claims due to the lower damages generally awarded by an arbitrator. In addition, attorney fees are generally much lower in arbitration. This could result in costs becoming prohibitive and force some LTC facilities to close.

Response: We agree with the commenters that arbitration offers advantages to both parties. We also realize that settling disputes in court might take longer and result in more costs to facilities. However, a resident or their representative's choice to engage in arbitration to settle a dispute should be informed and voluntary. This final rule does not prohibit binding

arbitration, only the use of pre-dispute binding arbitration agreements. Once a dispute arises between a resident and the facility, the parties can enter into an agreement for binding arbitration subject to the requirements in this rule. No resident, resident representative, or facility is being denied the opportunity to engage in arbitration to settle a dispute, and this rule has no effect on the enforceability of arbitration agreements in general.

Comment: Some commenters have argued that CMS should not be interfering with a matter that is a private contract between the parties. They noted that some states have already passed legislation concerning arbitration. This legislation may directly concern arbitration, arbitration in LTC facilities, or tort reform. Commenters argued that these issues should be left to the states.

Response: We disagree with the commenter's contention that LTC services are a private contractual matter between two independent parties. Unlike traditional arms-length commercial contracts that are, for the most part, business arrangements between two private individuals, the Medicare and Medicaid programs have a significant interest in both the services being delivered as well as the well-being of the beneficiary. In many cases, Medicare and Medicaid are the sole payors for the services. This is why, for example, Congress has required that the Secretary create a wide assortment of rules and regulations relating to quality of care and the delivery of services in the LTC context.

Furthermore, because the Congress has expressed an clear interest in protecting the rights of Medicare and Medicaid beneficiaries in LTC facilities, it has granted the Secretary statutory authority to establish rights for residents (sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act) and to protect the health, safety and well-being of residents in LTC facilities (sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act). Because of overriding Congressional mandate that the Secretary protect the health and welfare of LTC residents, we believe that a federal uniform response is both necessary and appropriate.

When, How Arbitration Agreement Is Reached

Commenters noted that residents or their representatives are typically asked to sign arbitration agreements during the admission process, and that the pre-dispute arbitration agreement is one clause in a contract comprising many pages. Since no dispute had yet occurred, the resident or their representative could not fully understand the rights they were waiving or how any future dispute would be handled. They might also not understand or be thinking about the possible problems that could occur during their stay, including substandard care that could result in serious injury or even death. It is also highly unlikely they would have consulted a lawyer about the agreement. Commenters noted that admission to a LTC facility is usually an extremely stressful time for the resident and his or her family. The resident may have a serious injury, surgery, or illness, is being removed from their usual living arrangements, and is being admitted to a facility for an indeterminate period of time.

One commenter noted that one state, Georgia, has a statute that states, concerning medical malpractice claims, ''no agreement to arbitrate shall be enforceable unless the agreement was made subsequent to the alleged malpractice and after a dispute or controversy has occurred and unless the claimant is represented by an attorney at law at the time the agreement is entered into'' (Ga. Code Ann., § 9–9–62).

Some commenters pointed out that in the state of Mississippi this proposal could result in neither the resident nor a healthcare surrogate being able to sign an agreement to arbitrate disputes with the facility. Miss. Code Ann. § 41–41–211 allows for a healthcare surrogate to make healthcare decisions for another person if that individual's primary care physician determines that he or she lacks capacity and no agent or guardian has been appointed or the agent or guardian is not reasonably available. Commenters also cited a court case, *Mississippi Care Center of Greenville, LLC. et al.* v. *Nancy Hinyub,* 975 So.2d 211 (Miss. 2008) (*Hinyub*), a case in which the Mississippi Supreme Court held that a health care surrogate could not bind a party to arbitration unless the arbitration provision was an essential part of the consideration for the receipt of ''health care.'' The commenters noted that after *Hinyub,* Mississippi LTC facilities now require patients or their surrogates to sign pre-dispute arbitration agreements as a condition of admission and receipt of services. Some commenters noted that a facility's explaining an arbitration clause to a resident could be viewed as providing legal advice and therefore the unlicensed practice of law.

Response: When a resident or his or her representative signs an agreement for binding arbitration, he or she is waiving the right to go to court and have a dispute decided by a judge and jury. We believe that any waiver of this right should be voluntary and informed. Would-be residents are often presented a ''take-it-or-leave-it'' contract under circumstances where meaningful or informed consent for pre-dispute arbitration is often lacking. Thus, we believe that voluntary post-dispute arbitration agreements are the best way to balance the policy favoring arbitration with the need to protect beneficiaries from unfairly waiving their rights to a jury trial. While we support the public policy behind the Georgia statute referenced by the commenter, we acknowledge that this provision was determined to have been preempted by the Federal Arbitration Act (*see Triad Health Management of Georgia, LLC, III* v. *Johnson,* 298 Ga. App. 204, 679 SE.2nd 785 (2009) and suggests that leaving this policy to the discretion of states may not be an effective strategy. Consequently, this case, like others, illustrates the necessity of prohibiting pre-dispute arbitration agreements.[4] With respect to the decision in *Hinyub,* we note that this rule will effectively moot the holding in this case, since LTC facilities will no longer be able to assert that pre-dispute binding arbitration agreement was an element of consideration in the admissions contract. To the extent that *Hinyub* would be applicable to surrogates' power to bind the resident to a post-dispute arbitration agreement meeting our requirements, we defer to state law on this matter.

Comment: A few commenters were concerned about the requirement in proposed § 483.70(n)(5)(iii) that indicated that another individual could sign the agreement for binding arbitration if, among other things, that individual had no interest in the facility. Commenters pointed out that some residents might have next-of-kin or representatives that work for the facility or are otherwise associated with, or have an interest in, the facility. This proposed requirement could result in representatives that might want to sign the agreement, but would be prohibited from doing so.

Response: We understand that, in some circumstances, this could mean that a particular representative for a resident would not be able to sign an agreement for binding arbitration. However, we continue to believe that individuals who have a financial or employment interest in a facility have

[4] According to the complaint in *Triad,* ''as a proximate result of Triad's negligence, Johnson's father, Matthew Johnson, developed bed sores, which led to his development of sepsis and his subsequent hospitalization, illness, and death.'' 298 Ga. App. At 204.

an inherent conflict of interest and must not sign an agreement for binding arbitration for another person. We believe that the resident's family would be able to find an individual not associated with the facility for such purposes. In any case, the rare occasion when the representative of the patient also has a financial interest in the facility will not prevent us from implementing a provision that generally protects residents against conflicts of interest.

Unequal Bargaining Power

Comment: Commenters noted that facilities would likely have experience with arbitrations, but not residents. The facility usually decides, and sometimes names in the arbitration agreement, how the arbitrator will be chosen and where the arbitration will be held. Some commenters argued that the arbitrator has a financial incentive to be favorable to the facility. It is unlikely that the resident will need to hire an arbitrator in the future; however, facilities are likely be involved in future arbitrations. Hence, the arbitrator will want facilities to select them for future arbitrations. Other commenters said that this potential bias could be addressed by educating residents and their representatives about local arbitrators. Other commenters believed that no regulation could overcome the problems with arbitration in LTC facilities, such as the facility's superior bargaining power, the risk that the resident or their representative will not fully understand the agreement, that signing the agreement would inherently be coerced, unfair, or unconscionable, and the inherent conflict of interest of having the facility explain the agreement (the potential future adversary in any dispute). Some commenters noted that facility may imply that the agreements were not voluntary such that the resident or their representative may not believe they have a choice on whether to sign it. As previously noted, arbitration agreements are often just one paragraph of an admissions package that generally that is quite extensive. The arbitration agreement may be a clause within another document or otherwise does not stand out. Thus, the resident or their representative may not even realize they are signing an arbitration agreement. The agreement may not be sufficiently explained so that the resident or their representative fully understands the rights they are waiving or the arbitration process. The facility employee admitting the resident may not even fully understand the agreement.

Response: We agree with those commenters that asserted that there is unequal bargaining power between the residents and their representatives and the facilities. The resident's immediate need for nursing care and lack of experience with arbitration means that residents are unlikely to ask for time to seek legal advice concerning the agreement for binding arbitration. We believe that this unequal bargaining power cannot be alleviated with the protections we initially proposed. Thus, in this final rule, in response to a significant volume of public comment, we are prohibiting the use of pre-dispute binding arbitration agreements between residents and the facilities. After a dispute arises, residents or their representatives will have the time to seek legal advice, if they choose to, and evaluate the option to arbitrate the dispute with the facility.

Three major legal or arbitration associations have made policy statements against pre-dispute binding arbitration agreements. In 2009, the American Bar Association (ABA) issued a policy statement that opposed the use of mandatory, binding, pre-dispute arbitration agreements between a long-term care facility and a resident or a person acting for the resident. That policy statement also indicated that the ABA supported enactment of federal regulations that would, among other things, invalidate such arbitration agreements (American Bar Association, Commission on Law and Aging, Policy on LTC facility Arbitration Agreements 11B, February 16, 2009, at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on August 3, 2016). The American Health Lawyers Association's Alternative Dispute Resolution Services Rules of Procedure for Arbitration, revised in May 2012, indicated that their ADR service would administer a ''consumer health care liability claim'' only if ''all of the parties agreed in writing to arbitrate the claim after the injury has occurred'' or arbitration is order by a judge (file:///G:/DIQS/LTC%20Facilities/Regulations/Resources/AHLA%20Arbitration%20Procedures%20May%2031,%202012.pdf, citation added). (A later revision to the statement did not include this prohibition, but did include requirements to ensure, among other things, that a pre-dispute arbitration agreement was voluntary, could not be a condition for obtaining care, and included a right to revoke the agreement within 10 days after being signed.) (*https://www.healthlawyers.org/dr/SiteAssets/Lists/drsaccordion/EditForm/Rules%20Effective%20April%207.pdf*, accessed on August 3, 2016). In addition, in 2003, the American Arbitration Association issued a Healthcare Policy Statement that said ''it would not administer healthcare arbitrations between individual patients and healthcare service providers that relate to medical services, such as negligence and medical malpractice disputes, unless all parties agreed to submit the matter to arbitration after the dispute arose'' (file:///C:/Users/PI47/Downloads/HC%20Policy%20Statement.pdf, accessed August 3, 2016).

After a dispute arises and residents or their representatives have the opportunity to seek legal counsel and review their options, we believe they can make a rational and informed decision about arbitration. Thus, while the bargaining power between LTC facilities and residents will undoubtedly never be equal, we believe that the requirements finalized in this rule will provide residents with the protections they need to preserve their rights, while still preserving the option of arbitration if both parties decide to arbitrate a dispute.

Confidentiality of Arbitration Process and Decisions

Comment: Several commenters indicated that the arbitration process is usually confidential and secretive. Most, arbitration agreements have confidentiality clauses that prohibit both parties from discussing the dispute and what happens during the arbitration process, including the decision, with outside parties. Some of the commenters were concerned that arbitration regarding disputes involving abuse and neglect shields facilities from having their poor quality or dangerous conditions exposed to the public and prevented judges who would hear the case if it were decided in court from making findings of fact and conclusions of law that would influence future nursing facility conduct. One commenter stated that not only did arbitration and its secrecy result in substandard care for residents but also that facilities had incentives to, and did, provide better care to residents who did not sign the pre-dispute arbitration agreements. Other commenters asked how CMS would be able to survey facilities for compliance with arbitration requirements.

Response: We agree that the secrecy surrounding the arbitration process is a substantial concern. We are also concerned that the arbitration process, especially the secrecy it involves, could

result in some facilities evading responsibility for substandard care. We are finalizing the proposed requirement at § 483.70(n)(4) that the agreement cannot contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials. When any dispute involves any allegations that relate to our long-term care requirements, especially the health care provided by the facility or instances of abuse or neglect, we believe it is necessary for the protection of the health and safety of residents that federal, state, and local health and regulatory officials have access to the relevant information and be able to conduct an investigation as appropriate. Anything that could interfere with federal, state, or local health and regulatory officials or LTC advocates from learning of, or restricting the investigation of, instances of substandard care or other serious instances affects the health and safety of residents. When a surveyor discovers substandard care or another violation of the LTC facility requirements of participation and cites the facility with a deficiency, the surveyor would cite the deficiency on a Form CMS–2567, which is filed with both the state surveyor agency and CMS. This form is available to the public and can be accessed on the LTC Facility Compare Web site at *https://www.medicare.gov/nursinghomecompare/search.html*. Concerning CMS' ability to survey for compliance with the requirements in this final rule, we have also inserted a requirement that when the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee. This will provide surveyors and CMS the opportunity to learn how often and under what circumstances arbitration is occurring at a facility, as well as the outcomes of any arbitrations. In addition, CMS will be publishing sub-regulatory guidance for surveyors concerning the requirements. Although arbitration proceedings will not have the potential publicity of a trial, arbitrations in LTC facilities will no longer be confidential and secret. CMS will be monitoring the use of arbitration in LTC facilities through the survey process, not only through the normally scheduled surveys but also through the complaint process.

General Comments

Comment: Some commenters argued that it was inconsistent for CMS to describe the problems associated with the use of binding arbitration agreements but nonetheless authorize their use in LTC facilities. Some commenters also believed the proposed arbitration requirements were inconsistent with other proposed requirements in the proposed rule. Specifically, commenters noted that § 483.15(a)(2)(iii), which prohibits facilities from requesting or requiring residents ''to waive potential facility liability for losses of personal property'' could be deemed to be at cross-purposes with binding arbitration. In addition, the commenters noted that proposed § 483.10 confirms the residents' rights to exercise rights as citizens or residents of the United States.

Response: We agree with the commenters that indiscriminate use of arbitration agreements in LTC facility contracts can create a risk of improperly insulating facilities from liability or loss of property, and they, likewise, create a risk of residents unwittingly waiving their rights. We also recognize, however, there are legal and policy reasons supporting post-dispute arbitration. We believe a balance be struck between protecting residents' rights and conducting arbitration when appropriate. We do not believe that the requirements identified by the commenters are inconsistent with the arbitration requirements. In cases where residents or their representatives sign arbitration agreements, they still have the right to pursue claims for losses of personal property. However, the dispute would be handled through arbitration, rather than in court. Section 483.10, which confirms the residents' rights to exercise their rights as citizens or residents of the United States, is also consistent with the arbitration requirements. The arbitration requirements in no way denigrate the residents' rights as citizens or residents of the United States. We will continue to monitor arbitration agreements to ensure that residents' rights are, in fact, protected.

Comment: Some commenters argued that our proposed requirements concerning arbitration were inconsistent with the positions taken by the legal community and other federal agencies. One commenter said that one legal scholar has called on the Department of Health and Human Services to declare arbitration agreements by LTC facilities unconscionable and to ''prohibit federal funding of LTC facilities that use them'' (citing Lisa Tripp's ''A Senior Moment''). They pointed to the 2009 Midyear Meeting of the American Bar Association, in which the House of Delegates adopted Resolution 111B, which was introduced by the ABA Commission on Law and Aging and co-sponsored by the Section of Dispute Resolution. The Resolution, which became official policy of the ABA, ''supports the enactment of federal, state, and territorial legislation and regulations that oppose the use of mandatory, binding, pre-dispute arbitration agreements between a long-term care facility and a resident of such facility or person acting on behalf of such resident'' accessed at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, on September 19, 2016). In addition, the commenters discussed an initiative of the Consumer Financial Protection Bureau (CFPB), which initiated rulemaking on arbitration agreements, and, in March 2015, issued a Congressionally-mandated report, which found that arbitration agreements limit consumer relief in disputes. Some commenters pointed to examples in which arbitration was specifically prohibited for specific types of claims. For example, commenters cited a 2009 amendment to the Department of Defense Appropriations Act, which imposed a restriction on the ability of certain DOD contractors and subcontractors to enter into or enforce mandatory arbitration agreements with their employees in cases of discrimination or sexual assault (Section 8116, Pub. L. 111–118 December 19, 2009). According to the commenters, since its passage, the amendment has been successfully implemented by the Department of Defense, the government's largest federal contracting agency. (*See* 48 CFR 252.222–7006 Restrictions on the Use of Mandatory Arbitration Agreements). Another example was from 2014, when President Obama issued an Executive Order (E.O.) aimed at ensuring safe workplaces and fair pay for American workers. Among its protections, the E.O. mandates that companies with federal contracts of $1 million or more cannot require their employees to enter into pre-dispute arbitration agreements for any disputes arising out of Title VII of the Civil Rights Act or from torts related to sexual assault or harassment. E.O. 13673, Section 6, 79 FR 45309 (July 31, 2014).

Response: While we recognize that some members of the legal community and other federal agencies may have taken different approaches to this issue,

each situation is different, and the legal and policy issues are unique to each particular agency and program. While some commenters have requested that we ban all arbitration, we have determined, at this point, to implement a policy that strikes a balance between banning arbitration in all situations and allowing unfettered use of arbitration clauses with no restrictions on their terms or usage. We are aware of attempts to regulate arbitration taken by these agencies, and we are also aware of the positions taken by some groups against arbitration and pre-dispute arbitration agreements. The regulations finalized in this rule prohibit pre-dispute binding arbitration agreement and are intended to protect residents from many of the problems identified by critics of arbitration. We also note that many groups do not call for an outright ban on arbitration in LTC facility contracts but, rather, encouraged us to add limits on arbitration agreements. For example, as noted above, the American Bar Association's comments stated that, while arbitration can be a viable means of resolving LTC facility resident-facility disputes, it is only appropriate after the dispute has arisen and each party knows the contours and seriousness of the claims. See the ABA's Position Statement 111B at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on August 1, 2016. The other requirements finalized in this rule also work to protect the rights of the residents and prohibit many of the unfair practices that have been identified by the commenters. We will continue to monitor this issue in order to ensure that the requirements implemented by these regulations adequately protect resident' rights and, if we determine that they do not, we may revisit the issue of banning arbitration or adding additional protections for residents.

Comment: Some commenters pointed out that the proposed requirements could adversely affect residents' legal positions in litigation regarding the enforceability of arbitration agreements in general. Facilities could use their compliance with the requirements to argue that the resident or their representative fully understood the agreement and voluntarily choose to sign the agreement. The requirements could also be interpreted as in some way condoning or authorizing binding arbitration agreements in facilities. It could make it more difficult for residents to challenge the arbitration.

Response: These regulations are not meant to limit or provide standards for courts to use in determining if an arbitration agreement should be enforced in, for example, a motion to compel arbitration. These requirements are minimum requirements for ensuring fairness for LTC facility residents. By addressing these agreements in this rule, we are not condoning them, but simply acknowledging that they are used by LTC facilities. The requirements will provide residents with the minimum protections they need and we intend that these rules will allow residents to make an informed and voluntary choice. With respect to the litigation posture of parties that might have wished to challenge a facility's motion to compel arbitration under our proposed rule, we believe that this concern has been mooted by our decision to prohibit the use of pre-dispute arbitration agreements entirely. Insofar as a party would wish to challenge a post-dispute arbitration agreement, we believe the existing jurisprudence interpreting the FAA would be applicable under such circumstances.

Comment: Commenters disagreed with our contention that the proposed requirements ensured that residents and their representatives would be offered a ''voluntary'' choice concerning binding arbitration. The commenters stated that both arbitration and mediation are alternatives to litigation and options for alternative dispute resolution (ADR). If arbitration is the only ADR option offered to residents and their representatives, it is a forced substitute rather than an alternative that is voluntarily and knowingly entered into by the parties.

Response: We agree that ADR consists of multiple options in addition to arbitration. However, we are only addressing arbitration in this rule. Rules regarding mediation are not within the scope of this rulemaking.

Comment: Some commenters cited *Hinyub* for the proposition that it is permissible for LTC facilities to require residents or their surrogates to sign arbitration agreements as a condition of admission and receipt of services. Commenters claim that, if these agreements were not part of the admissions contracts, there may be no one to sign them, which would deny the resident the option to choose arbitration, which would be a violation of the FAA.

Response: Although the commenters cite *Hinyub* as support for the legality of mandatory arbitration agreements under Mississippi law, to the contrary, this case illustrates the Secretary's concerns about the fundamental fairness of making arbitration agreements a mandatory condition for admission to a LTC facility. The dispute in *Hinyub* included, among other things, claims against a LTC facility and others for malpractice, negligence, fraud, breach of fiduciary duty, and wrongful death. The response of Mississippi's LTC facilities to require arbitration agreements as an organic part of the agreement, illustrates our underlying concerns about the incentives such agreements provide to deliver substandard care. Under our final rule, Mississippi LTC facilities that require new residents to agree to pre-dispute arbitration as a condition of admission will not be deemed to be in compliance with our requirements and will be subject to termination.

Comment: One commenter recommended that any regulations concerning arbitration be delayed. The commenter believed that there was insufficient evidence of what problems, if any, existed with arbitration in LTC facilities. The commenter noted that Congress has considered various pieces of legislation concerning this issue and not passed any of them; this demonstrates that the issues are not well understood or no optimal solution has yet to be determined. They recommended that CMS not finalize any requirements concerning arbitration until Congress has more fully explored this issue and determined what, if any, actions are appropriate.

Response: We disagree with the commenter. In response to the proposed rule, we received almost 1,000 comments about our proposed arbitration requirements. In addition, we believe that our review of case law and the literature, including law review articles, amply demonstrates the importance of the issues surrounding arbitration in LTC facilities. Because we believe that further monitoring of the effects of this rule are necessary, we are requiring that LTC facilities retain a copy of the signed agreement for post-dispute binding arbitration and the arbitrator's final decision for 5 years to that it can be inspected by CMS or its designee upon request. This will enable us to gather information on arbitrations that have taken place in LTC facilities to determine if the requirements finalized in this rule are providing the protections resident need.

We also note that although no specific legislation has passed, Congress has not been silent on this issue. Several hearings have been held on this issue, and there is a voluminous legislative record evidencing the need for action on this matter. We also note that there is broad support for protecting residents of LTC facilities. For instance, in a Joint Hearing of the Senate Judiciary Subcommittee on Antitrust, Competition, and Consumer Rights and

the Special Committee on Aging, Sen. Gordon Smith (R–OR) stated, ''The Federal Arbitration Act was enacted in 1925 as a means to ensure a framework for the enforcement and to determine the validity of arbitration agreements. . . . Today, however, we are talking about a particularly vulnerable population. And when we talk about such populations, we must ensure an additional level of scrutiny to guarantee that their rights are protected, as they may not be in a position to protect themselves.'' (Senate Special Committee on Aging, ''S. 2838, the Fairness in Nursing Home Arbitration Act'', 110th Congress, June 18, 2008, accessed at *http://www.aging.senate.gov/hearings/s2838-the-fairness-in-nursing-home-arbitration-act* September 15, 2016).

Comment: One commenter, an association of elected officials, believed that it was important that consumers be informed of the potential impact of binding arbitration agreements on LTC facility residents. They suggested that HHS develop a public information campaign concerning these agreements and tools to assist consumers to understand the implications of these agreements and how they would affect their rights as consumers.

Response: We understand and appreciate the commenter's concern that consumers, especially facility residents and their representatives, be informed about binding arbitration agreements, their implications, and how they affect consumer rights. However, such a campaign is beyond the scope of this rule.

Final Decision

We are adding a requirement to proposed § 483.70(n) to provide that Medicare and Medicaid-participating LTC facilities can no longer enter into pre-dispute binding arbitration agreements with their residents or their representatives. We are retaining the proposed requirements and specifying at paragraph (n) that they will apply if a facility chooses to ask a resident to sign a post-dispute arbitration agreement. We have also revised proposed § 483.70(n)(3) to provide that an LTC facility cannot require the resident to sign a post-dispute arbitration agreement as a condition of the resident's continuing to stay at the facility. Finally, to address commenters' concerns regarding the confidentiality of the arbitration process and its negative effects on patient health and safety, we have added a new paragraph (n)(2)(vi) to provide that when the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee. Although the arbitration proceedings themselves could still be confidential, this requirement will enable us to evaluate whether agreements for binding arbitration and the impact of arbitration in the long-term care industry is having desired effects for both the residents and the facilities.

We emphasize that this final rule does not prohibit all arbitration agreements between residents and the LTC facilities in which they reside, and does not have any effect on existing arbitration agreements or render them unenforceable. It has no effect on LTC facilities that do not participate in the Medicare or Medicaid programs. It does not create any new standard for determining whether an arbitration agreement is unconscionable. It only affects Medicare and Medicaid LTC facilities insofar as they wish to ask their residents if they wish to voluntarily enter into arbitration. After a dispute arises, the resident and the LTC facility may voluntarily enter into a binding arbitration agreement if both parties agree and comply with the relevant requirements set forth in § 483.70(n) of this final rule.

Social Worker (§ 483.70(p))

We proposed to relocate the requirement for and qualifications of a social worker from the current § 483.15(g)(3) to § 483.70(p). In addition, there is a list of human services fields from which a bachelor's degree could provide the minimum educational requirement for a social worker. We proposed to add ''gerontology'' to that list of human services fields.

Comment: Commenters were very supportive of and expressed their belief in the importance of social workers in LTC facilities. Some commenters were very concerned about the qualifications for social workers in LTC facilities, especially the education that is required. Some commenters disagreed with allowing individuals with bachelor's degree in a human services field other than social work, which is a human services field, to work as social workers in LTC facilities and believed that the minimum requirement for a social worker in a LTC facility should be a bachelor's in social work. Other commenters wanted a bachelor's or master's degree in social work as a minimum education requirement and that the degree be from a program accredited by the Council On Social Work Education (CSWE). Other commenters' objected to using the title of ''social worker'' for anyone who does not have a bachelor's (BSW), master's (MSW) or doctorate in social work. Commenters pointed out that individuals with a bachelor's in a human services field do not have the same education as social workers. Social workers, at both the bachelor's and master's degree levels, receive training in interviewing and psychosocial assessment, care planning, and intervention. Individuals with other human services degrees may not be adequately prepared to identify and address psychosocial issues. In addition, some commenters specifically disagreed with the proposed addition of ''gerontology'' to the examples of human services degrees that could qualify someone as a social worker. Commenters noted that CSWE-accredited programs provided competency-based education that integrates and applies knowledge, skills, and values and are based on nine competencies and that these competencies are congruent with the competency based emphasis in the proposed rule. They also noted that these programs provide for field placements that are under the supervision of professional social workers. They noted their concerns about CMS recognizing degrees in psychology, rehabilitation counseling, sociology, special education, and other ''human services'' as sufficient preparation for LTC facility social work. They were also concerned with the de-professionalization of LTC facility social work and cited to a study that indicated that 20 percent of social services director did not have even a bachelor's degree and only 50 percent held a bachelor's in social work. Commenters also noted that the educational preparation for BSWs and MSWs prepares individuals to fulfill the requirements in the proposed rule, such as, promoting quality of care and quality of life for all residents (§ 483.25), advocating for residents' rights and helping facilities uphold those rights (§ 483.10), preventing and addressing abuse, neglect, and exploitation of older adults and other LTC facility residents (§ 483.12), and facilitating transitions of care and discharge planning (§ 483.15 and § 483.20). Commenters also pointed to other areas that professional social workers were well-equipped to perform in the facility, such as, strengthening communication among residents, families, and facility staff; facilitating financial and medical decision making, including advance care planning; and providing individual, family, and group education and counseling related to

illness, disability, treatment, interpersonal relationships, grief, loss, dying, and death. Commenters also agreed with the one year of supervised social work experience in a health care setting working directly with individuals.

Response: We understand the commenters' concern for the qualifications for social workers in LTC facilities. However, pursuant to sections 1819(b)(7) and 1919(b)(7) of the Act, for skilled nursing facilities and nursing facilities, respectively, with 120 or more beds, the facility must have a full-time social worker with at least a bachelor's degree in social work or similar professional qualifications employed to provide or assure the provision of social services. This is a statutory requirement. Thus, we cannot remove the requirement that an individual with similar professional qualifications can provide or assure the provision of social services. Individuals with a bachelor's degree in a human services field, including but not limited to, sociology, special education, rehabilitation counseling, and psychology can be qualified social workers under the current requirements for long-term care facilities. We believe that LTC facilities need the flexibility to hire individuals who are qualified and have the competencies and skill sets to perform the jobs they are hired to do. According to this final rule, LTC facilities must conduct a facility assessment, which assesses, among other factors, the care required by the resident population and the staff competencies necessary to care for that resident population (§ 483.70(e)), and, must have sufficient direct care/direct assess staff with the appropriate competencies and skills to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident (§ 483.40(a)). If the LTC facility does employ an individual with a human services degree as a social worker, that individual must have the competencies and skill sets to perform the duties and responsibilities the LTC facility determines are needed for the social worker position in their facility. Thus, we are finalizing the social worker qualifications at § 483.70(p) as proposed, with ''gerontology'' as an example of a human services field that an individual with a bachelor's degree could qualify as a social worker in a LTC facility.

Comment: Some commenters wanted to delete the exemption for a full-time social worker in LTC facilities with 120 or fewer beds and require that all LTC facilities, regardless of size, be required to employ a full-time social worker. Other commenters recommended a ratio of one full-time equivalent (FTE) social worker for the first 50 residents and one FTE social worker for up to an addition 12 residents. Commenters noted that this is the ratio proposed by the National Nursing Home Social Work Network's Policy Committee. They believe that all LTC facility residents need the services of social workers because of their importance in ensuring residents' quality of care and quality of life and that there must be a sufficient number of social workers in each facility. Commenters also noted that the new requirements in the Mandatory Data Set (MDS) increased the social workers' workload and has already affected the quantity and quality of psychosocial services they can provide and the launch of MDS 3.0 will increase that workload. In addition, some commenters argued that the 120-bed rule was incompatible with the current and proposed requirements to provide person-centered care.

Response: As discussed above, the requirement for one full-time social worker for LTC facilities with more than 120 beds is statutory (sections 1819(b)(7) and 1919(b)(7) of the Act). One of the focuses of this final rule is person-centered care (see § 483.21 ''Comprehensive person-centered care planning''). Social services are essential; however, the requirements for social workers will vary depending up the needs of the resident population, as well as the staff and the facility itself. Smaller LTC facilities might not need a full-time social worker. Larger LTC facilities or facilities with residents with complex needs might require either more than one full-time social worker or more staff to assist the social worker. As discussed above, the facility assessment performed by the LTC facility should identify the social services the resident population requires (§ 483.70(e)). The LTC facility should then determine how to ensure that those social services are provided. Hence, we will be finalizing the requirement for the social worker as proposed.

Comment: Commenters noted that some LTC facilities might decide to hire social services staff to fulfill administrative function, such as completing financial paperwork, or meeting some of the residents' needs, such as arranging appointments or locating lost items. The commenters wanted these individuals to be called ''social services assistants'' and not be counted as ''qualified social workers,'' especially for any minimum staffing ratio.

Response: As discussed above, we are finalizing the qualifications for a ''qualified social worker'' as proposed. Hence, the facility may refer to anyone who meets those qualification as a ''qualified social worker'' regardless of the duties and responsibilities they are assigned. In addition, as discussed above, we will not be establishing any minimum staffing ratios for LTC facilities, including ratios for social workers.

Comment: Some commenters stated that social work practitioners with more experience providing quality psychosocial care could provide consultation to BSWs and MSWs, especially those with little experience, to ensure that residents receive high-quality psychosocial care. The commenters recommended that LTC facilities provide expert social work consultation to social work directors. This consultation should address practice, administrative, and organizational issues along with program planning and professional development. A consultant could also provide consultation to the facility administration and staff concerning program planning, policy development, and priority setting related to social work services; case consultation concerning the psychosocial needs of residents and their families; and in-service education on selected topics.

Response: We agree with the commenters that many LTC facilities and their residents could benefit from consultation with an expert in social work. However, we do not believe that we should require that consultation in this final rule. As discussed above, LTC facilities must perform a facility assessment and determine what resources it needs to care for its residents. LTC facilities need the flexibility to not only assess the needs of the resident population but determine how to satisfy those needs. When a LTC facility determines that it is deficient in the social services it needs to provide its residents, and perhaps the staff or facility itself, then we would encourage them to obtain consultation concerning social services. However, we will not require that consultation.

Comment: Some commenters acknowledged that some facilities had reported difficulties in locating an adequate number of BSWs or MSWs. These commenters offered some suggestions on how LTC facilities could recruit and retain BSWs and MSWs. These suggestions included partnering with social work degree programs, chapters in social work associations, and state associations that are concerned about the care provided by

LTC facilities to recruit social workers. Commenters also believed that LTC facilities could enhance their recruiting and retention of social workers by making their jobs more appealing and noted some of the challenges social workers encounter in LTC facilities, such as low wages, large caseloads, professional isolation, and assigned tasks being below their skill level. Commenters also recommended that CMS provide extra resources to support social worker recruitment and retention efforts for LTC facilities, especially for frontier and rural areas.

Response: We appreciate the commenters' suggestions. We encourage LTC facilities to consider these suggestions for recruiting and retaining social workers. However, requiring LTC facilities to follow these suggestions will not be included in this final rule. In addition, providing more resources is beyond the scope of this rule. LTC facilities are expected to comply with these requirements within the funding that is provided.

Mandatory Submission of Staffing Information Based on Payroll Data in a Uniform Format (§ 483.70(q))

Finally, we indicated that in the proposed rule entitled ''Medicare and Medicaid Programs; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (CMS–1622–P) (80 FR 22044), published on April 20, 2015, at § 483.75(u), we proposed to require that facilities submit staffing information based on payroll data in a uniform format. Section 6106 of the Affordable Care Act of 2010 (Pub. L. 111–148, March 23, 2010) added a new section 1128I to the Act that requires a facility to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary. We proposed to re-designate § 483.75(u) (as set out in the April 20, 2015 proposed rule at 80 FR 22044) to § 483.70(q). We note that the proposed rule was finalized on August 4, 2015 (see 80 FR 46389) and we are finalizing the re-designation of the requirement in the final rule at § 483.75(u) to § 483.70(q) in this final rule.

As a result of comments received, we are finalizing this section as proposed, with the following revisions:

- We have added 45 CFR part 92 to the regulations specifically referenced in § 483.70(c) ''Relationship to other HHS regulations.''
- We have withdrawn our proposal to delete the phrase ''where licensing is required'' from § 483.70(d)(2)(i).
- In § 483.70(n), we have modified paragraph (1) to prohibit the use of pre-dispute agreements for binding arbitration between any resident or their representative and the facility and allow post-dispute agreements for binding arbitration, if the facility complies with the requirements in this section.

V. Quality Assurance and Performance Improvement (QAPI) (§ 483.75)

Section 6102 of the Affordable Care Act amended the Act by adding new section 1128I. Subsection (c) of section 1128I of the Act requires that the Secretary establish and implement a QAPI program requirement for all SNFs and NFs, including those that are part of a multi-unit chain of facilities. Under the QAPI provision, the Secretary must establish standards relating to facilities' QAPI program and provide technical assistance to facilities on the development of best practices in order to meet these standards. No later than 1 year after the date on which the standards are issued, a facility must submit to the Secretary a plan for the facility to meet these standards and implement the best practices, including a description of how it would coordinate the implementation of the plan with quality assessment and assurance activities currently conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B) of the Act. In accordance with the QAPI provisions of the Affordable Care Act, we proposed to establish these standards.

Current regulations at § 483.75(o) require a facility to maintain a quality assessment and assurance (QAA) committee, consisting of the director of nursing services, a physician designated by the facility, and at least three other members of the facility staff. The QAA committee must meet at least quarterly and identify quality deficiencies and develop and implement plans of action to correct the deficiencies. The facility is only required to disclose records of the QAA committee if the disclosure is related to the compliance of the committee with the regulatory requirements. We proposed to retain the substance of the existing QAA requirements at § 483.75(o) and pursuant to the requirements of the Affordable Care Act, we proposed a revised § 483.75 entitled, ''Quality Assurance and Performance Improvement.''

At § 483.75(a), we proposed to require that a facility develop, implement, and maintain an effective, comprehensive, data-driven QAPI program, reflected in its QAPI plan, that focuses on systems of care, outcomes, and services for residents and staff. The QAPI program would be designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement. We proposed that the facility's governing body, or designated persons functioning as a governing body, would ensure that the QAPI program is defined, implemented, and maintained and addresses identified priorities. Therefore, we proposed at § 483.75(a)(1) that the facility maintain documentation and demonstrate evidence of its QAPI program. This would include, but would not be limited to, the QAPI plan. We proposed at § 483.75(a)(2) that the facility would be required to submit the QAPI plan to the State Agency or federal surveyor, as the agent of the Secretary, at the first annual recertification survey 1 year after the effective date of these regulations. In addition, we proposed at § 483.75(a)(3), based on the Secretary's authority at sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to establish other requirements relating to the health and safety of residents, to require that the facility present the QAPI plan to the State Agency surveyor at each annual recertification survey and upon request to the State Agency or federal surveyor at any other survey and to CMS upon request. Further, we proposed at § 483.75(a)(4), to require the facility to present its documentation and evidence of an ongoing QAPI program upon request of a State Agency, federal surveyor, or CMS. The State Agency, pursuant to its agreement with the Secretary under section 1864 (a) of the Act, would consider such plan in making its certification recommendation and providing evidence to the CMS Regional Office for a compliance determination.

At § 483.75(b), we proposed requirements for the design and scope of the QAPI program. We proposed to require that the facility design its QAPI program to be ongoing, comprehensive and address the full range of care and services provided by the facility. When implemented, the QAPI program would be required to address all systems of care and management practices and always include clinical care, quality of life, and resident choice. It would also require LTC facilities to utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have

been shown to be predictive of desired outcomes for residents of a facility and reflect the complexities, unique care, and services that the facility provides.

We proposed at § 483.75(c) to establish requirements for QAPI program feedback, data systems and monitoring. We proposed at new § 483.75(c)(1) that, as part of its QAPI process, the facility must maintain effective systems to obtain and use feedback and input from direct care/direct access workers, other staff, and residents, resident representatives and families to identify opportunities for improvement. At § 483.75(c)(2), we proposed to require that the systems, governed by appropriate policies and procedures, also include how the facility would identify, collect, and use data from all departments, including how the information would be used to identify high risk, high volume or problem-prone areas. At § 483.75(c)(3), we proposed to require that the policies and procedures include a description of the methodology and frequency for developing, monitoring, and evaluating performance indicators. Finally, at § 483.75(c)(4), we proposed to require that the system, policies and procedures include the process for identification, reporting, analysis, and prevention of adverse events and potential adverse events or near misses. We indicated in the proposed rule that this would include methods by which the facility obtains information on adverse events and potential adverse events from residents, family and direct care/direct access staff, and how the facility addresses and investigates the adverse event or potential adverse event and provides feedback to those same individuals.

We proposed to establish a new § 483.75(d) to address QAPI program systematic analysis and systemic action. We proposed in § 483.75(d)(1) to require that the facility take actions aimed at performance improvement and, after implementing those actions, to measure the success of those actions and to track performance to ensure that the improvements are sustained. We further proposed to require in § 483.75(d)(2), that the facility develop policies describing how they would use a systematic approach (such as, root cause analysis, reverse tracer methodology, and health care failure mode and effects analysis, for example) to determine underlying causes of problems impacting larger systems.

At § 483.75(e), we proposed to establish requirements for program activities. Specifically, we proposed to require at § 483.75(e)(1) through (3) that the facility establish priorities for performance improvement activities that focus on patient safety; coordination of care; autonomy; choice; and high risk, high volume, and/or problem-prone areas identified as a result of the facility assessment as specified in § 483.70(e). We proposed to require that performance improvement activities track medical errors and adverse resident events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the facility. Finally, we proposed to require that the QAPI program activities include Performance Improvement Projects (PIPs). Under the proposal, the facility is required to conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources. We proposed that each facility be required to implement at least one project annually that focused on a high risk or problem prone area identified through the required data collection and analysis.

Finally, at § 483.75(f), we proposed to require that the facility ensure, through the governing body or executive leadership, that an ongoing QAPI program would be defined, implemented, and sustained during transitions in leadership and staffing and that the QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed. Furthermore, we proposed that the governing body or executive leadership would have to ensure that the QAPI program identified and prioritized problems and opportunities based on performance indicator data; resident and staff input that reflected organizational processes, functions, and services provided to residents; that corrective actions addressed gaps in systems, and were evaluated for effectiveness; and that clear expectations were set around safety, quality, rights, choice, and respect.

We proposed to re-designate § 483.75(o) as § 483.75(g). At § 483.75(g)(1), we proposed revisions to clarify that the QAA committee membership requirements would be a minimum requirement. We also proposed the requirement that the Infection Control and Prevention Officer (ICPO) would participate in the quality assessment and assurance committee.

At § 483.75(g)(2), we proposed that the quality assessment and assurance committee would report to the facility's governing body, or designated persons functioning as a governing body, regarding its activities, including implementation of the QAPI program required under new § 483.75(a) through (f). We further proposed that the committee would coordinate and evaluate activities under the QAPI program, including performance improvement projects, and that the committee would review and analyze data collected under the QAPI program as well as data from pharmacists resulting from monthly drug regimen reviews and the resulting reports as specified in § 483.45(c)(4).

We proposed to add a new § 483.75(h) to address disclosure of information. We proposed to re-designate existing § 483.75(o)(3) as § 483.75(h)(1) and add a new § 483.75(h)(2) to clarify that facilities, in order to demonstrate compliance with the requirements of this section, may be required to disclose or provide access to certain QAPI information. Specifically, we proposed to require, to the extent necessary to demonstrate compliance with the requirements of this section, access to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; documentation demonstrating the development, implementation, and evaluation of corrective actions or process improvement activities; and other documentation considered necessary by a state or federal surveyor in assessing compliance. We further proposed to re-designate § 483.75(o)(4) as § 483.75(i).

In the proposed rule we included a discussion regarding technical assistance, materials, and resources available to LTC facilities on the development of best practices relating to QAPI (80 FR 42168, July 16, 2015). We encourage readers to review that discussion and take advantage of the tools available.

Comment: Many commenters stated that they generally support QAPI in facilities. One commenter stated that they were pleased that we have proposed standards for QAPI.

Response: Thank you. These standards build on our experience requiring QAPI for other providers and, importantly, on the knowledge gained during the CMS QAPI demonstration project in LTC facilities. We believe facilities are familiar with the principles we are using and expect that some facilities have or are in the process of developing QAPI programs using the materials developed during the project and now available through the CMS Web site.

Comment: Some commenters felt that mandating QAPI in facilities was unnecessary due to current voluntary

activities in hospitals and managed care, including quality improvement efforts to reduce unnecessary re-hospitalizations, and value-based purchasing.

Response: We disagree. Effective QAPI programs are critical to improving the quality of life, and quality of care and services delivered in facilities. Furthermore, QAPI in LTC facilities is mandated by Section 6102 (c) of the Affordable Act and CMS does not have any discretion to not implement the provision.

Comment: One commenter requested that we not use the word ''program'' to encourage facilities to make QAPI part of the everyday life and operations of the facilities.

Response: We thank the commenter and agree that QAPI should be part of the everyday life and operations of the home; however, the statute specifically refers to the ''QAPI program'' and, for clarity and consistency, we have chosen to remain consistent with statutory language.

Comment: One commenter supported our focus on ''high-risk, high-volume, or problem-prone areas'' and suggested we not include a list of areas that each facility must address. If we were to provide such a list, the commenter suggests that inclusion of topics addressing psychosocial well-being, mental and behavioral health, and quality of life are crucial. They specifically note that a positive approach that focuses on improving long-term residents' everyday experience, promotion of short-term residents' decision making, and improving palliative and end of life care would be particularly useful. One commenter stated that ''each organization should be able to determine their own areas of focus based on the collection of data, trends, and comparable benchmarks vs arbitrary mandates.''

Response: We are not adding a specific list of QAPI topics or required performance improvement projects at this time. We want to allow facilities the flexibility to determine what issues should be prioritized for their QAPI program based on the needs of the facility and its residents. If we decide to require specific topics or performance improvement projects in the future, we will consider the topics suggested by the commenter as well as other comments we may have received.

Comment: One commenter felt that the proposed requirements exceeded our authority, and suggested that we withdraw our proposal and replace it with the statutory language. Some commenters felt that the proposed requirements are very detailed, too prescriptive, and significantly exceed the requirements for other providers. One commenter believes that the number of system areas that must be minimally included is too large. Some commenters expressed general concern that our proposed QAPI provisions lack specific requirements or stated that additional guidance is necessary. One commenter suggested regional sharing of program development, training, program evaluation and other resources.

Some commenters suggested that we allow a 5 year implementation period during which the facility would show progress in its implementation process during the annual standard survey, while other commenters suggested a 2 to 3 year phase-in for the QAPI provisions.

Response: We appreciate the commenters concerns regarding both the need for sufficient specificity to meet requirements and sufficient flexibility. We have worked to achieve a balance between specificity and flexibility in recognition of the wide diversity that exists among LTC facilities. We have re-evaluated our proposal to determine if we can be less prescriptive in some areas, and have modified our language accordingly. For example, we have eliminated the specific methodologies listed in proposed § 483.75(d)(2)(i), as these may be more appropriate in sub-regulatory guidance. We do not agree that we have exceeded our authority and should include only the statutory language as suggested.

In addition, we have received many comments regarding the overall implementation of this rule and address that issue in section II.B. Implementation. With regard specifically to QAPI, we note that the statute requires at 1128I(c)(1) of the Act that the QAPI plan be submitted to the Secretary not later than one year after the date on which the requirements are issued. We have modified our regulatory provision to mirror the statutory language. We would expect facilities to show their efforts to effectuate the QAPI plan, on an ongoing basis thereafter, with no fixed start or end date.

QAPI is intended to be a continuous part of the everyday life and operations of the home. We note that facilities have been expecting these regulations for a number of years, since publication of the Affordable Care Act in 2010. In developing our proposal, we relied heavily on the experiences gained in the CMS QAPI demonstration project which was conducted from Sept 2011 through Sept 2013. Resources and tools were developed as a result of that pilot, were rolled out on June 7, 2013 (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-37.pdf*) and remain available on the CMS Web site (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html*). In addition, QIOs are currently using these tools in their work with LTC facilities and additional resources are under development. We would encourage facilities to share best practices and other resources as they develop their QAPI programs. Furthermore, this proposal, while tailored to long-term care facilities, is consistent with our requirements (Conditions of Participation and Conditions for Coverage) for QAPI for other providers, such as community mental health centers (§ 485.917), end stage renal disease facilities (§ 494.110), hospitals (§ 482.21), hospices (§ 418.58), organ procurement organizations (§ 486.348), and transplant centers (§ 482.96) as well as proposed requirements for home health agencies (79 FR 61164).

Comment: One commenter supports the concept of an effective QAPI program, but feels we have over-emphasized data and outcomes and do not adequately acknowledge the qualitative processes such as clinical reasoning, correct diagnoses, and the nuances of selecting individualized treatments that are the foundation of high-quality results. They further state that any requirements about QAPI programs should focus attention on improving processes and practices, including those related to both clinical and nonclinical decision making, reasoning, and problem solving. The commenter is concerned that excessive emphasis on data and results distracts attention from improving the basis for those results, that available quality measures and data only represent a small part of the many aspects of quality care, and that aggregate results may not faithfully reflect the quality of the overall care of individual residents. The commenter suggests language to strike a better balance between looking at data and focusing on practices and processes that need optimized regardless of the data. The commenter also suggests that the QAPI requirements specifically include case review.

Response: We believe that our focus on outcomes is appropriate. We agree that QAPI should focus on improving processes and practices, and believe that data is a necessary element in doing so. Data is used to identify problems in processes and practices and to set goals related to improving those processes and practices. It is then used to validate that a change is successful in improving

that process or practice and subsequently to monitor that the change is sustained. Using data involves critical reasoning and analytical thinking; these are not mutually exclusive. We agree that case review is one tool that can be used to identify problems and collect data. We would defer specificity regarding such tools to sub-regulatory guidance.

Comment: One commenter suggests we use the term ''information'' instead of ''data.'' They note that ''information'' includes data as well as other knowledge, whereas data could exclude other information.

Response: We agree that information other than data may be useful in the QAPI process, but we also believe that data-facts, measurements, and statistics collected for analysis and planning are an integral part of the QAPI process. Rather than substitute one term for the other, we have, where appropriate, used both.

Comment: One commenter believes the regulations should be more flexible with regard to performance improvement projects (PIP) and that the proposal is overly prescriptive. The commenter notes that there are many performance project activities that would not be considered a PIP but are activities that could be built into everyday activities and real-time problem solving. They state that the PIP requirement is problematic and these regulations need a better balance of diverse methods including qualitative reasoning and real-time problem solving.

Another commenter suggested that each facility be required to have at least three PIPs in place at a time, reflecting different areas of concern and at least one reflecting residents' rights and quality of life. The commenter further suggests that a facility cited with immediate jeopardy deficiency(ies) be required to initiate a PIP in the area where the immediate jeopardy was cited.

One commenter suggests that CMS develop and annually update a list of a dozen mandatory PIPs reflecting issues that CMS has identified as significant quality of care and quality of life issues. Each facility would then be required to choose at least one PIP from that list annually.

Response: The comments regarding the PIP requirements reflect opinions advocating for both less and more specificity in our PIP requirements. One of the critical elements of QAPI is to give facilities the flexibility to use QAPI to best meet their own needs. In order to give facilities this flexibility, we believe that a less prescriptive approach to PIPs is appropriate. However, this flexibility must occur in the context of a QAPI program that addresses the full range of care and services provided by the facility. Accordingly, we limited our proposal to require only one PIP annually, and declined to establish mandatory PIPs at this time.

We agree that not all improvement activities are PIPs and believe that our proposed regulatory language is inclusive of these activities. (See § 483.75(e)). In addition, we have reviewed our proposals and, where appropriate, have expanded our references to PIPs to include other improvement activities. While we agree that areas in which an immediate jeopardy deficiency is cited require immediate action, we are not certain that a PIP will always be an appropriate response, and therefore have not adopted this recommendation at this time.

Comment: One commenter stated that they were pleased that the medical director or his or her designee is specifically listed as a member of the QAA committee. They support medical director and other medical practitioner involvement in the development and assessment of the QAPI program.

Response: Thank you. We agree that medical director involvement in QAPI is an important leadership element. We also believe that the involvement of other medical practitioners can contribute to the success of a QAPI program.

Comment: Some commenters suggested that we needed to ensure resident, resident representative, and staff participation in the QAPI program. The commenters raised concerns and suggested additional language that would address resident, resident representative, and staff involvement in the QAPI program.

Response: Our proposed requirements include obtaining and using feedback and input from staff, residents and resident representatives. We are finalizing this particular requirement as proposed.

Comment: Some commenters recommend adding staffing and worker safety elements to the QAPI requirements.

Response: The QAPI program is required to address the full range of care and services provided by the facility. This would include staffing as well as a number of other areas. We defer additional specificity to sub-regulatory guidance. While facilities could certainly include worker safety in their QAPI processes, we have not specifically included worker safety in this regulation as we believe worker safety is more appropriately the purview of other federal agencies such as HRSA and OSHA.

Comment: One commenter suggested that we require effective collaboration training for members of the QAA committee.

Response: We agree that effective collaboration training could be useful for members of a QAA committee, as well as individuals in other positions. However, we do not mandate any specific trainings for QAA committee members and do not believe that we should mandate this specific training for all QAA committee members. There are many trainings that could be equally beneficial, and some that might be a greater priority, based on prior training and experience of the members of the QAA committee. We will defer such decisions to the facility.

Comment: One commenter recommended that we require a contracted consultant pharmacist sit on the Quality Assessment and Assurance Committee. The commenter stated that adverse medication events, including medication errors, remain a serious problem in LTC facilities.

Response: We appreciate the commenters' suggestion, but, while we would agree that this would be a good practice, we are not adopting this recommendation at this time. As part of the update of these requirements, we have updated our requirements related to pharmacy services and mandated adverse event monitoring as a part of the QAPI program. We believe that these requirements will help reduce adverse medication events. Mandatory membership on the Quality Assessment and Assurance Committee reflects a minimum standard and facilities can add members based on the needs and priorities of the facility.

Comment: Several commenters supported our proposed requirements regarding disclosure of QAPI information to demonstrate compliance with the requirements for the QAPI program. One commenter stated that they believed it would improve facility compliance with the requirements and would assist in federal and state oversight. Another stated that the purpose of the quality assurance provisions is to ensure that LTC facilities identify and act on information about neglect, abuse, and other adverse events, not that they be able to hide this information by making it part of a QAPI record. Another asked that we clarify that documents and reports used or relied on by QAPI are not confidential and that non-disclosure applies only to minutes, internal working papers, or statements of conclusions of QAPI and

QAA. They further stated that we should clarify that records and materials submitted to the QAA committee for review are not confidential solely because they are used or reviewed by the QAA committee. Others stated that the QAPI plan should be made available to residents, resident representatives, and staff.

Other commenters objected to our proposed provisions regarding information disclosure to demonstrate compliance with the QAPI requirements. One commenter stated that this requirement could be misconstrued. Several suggested that these requirements could have a chilling effect on advancing QAPI efforts and should be deleted or substantially modified. Several commenters felt that the proposed rules for QAPI would discourage open and honest evaluation of areas of concern without fear of negative consequences. A number of commenters were concerned that disclosing quality assurance records to surveyors would expose providers to increased risk of sanctions and litigation. One commenter stated that surveyors should not have broad access to facilities' QAPI data or deliberations. Another commenter stated that they believe that the proposed regulations exceed the statutory authority granted to CMS. The commenter stated that we have significantly expanded upon the statutory mandate by requiring a ''laundry list'' of requirements related to the QAPI program, including requiring the disclosure of, or potentially requiring a facility provide access to, a plethora of QAPI-related documents and records. They further stated that proposed 42 CFR 483.75(a)(4), requiring facilities to present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the requirements to a State Agency, Federal surveyor, or CMS upon request exceeds the permissibly required disclosures under the statute. One commenter stated that these provisions are contrary to state law. Finally, they believed that proposed § 483.75(h) is internally inconsistent.

Response: We thank those commenters who support our proposal regarding the need to provide documentation demonstrating compliance with the QAPI requirements. We have attempted to strike an appropriate balance between concerns about inappropriate use of QAPI materials and our obligation to provide effective oversight of Medicare and Medicaid participating facilities.

We do not agree with commenters who believe that we have exceeded our authority in establishing these requirements. Under section 1128I(c) of the Act, as added by section 6102 of the ACA, Congress required the Secretary to establish and implement a quality assurance and performance improvement program for facilities. The Secretary is also required to set forth standards for QAPI and provide technical assistance to develop best practices for facilities to meet those standards. The expectation that facilities will implement a QAPI program that meets those standards is clear, and facilities must be able to demonstrate that they have implemented their QAPI plan and have an effective, ongoing QAPI program. The standards, the best practices, and the tools to support facilities as they implement their plan to meets those standards were developed in the course of the QAPI demonstration project conducted by CMS. We also consider our experiences with requiring QAPI programs from other providers such as community mental health centers (§ 485.917), end stage renal disease facilities (§ 494.110), hospitals (§ 482.21), hospices (§ 418.58), organ procurement organizations (§ 486.348), and transplant centers (§ 482.96) as well as proposed requirements for home health agencies (79 FR 61164).

QAPI is intended to be one aspect of a LTC facility's operations that helps to maintain and protect the health and safety of the residents of the facility. Section 1819(f)(1) of the Act states that it is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities under Title XVIII, and the enforcement of such requirements, are adequate to protect the health, safety welfare, and right of residents and to promote the effective and efficient use of public moneys. Therefore, we have an obligation to ensure that the QAPI plan becomes more than a paper exercise. To that end, we proposed requirements that would demonstrate that a facility has not only written a plan that meet the established standards, but has actually implemented that plan. In our proposed requirements, we stated that the facility must present its QAPI plan at its annual recertification (or in the case of a new facility, during its initial certification) after the effective date of this regulation and at every annual survey thereafter, as well as during other surveys or upon our request. We included this ongoing requirement because we understand that a QAPI plan will need to be updated and modified as a facility implements it and learns from the QAPI program. We proposed that the facility would have to present documentation and evidence of its ongoing QAPI implementation to reflect the ongoing nature of the QAPI program.

It is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation. At the same time, we cannot ignore our obligation to ensure that facilities implement their QAPI plan, and continue to modify and implement that plan over time. What we require is satisfactory evidence that a facility is implementing its QAPI plan and maintaining an ongoing QAPI program. We further articulated in the proposed rule what sort of evidence and documentation we believe may be necessary to demonstrate compliance. We retain the proposed requirement, as required by statute, that a State or the Secretary may not require disclosure of a QAA committee's records except insofar as such disclosure is related to the compliance of such committee with the requirements of the statute. Clearly, this requirement recognizes that, in some cases, such records will be necessary to evaluate compliance. However, much information relating to the implementation of the QAPI plan could be available outside of the QAA committee's records. Further, we do not believe that every document, piece of information, or data reviewed or generated in the course of implementing QAPI is a ''record of the QAA committee.''

We also retain the proposed requirement that ''Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanction.'' This requirement is not new; however, it now also includes QAPI activities. As is currently the case, surveyors are instructed not to cite as a deficiency for a requirement other than the QAPI requirements a concern that would not have been identified but for a review of QAPI materials for the purpose of determining compliance with the QAPI regulations. That said, nothing in this section would preclude a surveyor from citing a concern that is identified based on a review of materials or on observations separate and apart from an assessment of QAPI compliance. Excluding such a concern simply and only because it has also been identified by the QAPI program would be irresponsible of CMS. We understand that the ability to discern when and how a deficiency is identified is of concern to facilities. We have and will continue to educate surveyors on the parameters of this provision and the need to not

inappropriately request or use QAPI documentation.

With regard to concerns about increased litigation, we reiterate that our purpose is neither to inappropriately make documents public nor to expose facilities to litigation risk. In fact, section 1106 of the Act specifically states that, for health programs established by titles XVIII and XIX, reports (including program validation survey reports and other formal evaluations of the performance of providers of services) made public by the Secretary or the State Agency shall not identify individual patients, individual health care practitioners, or other individuals. Our obligation to conduct effective oversight is not waived in the face of litigation fears. We have attempted in these regulations to establish an appropriate balance between ensuring that QAPI can be conducted in an open, non-punitive environment and ensuring that we can provide effective oversight of requirements necessary to protect the health and safety of LTC facility residents. We have re-evaluated our proposed language and made some modifications in order to be less prescriptive and duplicative. In order to address the commenters concerns about internal consistency and overreach, we have moved the language regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated, as potentially overbroad, proposed paragraph (iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.'' We are finalizing as proposed the requirement that facilities must provide documentation and information that demonstrates that they are effectively implementing their QAPI plan, on an ongoing basis, and surveyors must have sufficient information to evaluate if a facility is in compliance with the requirements of this section.

Comment: One commenter supported our proposed QAPI provisions and stated that QAPI must be among the services disclosed to residents on the notice of services. The commenter suggested that there be some method for a resident to ''trigger'' a QAPI performance improvement project (PIP).

Response: Our requirements include obtaining and using feedback and input from staff, residents and resident representatives. While not all such input would trigger a PIP, it is important that it be included in the facility's assessment of concerns and priorities.

Comment: One commenter asked if using programs such as Abaqis or PCC are sufficient to meet the QAPI regulation.

Response: Programs such as PointClickCare and Abaqis may assist facilities to meet the QAPI requirements, but using them is neither necessary nor sufficient for compliance. Facilities must evaluate their use of such tools and ensure that they comply with the QAPI requirements.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified paragraph (a)(2) to mirror the statutory language to indicate that the facility must present its QAPI plan to the State Survey Agency not later than one year after the date the regulation is issued.
- We have added the term ''information'' in paragraphs (c)(2) and (f)(4).
- In paragraph (e)(3), we have referenced performance improvement activities in the context of our PIP requirement.
- We eliminated the parenthetical examples in paragraph (d)(2)(i)
- We have moved the language in proposed § 483.75(h)(2) regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated proposed paragraph (iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.''

W. Infection Control (§ 483.80)

As part of our overall reorganization of these regulations, we proposed to re-designate the provisions under existing § 483.65 as § 483.80. We proposed to modify the introductory language to include infection prevention as well as control and to clarify that the program must help prevent the development and transmission of communicable diseases as well as infections. We proposed to revise paragraph (a) to read ''Infection prevention and control program'' (IPCP) and add new § 483.80(a)(1), (2) and (3) to specify the elements of the IPCP. We proposed to require that the program must follow accepted national standards, be based upon the facility assessment conducted according to § 483.70(e) and include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement. We proposed to require the facility to have written standards, policies, and procedures for the IPCP, including but not limited to, a system of surveillance designed to identify possible communicable disease or infections before it can spread to other persons in the facility; reporting requirements for possible incidents of communicable disease or infections; standard and transmission-based precautions to be followed to prevent spread of infections; circumstances in which generally, isolation should be used for a resident; the circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if the contact is likely to transmit the disease; and the hand hygiene procedures to be followed by all staff as indicated by accepted professional practice. We also proposed that the facility be required to train staff related to the IPCP as specified in § 483.95.

We proposed that the facility's IPCP must also include an antibiotic stewardship program that includes antibiotic use protocols and systems for monitoring antibiotic use and recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

We further proposed to add a new paragraph (b) to require that the facility designate an infection prevention and control officer (IPCO) who is responsible for the IPCP and who has received specialized training in infection prevention and control. We proposed that the IPCP be a major responsibility for the individual assigned as the facility's IPCO. We proposed to require that the IPCO be a healthcare professional with specialized training in infection prevention and control beyond their initial professional degree. At § 483.80(c), we proposed to require that the IPCO be a member of the facility's Quality Assessment and Assurance (QAA) committee.

We proposed to eliminate the exception that is currently located at § 483.25(v), which provides that, based on an assessment and practitioner recommendation, a second pneumococcal immunization could be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

We proposed to add a new § 483.80(f) to require that the facility review its IPCP annually and update the program as necessary. We also proposed to relocate the requirements for influenza and pneumococcal immunizations from the current § 483.25(n) to § 483.80(d). The language in § 483.80(d) is identical to the current § 483.25(n), except that

we proposed using the term ''resident representative'' instead of ''legal representative.'' Finally, we proposed moving the requirement concerning linens from the current § 483.65(c) to the proposed § 483.80(e).

Infection Prevention and Control Program (IPCP)

Comment: Many commenters agreed that infection control is very important for residents in LTC facilities and commended CMS for proposing to significantly enhance the infection control requirements given the physical harm and financial cost of HAIs. One commenter said the proposed measures are an important step forward.

Response: We would like to thank the commenters for their support. We agree that infection control is very important for residents, as well the staff and other individuals who work or visit the facility. We believe the requirements that are finalized in this rule will contribute to the reduction in HAIs, which should result in a reduction in physical harm to residents and others, as well as a decrease in the associated health care costs.

Comment: One commenter expressed a concern that the infection control efforts could not be effective without adequate numbers of consistently assigned, well-trained and well-supervised direct care nursing staff. Nurses and nursing assistants are essential for infection control prevention, detection and intervention. The commenter recommended a minimum staffing standard of at least 4.1 hours of direct care nursing per resident day, 24-hour registered nurse coverage for the facility, and staffing practices to promote successful infection prevention.

Response: We agree with the commenter that for the infection control requirements finalized in this rule to be effective, the facility would need a sufficient number of trained and supervised direct care nursing staff. However, we disagree that this final rule should establish a minimum staffing standard for LTC facilities. In this final rule, each facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for it residents competently during both day-to-day operations and emergencies (§ 483.70(e)). That assessment must include, among other things, the resident population and the care required by that population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present in that population, as well as the staff competencies that are necessary to provide the level and types of care needed by that population. This assessment must then be used to determine what is the number of sufficient nursing staff and the competencies and skill sets the nursing and related staff must have to care for their resident population (§ 483.35). Based on these requirements, as well as the infection control requirements finalized in this rule, each facility will need to determine the resources it needs to devote to its infection control program.

Comment: Commenters recommended that the guidelines from the Centers for Disease Control and Prevention be inserted into § 483.80(a)(1), so that it reads, ''staffing practices, and following accepted national standards including, but not limited to guidelines from the Centers for Disease Control and Prevention; . . .''

Response: We disagree with the commenters. We believe that facilities need the flexibility to determine which national standard they are going to follow. We also believe it is appropriate for the different types of national standards that are acceptable to CMS to be included in the sub-regulatory guidance for this rule. Although we are not requiring that LTC facilities follow the CDC guidelines, we agree with the commenters that the CDC is an excellent resource for guidelines, as well as other information on infection control, and encourage LTC facilities to consider the CDC guidelines. For example, the CDC has a Web site for information on infection control in LTC facilities, ''New CDC Infection Control Web site for Nursing Homes and Assisted Living,'' (*http://www.leadingage.org/Infection_Control_Website.aspx*). Other organizations also have information available on their Web sites, such as The Society of Healthcare Epidemiology of America (SHEA) (*http://www.shea-online.org/*), Infectious Diseases Society of America (IDSA) (*https://www.idsociety.org/Index.aspx*), and the Association for Professionals in Infection Control and Epidemiology (APIC) (*http://www.apic.org/*).

CDC and CMS are also exploring opportunities to develop and implement infection prevention and control training specific for LTC facility clinical personnel. We expect that this would provide training on a variety of infection control topics relevant for LTC facility staff developing and sustaining an IPCP. We expect that any training would be widely available for all providers, surveyors, and other partners. We are also exploring opportunities for continued education, dissemination of promising practices, and ensuring that new infection prevention and control guidance and information for LTC facility staff can be shared widely. CMS is pleased to be collaborating with CDC on this type of comprehensive training for providers. CMS has previously developed specific surveyor training on infection control topics in 2014 and 2015. CMS is also exploring processes for reviewing infection prevention and control practices in the context of transitions of care. Please see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-05.pdf* for additional information about that pilot.''

Comment: One commenter stated that the detail in the scope and components in the infection control program went well beyond what is required in the hospital CoPs. They noted that hospitals are a setting with much greater risk of infections and individuals at higher risk of adverse events from infections. They recommended adopting more general language similar to that used in the hospitals CoPs and specify the details in interpretive guidance that should be developed in partnership with stakeholders. They noted that referring to the goal and purpose of the infection control program along with following national standards allows the goal and intent to be accomplished. This affords the providers greater flexibility and creativity in how to achieve the goals also provides CMS flexibility to provide additional suggested approaches in interpretative guidance. They also noted that modifying and updating the guidance as new and better practices are identified over time is preferable to the long and arduous formal rulemaking process to update the requirements.

Response: We disagree with the commenters. As we discussed in the proposed rule, it is estimated that there are between 1.6 and 3.8 million HAIs in LTC facilities annually (80 FR 42215). These infections result in an estimated 150,000 hospitalizations; 388,000 deaths; and healthcare costs between $673 million to $2 billion. In addition, residents may be more susceptible than individuals in other types of healthcare facilities due to malnutrition, dehydration, comorbidities, or functional impairments, such as urinary and fecal incontinence, or medications that diminish immunity or mobility. Also, due to the length of their stays, there is more opportunity for exposure to infectious agents from the socialization between residents. This clearly indicates that infection prevention and control is a critical issue for LTC facility residents. In addition,

due to transfers between hospitals and LTC facilities, infection control in LTC facilities directly affects hospitals as well. The LTC facility resident with an infection today maybe the patient that the hospital must treat tomorrow when he or she arrives in the hospital's ED.

Concerning the level of detail in the infection control requirements, we disagree with the commenter. Hospitals and LTC facilities are different types of facilities. LTC facility residents generally stay much longer than patients in hospitals and generally require care for chronic conditions instead of acute illnesses, injuries, or surgeries. In addition, there must be sufficient detail in the regulatory text so that LTC facilities know what will be needed to be in compliance with requirements. We believe there is sufficient detail in the infection control requirements so that LTC facilities and the public understand what is expected for compliance. We also note that CMS published a proposed rule on June 16, 2016 entitled, ''Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility and Improvement in Patient Care (CMS–3295–P) (81 FR 39448). These proposed regulations update and add specificity to the infection prevention and control requirements for hospitals.

Concerning the commenter's recommendation that referring to the goal and purpose of the infection control program along with following national standards allows the goal and intent to be accomplished. We do not believe this is needed in the regulatory text. However, further direction will be provided in sub-regulatory guidance. Concerning the use of interpretative guidance, sub-regulatory guidance for this final rule will be developed and published as soon as possible. That guidance will contain more specific direction for long-term care facilities, surveyors, and others concerning compliance with these regulatory requirements. Thus, we believe that the level of detail in the infection prevention and control requirements in this final rule are appropriate and ensure that LTC facilities are aware of what is required to comply with these requirements.

Comment: One commenter was concerned about the specificity of the language in the infection control comments. They recommended specific language changes to remove much of the detail in this section and suggested using ''should'' instead of ''must'' to allow more flexibility for both the providers and CMS when legitimate exceptions are identified or new and better practices are identified.

Response: We disagree with the commenter. While the commenter is correct that the use of ''should'' would convey more flexibility, that is not the purpose of these requirements. This final rule contains requirements for LTC facilities, not suggestions. LTC facilities must be in compliance with these requirements. In addition, further guidance will be provided through sub-regulatory guidance. As practices change in the future, we would appreciate comments from the commenter, as well as any other individuals, on any recommended changes to these requirements.

Comment: One commenter supports the efforts to address antibiotic stewardship; however, they noted that the problem is not isolated to LTC facilities. For example, hospital emergency departments (EDs) will usually obtain a urine analysis on residents who are sent to the ED. Over 50 percent of these tests will show asymptomatic bacteria which would not meet the Society for Healthcare Epidemiology of America (SHEA) criteria for giving antibiotics. However, the ED frequently starts the resident on antibiotics before the resident returns to the facility. In addition, a State Survey Agency will cite a facility for an adverse event when the LTC facility does not begin an antibiotic based upon an asymptomatic urinalysis but the resident later develops an infection. The commenter noted that this has occurred across the country over the past several years as providers have attempted to follow the SHEA criteria. If the proposed requirements are finalized as proposed, the commenter requested that language be added that indicates that providers will not be cited if an infection develops when the provider has followed nationally accepted guidelines for antibiotic use, such as SHEA. The commenter recommended that the hospital CoPs also be modified to prevent citation for an adverse event under these circumstances.

Response: We agree with the commenter that antibiotic stewardship is not an issue for LTC facilities alone and as noted above, we have published a proposed rule with requirements for antibiotic stewardship programs for hospitals (81 FR 39454 through 39459). However, it is crucial that LTC facilities establish an infection prevention and control program that contains an antibiotic stewardship program. As we discussed in the proposed rule, antibiotic resistance has become a national concern and both the inappropriate and even appropriate use of antibiotics contribute to this problem (80 FR 42215). In addition, LTC facilities are part of the overall healthcare system. With the growth in the short term resident population, more residents with complex healthcare issues are coming from the hospital into the LTC facility. Residents with infections in the LTC facility may become patients in the hospitals ED. In addition, residents also may go to other healthcare facilities for care, such as ambulatory surgical centers (ASCs) and dialysis centers. Therefore, the facility's IPCP, and its antibiotic stewardship program, also affects other facilities and individuals throughout the healthcare system. Therefore, we are finalizing the requirement for LTC facilities to establish and maintain an IPCP, which must include, among other things, an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

Regarding the commenter's concern about being cited by a surveyor for following national standards and modification of the hospital CoPs, we will be working on developing sub-regulatory guidance and training for the surveyors that should address situations that the commenter described.

Comment: One commenter expressed concerns about § 483.80(a)(2)(iv), which requires ''(2) [w]ritten standards, policies and procedures, which must include, but not limited to: . . . (iv) [w]hen isolation should be used for a resident.'' The commenter said they had heard directly from residents, families and ombudsmen about situations where facilities have barred all visitors from accessing residents for a significant period of time due to the outbreak of certain infectious viruses among residents and/or facility staff. The commenter noted that the practice of facilities restricting visitation as part of an infection control protocol has been regularly reported in the news. The commenter noted that the current interpretive guidelines already recognize the potential adverse psychological impact on residents when instituting any precautions to control outbreaks. According to the guidelines, ''because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections,'' and it is appropriate for facilities to ''use the least restrictive approach'' to infection control while adequately protecting the residents and others.'' The commenter recommended that the language from the interpretive guidelines be inserted in the rule to strike a balance between protecting the

health of the residents and their psychological well-being. They recommended the following language, ''[t]he facility must isolate infected residents only to the degree needed to isolate the infecting organism. The method used must be the least restrictive possible:''

Response: We agree with the commenter that isolation should only be used when necessary to control the spread of infections and should be the least restrictive as possible to the resident. The current interpretative guidelines contain language about using the least restrictive approach possible that adequately protects both the resident and others and that maintaining isolation longer than necessary my adversely affect the resident's psychosocial well-being, We also agree that there should be more detailed requirements for isolation in the regulatory text. Thus, in this final rule we have modified the text of § 483.80(a)(2)(iv) to read: ''When and how isolation should be used for a resident, including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) that the type and duration of the isolation should be the least restrictive possible for the resident under the circumstances.''

Infection Prevention and Control Officer (IPCO)/Infection Preventionist (IP)

Comment: Some commenters were concerned about the requirement for an IPCO. They question whether the requirement was even viable, particularly in areas that already lack adequate numbers of registered nurses. They indicated that for many locations, particularly rural areas, individuals with this expertise are simply not available. The commenter also expressed concern that the requirement was mandating structure instead of focusing on process expectations, which left little to no opportunity to accomplish the objectives of infection prevention and control through means other than those prescribed by the structure-related regulation.

Response: We disagree with the commenters. We do not believe that requiring an IPCO is unrealistic. We believe it is necessary to have one or more individuals responsible for the infection control program in each facility. However, as discussed below, we have modified this requirement based upon other comments.

Comment: Some commenters recommended that the requirement for the IPCO, allow two or more individuals to be responsible for the IPCP. Another commenter noted that the director of nursing (DoN) is often the part-time infection prevention and control officer for the facility. When the DoN is unavailable because he or she is on vacation or busy with other responsibilities, there is no one to address the infection prevention and control responsibilities. The commenter recommended that we not allow the DoN to be the primary IP.

Response: After reviewing the comments, we agree that LTC facilities should have the flexibility to determine if more than one individual should be designated to be responsible for the facility's IPCP. We also believe that LTC facilities should ensure coverage whenever the designated IP(s) is unavailable. However, we disagree with the commenter that recommended that we prohibit the DoN from being an IP. We believe that each facility should have the flexibility to determine how their facility should comply with the requirements in this final rule, including which individuals should be designated as the IP(s). Therefore, we have modified the requirements at proposed § 483.80(b) to allow for more than one individual to be responsible for the IPCP and be the designated IP.

Comment: Some commenters argued that the requirement for the IPCO was inconsistent with our assertion in the proposed rule, ''[w]e considered prescriptive approaches, such as requiring specific numbers and types of staff . . .'', but instead decided on a ''competency-based approach.'' The commenters recommended that a more reasonable approach that would be to provide detailed standards for the infection control activities and procedures, and then allow LTC facilities to make the determination as to whether the individual responsible for this function possesses the competency and expertise to function effectively in the role to accomplish the defined processes.

Response: We disagree with the commenters. The language referenced by the commenters in the proposed rule (80 FR 42175) is located under our discussion of the facility assessment and competency based approach taken in the proposed rule and finalized in this rule. It pertains to the approach we have taken towards staffing. We noted in the proposed rule that we wanted to ensure that our requirements would ''align with current clinical practice and allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services in these facilities'' (80 FR 42175). However, regardless of the facility assessment, each LTC facility must have an IPCP. As we said in the proposed rule, ''[w]hile all staff should be responsible for infection prevention and control, we agree with the SHEA/APIC guidelines that establish that an effective IPCP should have a designated IPCO for whom implementation and management of the IPCP is a major responsibility'' (80 FR 42216). As discussed above, we are not finalizing ''major'' to describe the IP's responsibility due to the burden it would impose on nursing facilities. However, we continue to believe that it is essential at least one individual be designated the IP for each LTC facility. In addition, we have modified this final rule so that LTC facilities can designate more than one individual as an ICPO. Thus, requiring that at least one individual be responsible for the IPCP is consistent with the facility assessment and competency-based approach in this final rule.

Comment: Commenters disagreed with using the term ''officer'' for the infection prevention and control officer (IPCO). The commenter said that officer was ill-defined and its rationale is unclear. The commenter recommended that the term ''coordinator'' or infection prevention and control coordinator (IPCC).

Response: We understand that different terms are used to identify the individual or individuals who are responsible for the facility's infection control program. For example, in Appendix A-Survey Protocol, Regulation and Interpretive Guidance for Hospitals, (Rev.151,11–20–15), it states that the individual(s) ''responsible for the infection control program may be called a hospital epidemiologists (HEs),'' ''infection control professionals (ICPs)'' or ''infection preventionists (IPs).'' In the Appendix PP-Guidance to Surveyors for Long Term Care Facilities in the SOM, accessed on January 28, 2016), the interpretative guidelines refer to an ''infection Preventionist (IP)'' or an ''infection control professional (ICP)''. Regardless of the title used by the facility, we are referring to the individual who is responsible for the facility's IPCP. However, to prevent any confusion, we have modified this final rule to use the term ''infection preventionist'' or IP. Therefore, there must be at least one individual who is responsible for the facility's infection control program.

Comment: Some commenters were concerned about the qualifications for the ICP. Some commenters asked who would be included in the term ''clinician'' and asked that it be defined. Other commenters were concerned about the requirement that the IPCO

(now IP) to have specialized training in infection prevention and control beyond their initial professional degree. One commenter noted that APIC provides specialized training in infection prevention and control and also provides the opportunity for individuals to become certified. Some were unsure what training would qualify, while others believed it would difficult for facilities to find qualified staff with this training or get the training for their staff due to availability or cost.

Response: We understand that there is a substantial amount of concern and confusion about the qualifications for the IP. We also understand that many LTC facilities currently have individuals who are responsible for infection control who might not qualify under the proposed requirements, but who have been performing their duties exceptionally well. These individuals may have obtained their knowledge through training at the facility or other experience. Thus, we have modified the requirements to allow for flexibility and for individuals with a broader range of experience to be a qualified IP. Specifically, we have removed the term ''clinician'' and instead provide at § 483.80(b) that the IP's primary professional training must be in nursing, medical technology, microbiology, or epidemiology, or other related field and that IPs can be qualified by education, training, experience or certification.

Comment: Commenters supported the requirement for a LTC facility to designate an IP for whom the IPCP is their major responsibility and who serves as a member for the facility's QAA committee. However, other commenters argued that it is unrealistic to specify that the IPCP must be a ''major responsibility'' for the IP and that this requirement was unclear. The commenter said that this could easily be interpreted as 0.50 FTE or more. This lack of clarity will lead to confusion and inconsistencies for providers and surveyors, resulting in technical misunderstandings that will undermine the intent of the requirement. One commenter pointed out that the hospital CoPs do not require the IPCP as a major responsibility of the IP or require the IP to have specialized training in infection prevention and control. The commenter recommended that the word ''major'' not be finalized. If the requirement is finalized, the meanings of ''major responsibility'' and ''specialized training'' should be clarified. However, other commenters wanted the requirement strengthened by changing ''major'' to ''primary'' responsibility.

Response: Depending upon the facility, we understand that there is a substantial variation in the amount resources required for the IPCP, especially the amount of time the IP needs to devote to those responsibilities. For some facilities, especially small and rural LTC facilities, it may not be feasible or even necessary to have one staff person devote a substantial amount of their time to the IPCP or have it be their primary responsibility. Hence, we have modified the requirement for the IP by removing the language at § 483.80(b) indicating the IPCP must be a major responsibility for the IP. However, we expect that each facility will review their facility assessment they conducted according to § 483.70(e) to determine the resources it needs for its IPCP and ensure that those resources are provided for the IPCP to be effective. In addition, we are finalizing the requirement that the IP work at the facility at least part-time.

Comment: One commenter questioned whether the reference in proposed § 483.80(a)(1) to § 483.75(e) should be § 483.70(e).

Response: We would like to thank the commenter for pointing out this discrepancy in the reference. Yes, the reference should be to § 483.70(e). We have inserted the correct reference to that section in this final rule.

Influenza and Pneumococcal Immunizations

Comment: Some commenters disagreed with many of the requirements related to influenza and pneumococcal immunizations. They noted, among other things, that no justification had been provided for a different process for immunizations in LTC facilities as compared to other healthcare facilities and that it was unclear why these particular vaccines should have these detailed requirements when other vaccines may have higher side effects. They also noted that the requirements did not recognize electronic medical records (EMRs). They noted that specifying the date ranges is not consistent with good public health practices and that the level of detail makes it more difficult to modify or update standards. The commenter recommended that most of the section be removed and that the facility should be required to develop policies and procedures to ensure that all residents and employees with direct patient care contact be offered and receive the influenza vaccine, unless they decline, per CDC guidance and that all residents be offered and receive the pneumococcal vaccine, unless they decline, per CDC guidance. Other commenters expressed concerns about the recommended dates for immunizations since this may change or vary in different regions. The commenter saw no valid reason to be so prescriptive about the exact date range and stated that doing so may make the regulations obsolete in the future. One commenter agreed with informing residents and/or their representatives about influenza and pneumococcal immunizations. However, since it is impossible to identify or judge whether they were sufficiently ''educated,'' the commenter recommended that the wording be changed.

Response: We disagree with the commenters. As we explained in the proposed rule, we reorganized the requirements for influenza and pneumococcal immunizations for their previous location at § 483.25(n) to where it is now finalized, § 483.80(d). With few exceptions, it is the identical requirement. We eliminated the exception that was set out at § 483.25(v), which provided that based on an assessment and practitioner recommendation, a second pneumococcal immunization could be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization because this was no longer the standard of care (80 FR 42216). We replaced the term ''legal representative'' with ''resident's representative'' because we believe it is a broader term and encompasses individuals whom the resident has personally identified as their representative (80 FR 42216 through 42217). We believe that reorganizing this requirement to the infection control requirement was appropriate. According to the CDC, a vaccine is a product that stimulates the immune system to produce immunity to a specific disease (Immunization: The Basics, located at *http://www.cdc.gov/vaccines/vac-gen/imz-basics.htm, accessed on January 26, 2016*). Based upon our experience with LTC facilities, these immunizations are generally given by nursing personnel. Therefore, we believe that the infection control section is the most appropriate place for the requirements related to influenza and pneumococcal immunizations.

Concerning the other comments on requirements for the pneumonia and pneumococcal immunizations, we did not propose any changes to these requirements. Influenza and pneumococcal immunizations are crucial for the resident populations. Due to the higher morbidity and mortality rates, we believe it is crucial that these immunizations be offered to the resident

population. Thus, we believe it is appropriate to specifically address these immunizations in these requirements. We also believe that the details, including dates and documentation, are also necessary to ensure appropriate immunizations for the residents. Although EHRs are not specifically addressed in this requirement, we do discuss health IT in other sections of this final rule. We expect that LTC facilities that use EHRs will include documentation concerning immunizations in those EHRs, as LTC facilities that use paper charts are expected to include the immunization documentation in the paper record. We have decided to retain the wording about ''education'' in the requirement. We believe further details concerning this requirement are best addressed in sub-regulatory guidance, which we will be producing for this final rule after it is published.

Implementation

Comment: One commenter recommended that LTC facilities be allowed a minimum of two and up to three years to meet the requirements for a healthcare professional with additional training to serve as an IP and that there be a waiver process when the facility can not comply when due diligence has been followed but such a person is not available. They also recommend a minimum of two years and up to three years for a LTC facility to fully develop and implement the IPCP.

Response: We understand that for some facilities, especially the smaller and rural LTC facilities, coming into compliance with the infection control requirements in this final rule may require an extended period of time. We are finalizing a phased in delay of the implementation date for these requirements. We refer readers to Section II. B for a detailed discussion regarding the implementation deadline for these specific requirements.

Costs

Comment: Commenters pointed out that the proposed infection control requirements, especially those concerning the IP, are unnecessary and will increase costs.

Response: We agree that coming into compliance with the infection control requirements in this final rule will require additional resources for many facilities. However, we have modified the requirements for the IP, now the infection control professional or ICP, which we believe will decrease the burden associated with this provision and address many of the commenters' concerns related to increased costs.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified § 483.80(a)(1) by changing the reference from § 483.75(e) to § 483.70(e).
- We have modified § 483.80(a)(2)(iv) by inserting after, ''[w]hen and how isolation should be used for a resident,'' the following language, ''including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and a requirement that the isolation should be the least restrictive possible for the resident under the circumstances.''
- We have modified § 483.80(b) to change the infection prevention and control officer (IPCO) to an infection preventionist (IP).
- We have modified § 483.80(b) to allow LTC facilities to designate more than one IP.
- We have modified § 483.80(b)(1) and (2) to establish that IPs must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field and can be qualified by education, training, experience or certification.
- We have modified § 483.80(b) by removing the requirement that the IPCP be a major responsibility for the IP.

X. Compliance and Ethics Program (§ 483.85)

As noted previously, section 6102 of the Affordable Care Act amended the Act by adding new section 1128I. Subsection 1128I(b) of the Act requires the operating organizations for SNFs and NFs to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations developed by the Secretary. In the proposed rule we included a robust discussion regarding several industry-specific guidance documents on compliance issued by the DHHS OIG. In addition, we also included a detailed discussion regarding a September 23, 2010 proposed rule entitled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,'' in the **Federal Register** (75 FR 58204), to which we received feedback through public comment regarding compliance program requirements that are required by both sections 6102 and 6401(a) of the Affordable Care Act. We encourage readers to review the proposed rule for this background information.

Proposed § 483.85(a) and § 483.85(b)

At § 483.85(a), we proposed to define the terms ''compliance and ethics program,'' ''high-level personnel'', and ''operating organization.'' We proposed to define ''compliance and ethics program'' to mean with respect to a facility, a program of the operating organization that has been reasonably designed, implemented, and enforced so that it is effective in preventing and detecting criminal, civil, and administrative violations under the Act, and in promoting quality of care; and includes, at a minimum, the required components specified in § 483.85(c). We did not propose using the term ''managing employee'' that is contained in the current LTC facility requirements, but rather proposed to retain the use of the term ''high-level personnel'', which is used in the Affordable Care Act. We proposed to define ''high-level personnel'' as individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. We indicated that the individuals considered ''high-level personnel'' will differ according to each operating organization's structure. However, some examples include, but are not limited to, the following: (1) A director; (2) an executive officer; (3) an individual in charge of a major business or functional unit; and (4) an individual with a substantial ownership interest as defined in section 1124(a)(3) of the Act in the operating organization.

We also proposed to define ''operating organization'' to mean the individual(s) or entity that operates a facility. Section 1128I(b)(1) of the Act defines an ''operating organization'' as ''the entity that operates the facility.'' Although many LTC facilities are part of corporate chains, there are still some LTC facilities that are owned by an individual or a small group of individuals. Therefore, we proposed to add ''individual(s)'' to the definition to make it clear that all LTC facilities, regardless of their legal structure, are required to comply with these requirements.

In § 483.85(b), we proposed that the operating organization for each facility must have in operation a compliance and ethics program (as defined in § 483.85(a)) that meets the requirements of this section beginning on the date

that is one year after the rule's effective date.

Proposed § 483.85(c)

In § 483.85(c), we proposed that the operating organization for each facility be required to develop, implement, and maintain an effective compliance and ethics program that contains at a minimum several components. First, at § 485.85(c)(1) we proposed that the operating organization must establish written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Second at § 483.85(c)(2), we proposed that the operating organization must assign specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization (proposed § 483.85(c)(2)). At § 483.85(c)(2), we proposed that the program must include provisions ensuring that the specific individuals designated with oversight responsibility in proposed § 483.85(c)(2) have sufficient resources and authority to assure compliance with these standards, policies, and procedures.

Next at § 483.85(c)(4), we proposed that the operating organization is required to use due care not to delegate discretionary authority to individuals whom the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, or administrative violations under the Act.

We also proposed at § 483.85(c)(5) that the operating organization be required to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff including individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training or orientation programs, and/or dissemination of information that explained in a practical manner what was required under the program.

Next at § 483.85(c)(6), we proposed that the compliance program must ensure that reasonable steps were being taken to achieve compliance with the program's standards, policies, and procedures, such as utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retaliation, and having a process for ensuring the integrity of any reported data. We also proposed at § 483.85(c)(6) that the operating organization be required to enforce consistently the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the appropriate party identified in the operating organization's compliance and ethics program. We proposed that an operating organization is required to consistently enforce its standards and procedures through appropriate disciplinary mechanisms.

Lastly, at § 483.85(c)(8) we proposed that after an operating organization detected a violation, it must ensure that all reasonable steps identified in its program were taken to respond appropriately to the violation and, to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act. We noted in the proposed rule that in sections 1128I(b)(3)(F) and (G) of the Act, which correspond to § 483.85(c)(7) and (8), the term ''offense,'' is used instead of ''violation'' and that the previously described components are mandatory for all of the SNF and NF operating organizations' compliance and ethics programs.

Proposed § 483.85(d)

At § 483.85(d), we proposed to require operating organizations that operate five or more facilities to designate a compliance officer, and require that such individuals be designated as high-level personnel of the operating organizations with the overall responsibility to oversee the compliance and ethics program. In addition, the designated compliance officer must report directly to the governing body for the operating organization. We also proposed that all operating organizations designate a compliance and ethics program contact.

In addition at § 483.85(d), we proposed that operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

- A mandatory annual training program on the operating organization's compliance and ethics program (§ 483.85(d)(1)).
- A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility (§ 483.85(d)(2)).
- Designated compliance liaisons located at each of the operating organization's facilities (§ 483.95(d)(3)).

Proposed § 483.85(e)

Lastly, at § 483.85(e), we proposed that the operating organization for each facility must review its compliance and ethics program annually, and revise its program, as needed to reflect changes in all applicable laws or regulations and within its organization and facilities to improve its performance in deterring, reducing, and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.

General Comments

Comment: Some commenters were very supportive of the proposed requirements for compliance and ethics programs, especially the components that are required for all facilities. Some commenters also appreciated the recognition of the different levels of resources that were available to smaller and larger operating organizations to develop, implement, and maintain compliance and ethics programs.

Response: We thank the commenters for their support. We do recognize that there would be varying levels of resources available to smaller and larger organizations. Although the requirements for compliance and ethics programs finalized in this rule go to all operating organizations. with additional requirements for those with five or more

facilities, we would expect that all operating organizations would also use the facility assessment they developed according to § 483.70(e) in developing and maintaining their programs. For example, the operating organization must provide, among other things, sufficient resources to reasonably assure compliance with the program's standards, policies, and procedures (§ 483.85(c)(3)). In addition, operating organizations must also take steps to effectively communicate the standards, policies, and procedures of its program to its entire staff, individuals providing services under contractual arrangements; and volunteers, consistent with their expected roles (§ 483.85(c)(5)). This can be accomplished by mandatory training, orientation programs, or disseminating information that explains in a practical manner what is required under the operating organization's program (§ 483.95(f)). Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably assure compliance with the requirements finalized in this rule.

Comment: Some commenters supported the proposed requirements, but also recommended certain individuals who they believed should be involved in developing and maintaining the facility's compliance and ethics program. Some commenters said that professional social workers, who are guided by the National Association of Social Work (NASW) *Code of Ethics* (2008), would be well equipped to contribute to and help to lead such programs.

Response: We appreciate the commenters support for the proposed requirements. We also agree that social workers could play an important role in compliance and ethics programs. However, not all LTC facilities are required to have a full-time social worker on staff so we cannot require that a social worker be involved in developing, implementing, and maintaining these programs. We also believe that each facility needs the flexibility to determine how it will comply with the requirements finalized in this final rule, including choosing the individuals who will be involved in compliance and ethics programs.

Comment: Some commenters noted there were definitions for some terms used in proposed § 483.85, including ''compliance and ethics program'', ''high-level personnel'', and ''operating organization''; however, there was no definition for ''reasonable'' or ''reasonably''. They also noted that CMS did ask for comments on how to evaluate ''reasonableness'' in the proposed rule (80 FR 42221). The commenters supported our statement that ''reasonableness'' may depend on the applicable facts and circumstances. Some commenters also recommended that the term ''reasonable'' be defined and that we use the Black's Law Dictionary definition of ''reasonable person'' as it is often used in other areas of the law, such as, an ordinary person who exercises care while avoiding extremes of boldness and carefulness.

Response: We do believe that reasonableness depends upon the applicable facts and circumstances surrounding any particular situation. As stated in the July 16, 2015 proposed rule (80 FR 42168), the terms ''reasonable'' and ''reasonably'' were used in the section 6102 of the ACA and consequently used in proposed § 483.85(c)(1), (6), and (8). We did not propose a definition of these terms in the proposed rule, but did state that ''[w]e would appreciate comments on how to evaluate the reasonableness of the design, implementation, and enforcement of an operating organization's compliance and ethics program and how to determine the reasonableness of the steps an operating organization has taken to achieve compliance with its standards and the steps an operating organization should take in response to offenses and prevent similar occurrences (80 FR 42221). We will not be finalizing a definition of ''reasonable'' or ''reasonably'' in this rule. However, we will be publishing further sub-regulatory guidance on how to determine reasonableness for these requirements''.

Comment: Some commenters were concerned about including contractual staff and volunteers in some of the requirements. Specifically, proposed § 483.85(c)(1), (5), and (6) that state that LTC facilities must establish ''disciplinary standards,'' communicate ''the standards, policies, procedures . . . includ[ing] . . . mandatory participation in training or orientation programs and/or dissemination of information,'' and ''ensure that reasonable steps were being taken to achieve compliance'' by the facility's staff, and ''individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.'' They argued that it would not be a good use of the facility's time and resources and that some LTC facilities could find it burdensome to train and orient contractor staff and volunteers to their compliance and ethics program. It should be the contractor that it responsible for training the contract staff and the LTC facility should only be responsible for orienting the contract staff to the nuances in their program. In addition, they argued that training for these individuals could be inconsistent with the best practices that are currently in place for LTC facilities, which is to educate contractors or volunteers about the facility's compliance program, seven core elements of an effective compliance program, code of conduct, reporting processes (hot line numbers and other alternative reporting mechanisms) and correction processes by furnishing written materials to contractors or volunteers to review and having them attest to reviewing the materials. The contracting agency should be discussing compliance and ethics matters with their employees and this is often covered in their contracts with the LTC facilities. It should be understood that the LTC facility would be responsible for orienting contractual staff to the individual nuances of the compliance and ethics program for the facility. The commenters recommended that LTC facilities not be required to provide full training and education to volunteers and contractor agency personnel but that the facilities be required to provide these individuals with an overview of their programs.

Response: For any operating organization's compliance and ethics program to be effective, it is crucial that all of the organization's staff, including those who are providing services under contract, and volunteers, consistent with their roles, need to understand the standards, policies and procedures for that program. If these individuals do not understand the program's requirements and their responsibilities under that program, they will not be able to comply appropriately and that will severely reduce, or perhaps eliminate, the effectiveness of the program. Operating organizations with four or less facilities ''must effectively communicate'' to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. It could be formal training, but they could also comply with this requirement through dissemination of materials, as the commenters noted above. For operating organizations with five or more facilities, annual training is required. However, these requirements do not specify how the training or dissemination of information is to be performed. Further, as set forth in § 483.95, it states that ''[a] facility must determine the amount and types of

training necessary based on a facility assessment as specified at § 483.70(e).'' We believe that each operating organization needs to have the flexibility to determine the best way for each of them to comply with this requirement and this final rule provides them that flexibility to determine what kind of dissemination of information or training they need to provide. In addition, it is the training or dissemination of the information that is crucial. For example, the operating organization could choose to arrange with the contractor to have the contractor provide the required training or dissemination of information for the compliance and ethics program as some commenters indicated happens today.

Comment: Some commenters recommended that LTC facilities be required to integrate the information from the compliance program into the facility's QAPI program. The commenters believed that compliance must be coordinated into the current ongoing activities so that the primary focus remains on doing the right thing in the right way routinely, and on proper clinical reasoning and problem solving, with regulatory and legal compliance always kept in mind but not as a separate or predominant activity. They were concerned that an excessive or separate focus on compliance could potentially result in clinically questionable activities in the name of ''compliance'' that could be inconsistent with desirable care approaches.

Response: We agree that the information and data obtained through the facility's compliance and ethics program should be integrated into the facility's QAPI program. However, the QAPI requirements finalized in this rule already provide for this integration. The facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility and must address, among other things, all of the systems of care and management practices (§ 483.75(b)(1)). In addition, each facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring (§ 483.75(c)). Also, the QAA committee must regularly review and analyze data and act on available data to make improvements (§ 483.75(g)((2)(iii)). Thus, LTC facilities should be integrating the information and data they collect or arises out of their compliance and ethics programs into their QAPI program.

The requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not only ensure compliance with the requirements in this final rule but also improvements in the quality of care provided to the residents. Also, we do not believe this will result in an excessive or separate focus on compliance or result in negative consequences to the residents, staff, or facility.

Additional Requirements for Operating Organizations With Five or More Facilities

Comment: Some commenters were concerned that our proposal for additional requirements for operating organizations with five or more facilities was imposing additional requirements on certain operating organizations based upon an arbitrary number of facilities. Some commenters recommended that only operating organizations with 15 or more facilities be required to comply with the additional requirements.

Response: We proposed additional requirements for operating organizations with five or more facilities, because section 1128I(b)(2)(B) of the Act, as added by section 6102 of the ACA (Pub. L. 111–148 (2010), states that ''with respect to specific elements or formality of a program, in the case of an organization that operates 5 or more facilities, vary with the size of the organization.'' Since the statutory language specifically indicates that the compliance and ethics programs for operating organizations with five or more facilities should be a more formal program or have more elements, we will be not finalize § 483.85(d) to apply to operating organizations with 15 or more facilities. Hence, we have finalized that section so that the additional requirements apply to operating organizations that have five or more facilities.

Comment: Other commenters were very supportive of the proposed additional requirements for operating organizations with five or more facilities as set forth in § 483.85(d): Mandatory annual training programs on the operating organizations' compliance and ethics programs that meet the requirements set forth in § 483.95(f); designated compliance officers for whom their operating organization's compliance and ethics program is a major responsibility; and designated compliance liaisons located at each of the operating organization's facilities.'' These commenters recommended that all operating organizations, regardless of size, be required to comply with these additional requirements.

Response: We appreciate the commenters support for these additional requirements. However, in developing requirements, we must balance the necessity of the requirement for the health and safety of the residents with the burden of that requirement to the operating organization. We believe that the additional requirements are necessary for larger operating organizations to develop and maintain effective compliance and ethics programs. Larger organizations will generally be caring for more residents and have more locations for which they are responsible. We believe this requires that the larger operating organizations have a compliance officer. Since that compliance officer will be responsible for the organization's program at five or more facilities, we believe he or she will need someone at each facility, the compliance liaison, to assist them with the program at each facility. In addition, considering the number of facilities, we believe this requires annual training to ensure that all staff, including those who are providing services under a contract and volunteers, consistent with their roles, are knowledgeable about the operating organization's program and how they are expected to comply with its standards, policies, and procedures. For operating organizations with four or fewer facilities, we believe they can develop and maintain a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act as required by section 1128I(b)(1) of the Act without the additional requirements for larger operating organizations. However, we would encourage operating organizations with four or fewer facilities to incorporate these additional elements if their facility assessments indicate that they are necessary to ensure that their compliance and ethics programs are effective. Thus, we will not be extending the addition requirements set forth in § 483.85(d) to all operating organizations.

Comment: Some commenters were concerned about the requirement for designated compliance liaisons at each facility for operating organizations with five or more facilities (§ 483.85(d)(3)). They did not believe it was good policy to appoint someone at each facility who does not have the critical experience, education, or knowledge of a compliance officer. It is also not feasible to expect that each facility could hire someone with the background or expertise to be a compliance officer in the operating organization's compliance and ethics program.

Response: Compliance liaisons are not compliance officers. In the proposed rule, we did not define ''designated compliance liaison'' but stated that

''[w]e would expect that operating organizations would develop a description for these positions and the duties and responsibilities these individuals would have in the operating organization's compliance and ethics program . . . [a]t a minimum, these liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization's program at their individual facilities'' (80 FR 42220). We believe that each operating organization needs the flexibility to determine what the qualifications, duties, and responsibilities that these compliance and ethics program liaisons should have in their organization. Thus, it is the operating organization with five or more facilities that will develop its own definition for the position of ''designated compliance liaison'' and determine the qualifications, duties, and responsibilities for the individuals in this position.

Comment: Some commenters noted that compliance officers could not to be subordinate to the general counsel (GC), chief financial officer (CFO) or chief operating officer (COO) in proposed § 483.85(d)(2). They were very supportive and noted that in many large organizations the GC is the compliance officer and is often the best qualified to address potential legal violations and other areas of concern. In addition, the commenters noted that in many mid-sized organizations the GC, CFO, or COO is the compliance officer because the organization cannot financially support a full-time compliance officer. Some commenters recommended that we insert a sentence that specifically indicates that the GC, CFO, or COO may serve as the compliance officer. Other commenters recommended that the compliance officer also not be subordinate to the facility's chief executive officer (CEO) or the administrator.

Response: We agree with the commenters that it is very important that the compliance officer not be subordinate to certain individuals in the operating organization. We agree that the compliance officer should also not be subordinate to an administrator; however, we believe that the compliance officer would be within the operating organization's staff and not located at an individual facility to avoid any interference or influence of the compliance officer by an administer. We do not agree that the compliance officer could not be subordinate to the CEO, who is generally the highest ranking officer in an operating organization. For these reasons, we did not propose that the compliance officer could not be subordinate to the CEO or an administrator. The compliance officer must be able to communicate with the governing body without being subject to any coercion or intimidation. This is why we proposed § 483.85(d)(2) that states that the compliance officer must be able to report directly to the governing body. Thus, we have finalized § 483.85(d)(2) as proposed. We believe any further detail on who can and cannot serve as the compliance officer should be provided in the sub-regulatory guidance for this requirement. We refer facilities to additional guidance the OIG has published for nursing home compliance programs, ''OIG Supplemental Compliance Program Guidance for Nursing Facilities'' (73 Fr 56832) (*https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf*).

Implementation and Costs

Comment: Some commenters were concerned about the 1-year timeframe for implementation of the compliance and ethics programs. Commenters wanted at least 2 years for LTC facilities to develop their compliance and ethics programs. They based the 2 years on both the statutory language in ACA that stated that the Secretary had 2 years to promulgate regulations for compliance and ethics programs and to allow adequate time to change and adjust current compliance and ethics programs allow adequate time to change and adjust current processes and procedures and to reconfigure facility budgets.

Response: We appreciate the commenters' concerns about the implementation of the requirements for compliance and ethics programs. We are finalizing a phased in delay of the implementation dates for this final rule. We refer readers to Section II.B. for a detailed discussion regarding the implementation deadlines for these requirements. The estimated costs for complying with these requirements are discussed in sections V. Collection of Information Requirements and VI. Regulatory Impact Analysis (RIA).

Comment: Some commenters believed that the requirements for the compliance and ethics program were unduly prescriptive and costly and could impose an unnecessarily onerous burden on some LTC facilities. However, some of these commenters also indicated that a major organization for long-term care facilities had already been educating its membership on the requirements in ACA for compliance and ethics program in LTC facilities and had educational tools on its Web site.

Response: Section 6102 of the ACA mandated compliance and ethics programs in LTC facilities. Hence, these are not discretionary requirements. In developing these regulations, we have established the requirements contained in the ACA and have been mindful of the burden which will be required to comply with these requirements. In finalizing these requirements, we strived to avoid not only any unnecessary burden but also to provide maximum flexibility for operating organizations to comply with the requirements established in ACA.

Surveys

Comment: Some commenters were concerned about how the LTC facilities would be surveyed for the compliance and ethics program requirements. Some commenters wanted a tangible observational process established for the surveyors, which would validate that facilities are providing compliance and ethics policies and procedures to the staff and that governing bodies are implementing those policies and procedures.

Response: We understand that commenters have concerns about how surveyors would determine compliance with these requirements. As discussed above, we will be developing and publishing or disseminating sub-regulatory guidance, including interpretative guidelines (IGs), before surveyors begin to survey LTC facilities for these requirements. That guidance will provide the detailed information surveyors need to determine compliance with these requirements.

After consideration of the comments we received on the proposed rule, we are finalizing the requirements as proposed.

Y. Physical Environment (§ 483.90)

In the proposed rule we indicated that the facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. Many of these provisions relate to Life Safety Code (LSC) requirements. We recently published a final rule which adopts many provisions of the 2012 LSC ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,'' (81 FR 26871, May 4, 2016). As part of our comprehensive review and restructuring, we re-designate the existing provisions of § 483.70 as new § 483.90; however, the language in existing § 483.70(a) ''Life safety from fire'' and § 483.70(b) ''Emergency power'' are unchanged, including new provisions related to the requirement that long term care

facilities have automatic sprinkler systems added by the final rule ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, Part II'' published in the **Federal Register** on May 12, 2014 (79 FR 27106).

In § 483.90(c) ''Space and equipment'', we proposed to add the resident's individual assessment, including preferences and choices, as an element to consider in addition to the resident's plan of care when considering the space and equipment requirements of the facility. We proposed to eliminate the word ''essential'' from § 483.90(c)(2) (re-designated from § 483.70(c)(2)). In addition, we proposed to add a new § 483.90(c)(3) to specifically require that facilities conduct regular inspections of all bed frames, mattresses, and bed rails and to ensure that bed rails are compatible with the bed frame and mattress.

Currently, in existing § 483.70(d), the regulations allow for bedrooms that accommodate up to four residents. We proposed to require at § 483.90(d)(1)(i) that bedrooms in facilities accommodate not more than two residents unless the facility is currently certified to participate in Medicare and/or Medicaid or has received approval of construction or reconstruction plans by state and local authorities prior to the effective date of this regulation. We indicated in the proposed rule that reconstruction means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified. We also proposed to require that the bed size and height be not only convenient for the resident's needs, but also safe.

Section 483.70(e) currently requires that each bedroom be equipped with or located near toilet and bathing facilities. We proposed at § 483.90(e) to add the requirement that, for facilities that receive approval of construction or reconstruction plans by state and local authorities or are newly certified to participate in Medicare and/or Medicaid after the effective date of this rule, each resident room must have its own bathroom equipped with at least a toilet, sink and shower. In addition, we proposed that if a facility undergoes reconstruction, each resident room in the reconstructed space must have its own bathroom equipped with at least a toilet, sink and shower. We indicated in the proposed rule that reconstruction means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified.

At § 483.90(f) (proposed to be re-designated from § 483.70(f)), a resident call system is required. We proposed to revise this revision and require that the facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from the resident's bedside, toilet and bathing facilities.

At § 483.90(g) (proposed to be re-designated from § 483.70(g)) we address dining and activity rooms and include a requirement to designate non-smoking areas. We proposed to eliminate the language ''with non-smoking areas identified''.

We also proposed to add a new paragraph at § 483.90(h)(5) to require facilities to establish policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety, including but not limited to non-smoking residents.

Comment: One commenter asked that we adopt the 2012 Life Safety Code.

Response: This concern has been addressed through separate rule-making. As noted above, we published the final rule, ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,'' which would adopt many provisions of the 2012 LSC on May 4, 2016 (81 FR 26871).

Comment: Some commenters recommended that CMS consider adopting the ''Guidelines for Design and Construction of Residential Health Care and Support Facilities,'' produced by the Facilities Guidelines Institute, in addition to and in the same manner as we currently adopt the Life Safety Code.

Response: We thank the commenters for their suggestion. We will evaluate this suggestion further and consider it for future rulemaking.

Comment: Some commenters disagreed with our proposed requirement regarding bed rails. One stated that their facility already had a process in place and this would require an additional inspection that would take away from their ability to complete other maintenance tasks. Another stated that our requirements were inadequate given the risks posed by bed rails, citing concerns about the availability of manufacturer information and guidance. One commenter recommended strengthening our requirements including adding additional detailed requirements, especially to safeguard against entrapment.

Response: We agree that resident safety in important when considering the use of bed rails. However, detailed guidance regarding the use of bed rails is more appropriate in interpretive guidance. As noted in the proposed rule, additional resources are available at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm.* If a facility already conducts regular inspections of all bed frames, mattresses, and bed rails, no new process would be required as long as the requirements at § 483.25(n) and § 483.90(c) were met. If a facility was unable to identify a manufacturer and access manufacturer information and guidance for bed rails that they used, they would not be meeting requirements to follow the manufacturers' recommendations and specifications for installing and maintaining bed rails set forth in § 483.25(n)(4).

Comment: Several commenters supported our proposal to limit the number of residents in a room to two. Many suggested that the requirements do not go far enough. Several suggested that this requirement should apply to all facilities, not just newly constructed, certified, or renovated. Others suggested that private rooms should be the standard, with a few double rooms to accommodate couples or those desiring a roommate. A few commenters objected to the requirement. Some commenters stated that this requirement was burdensome and would discourage new construction and renovation. Some commenters felt that this requirement should apply to new construction only and were concerned about the definition of reconstruction. One commenter stated that their facility had large rooms and putting an occupancy limit on all rooms regardless of considering the size of the rooms would be unreasonable.

Response: We have taken into account all of the comments received, both supportive comments and those pointing out concerns with our proposal to limit room occupancy only in newly constructed, reconstructed, or newly certified facilities and considered multiple alternatives. We believe that semi-private rooms are far more supportive of privacy and dignity. We recognize that for many residents, a private room would be ideal. However, for others, a spouse or other roommate is desirable. We note that many states have physical environment requirements that exceed our requirements. These requirements vary widely, but many states include a

requirement for no more than two beds per resident room or establish a minimum percentage of rooms that must be private or semi-private. Individual facilities can choose to offer private rooms as well. However, as these regulations apply to every Medicare- and Medicaid- certified facility, we must also consider the potential for our requirements to discourage innovation, new construction, or reconstruction and to negatively impact access to care. Therefore, at this time, we believe our proposal represents an appropriate balance among the concerns voiced and we are finalizing this requirement as proposed. With regard to the definition of reconstruction, we have stated that this means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified. We would clarify that, for reconstruction, the requirement applies to the reconstructed area, so that where reconstruction involves a limited area within a building, we would not expect the entire building to upgrade to the new requirements. This should not deter facilities from making needed renovations. We defer additional discussion to sub-regulatory guidance.

Comment: One commenter noted that residents benefit from being outdoors, not just in the facility. The commenter suggested that CMS should establish goals that help pave the way to more universal standards for facilities that are person-centered in all aspect, including physical environment that recognizes the needs of residents for privacy, dignity and personal choice and included should look to models such as Green House® to ''borrow'' as appropriate. Another commenter recommended that we include a requirement that the facility provide sufficient outdoor space that is accessible to residents and where residents can sit and move around as independently as possible.

Response: We thank the commenter for their suggestions. We agree that some residents may benefit from access to outdoor spaces. Such access, of course, must be balanced with safety and supervision concerns, which may vary significantly across resident populations. In addition, such requirements would need to be equally applicable to all long-term care facilities, whether urban, suburban, or rural, or small, medium, and large. We are aware of the Green House® and other models and will continue to evaluate these models and new innovations, including requirements for outdoor space, and consider their application in future rule-making.

Comment: A couple of commenters asked that we consider using terms other than ''toilet facilities'' or other terms that reflect an institutional mindset.

Response: We appreciate the comment and have modified language at § 483.90(e).

Comment: Several commenters objected to our proposal to include a shower, in addition to a toilet and sink, in rooms that are renovated, or newly constructed or certified after the effective date of the final regulation. A number of commenters suggested that not only would such showers be under-utilized, they would present a safety hazard. Some commenters raised, in particular, safety concerns related to residents with dementia having unsupervised access to a shower. One referred to a shower as ''costly, wasted space'' and another stated that ''it has been our experience . . . that current showers in private rooms go unused.'' Some commenters suggested this requirement should not apply to facilities being renovated, as this would discourage needed upgrades to facilities. A commenter suggested that building configuration and existing spaces would not be conducive to adding showers, given other square footage and code requirements applicable to resident spaces. Further, showers in these rooms would need to be of substantial size to accommodate specialized equipment when necessary, resulting in reduced living space for the resident. Some commenters suggested that construction costs may make this prohibitive for many companies to build new facilities, resulting in reduced construction at a time when additional facilities may be needed due to demographic factors or that such costs would create a disincentive to update and modernize resident rooms. Other commenters supported the inclusion of a shower for each resident room, stating that this would eliminate residents needing to go down the hall to a common bathing room. Another suggested that portable showers could serve the intended purpose but avoid some of the concerns that have been raised.

Response: We have taken into account all of the comments received, both supportive comments and those pointing out concerns with our proposal. We considered suggestions to require facilities to install safety features or special monitoring in bathrooms. We acknowledge concerns about safety as well as the disincentive for facility upgrades that our proposal could create, particularly in light of space requirements for a safe, effective shower. Given these concerns, at this time, we have decided to modify the proposed requirement at § 483.90(e) to require that resident rooms have a toilet and sink in facilities that receive approval of construction plans by state and local authorities or are newly certified to participate in Medicare and/or Medicaid after the effective date of this rule. Facilities continue to have the option to exceed our requirements, in keeping with the health, safety and quality of life of its residents.

Comment: Several commenters supported our proposal to require that each resident room must have its own commode and sink. Some commenters objected to our requirement that each room must have its own commode and sink. Several commenters stated that existing facilities are likely not to have adequate space to accommodate this requirement and believed that this would prevent facilities for undertaking renovations. One commenter asked if a bathroom shared between two resident rooms would be permissible.

Response: Our requirement states that each resident room must have its own bathroom. A shared bathroom would not meet this requirement. We have considered commenters concerns about cost and the lack of available space to add additional bathrooms deterring upgrades to existing facilities and have revised this requirement to apply only to facilities that receive approval of construction from State and local authorities or are newly certified after the effective date of this rule. Furthermore, we believe removing the requirement for each bathroom to include a shower substantially reduces the burden, both financial and in terms of space, that this requirement imposes on facilities subject to the heightened requirement.

Comment: One commenter asked that it be made clear that ''newly certified'' does not include facilities where there has been a change of ownership. Other commenters echoed similar concerns about certification after change of ownership.

Response: When facilities change ownership, the new owners have the option of accepting the existing provider agreement. In this case, the facility would not be ''newly certified.'' However, when a new owner does not accept the existing provider agreement, the facility does require a ''new certification'' and these requirements would apply. We considered explicitly exempting all changes of ownership from this requirement, however, there is the potential for significant abuse of

such an exemption and we believe that to do so is not appropriate.

Comment: One commenter objected to our inclusion of smoking cessation in proposed paragraph (h)(5). The commenter stated that while smoking cessation is a noble cause, it should not be required in every center's policies, particularly if a facility has adopted a policy for non-smoking. They further stated that smoking cessation programs are appropriate for some facilities but not for all. Finally, the commenter stated that the requirement, as written, was confusing and should also reference electronic cigarettes. Another commenter stated that smoking should not be considered a resident right and that accommodating smoking takes CNAs away from caring for residents.

Response: We appreciate the commenter's thoughtful suggestions. We have revised the provision to remove the reference to smoking cessation, and improve clarity. We did not at this time add electronic cigarettes, but will evaluate whether or not electronic cigarettes should be included in this provision in the future. We agree that a smoking cessation program may not be appropriate for some facilities, such as those facilities that are ''smoke-free.'' However, even ''smoke-free'' facilities may admit residents who smoke. Smoking cessation support should be offered to residents who smoke and addressed in their person centered plan of care. Smoking is not addressed as a resident right; rather, we require that facilities have policies and procedures to safeguard residents, whether smoking or non-smoking, if and where smoking occurs.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified our proposal at § 483.90(e) to require that, for facilities that receive approval of construction or are newly certified after the effective date of this final rule, each resident room must have its own bathroom with at least a commode and a sink.
- We have modified our proposal at § 483.90(h)(5) to state that facilities must establish policies in accordance with applicable Federal, State, and local laws and regulations regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

Z. Training Requirements (§ 483.95)

We proposed to add a new § 483.95 to subpart B which sets forth training requirements. We proposed that a facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. We also proposed that a facility be required to determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e).

We proposed at § 483.95(a) to include effective communications as a required training topic for direct care personnel. We did not propose to require a specific amount of time, specific communications topics, or specific training mechanisms to meet this requirement. We proposed at § 483.95(b) to require that facilities train staff members on the rights of the resident and the responsibilities of a LTC facility to properly care for its residents as set forth at § 483.10 and § 483.11, respectively. At § 483.95(c) we proposed to require that a facility provide training to its staff on the freedom from abuse, neglect, and exploitation requirements found in § 483.12. We proposed to specify that facilities must provide training to their staff that at a minimum educates staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property and procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

At § 485.95(d), we proposed to require that a facility must provide mandatory QAPI training to its staff that outline the elements and goals of the facility's QAPI program. At § 483.95(e) we proposed to require LTC facilities to include staff training as part of their efforts to prevent and control infection. It would be the facility's responsibility to ensure that their staff was effectively educated on the facility's infection control policies and procedures.

At § 483.95(f)(1), we proposed that the operating organization for each facility must include as part of their compliance and ethics program training for staff that outlines the standards, policies, and procedures. We did not specify how a facility should develop this training; however we indicated in the proposed rule that the training must explain in a practical manner the requirements under the compliance and ethics program. In addition, at § 483.95(f)(2) we proposed to require that if the operating organization operates five or more facilities, it must include mandatory training annually.

Section 6121 of the Affordable Care Act added sections 1819(f)(2)(A)(i)(1) and 1919(f)(2)(A)(i)(1) of the Act. These sections require all NAs to receive on-going training in both dementia management and patient abuse prevention training, ''if the Secretary determines appropriate.'' We proposed to amend the LTC requirements by requiring that the current mandatory on-going training requirements for NAs include dementia management and resident abuse training.

We also proposed to relocate the training requirements for NAs at § 483.75(e)(8) to § 483.95(g). Specifically, we proposed to re-designate existing § 483.75(e)(8)(i), (ii), and (iii) to § 483.95(g)(1), (3), and (4), respectively. At § 483.95(g)(2), we proposed to add the new requirement that the 12 hours of annual in-service training for NAs must include dementia management and abuse prevention training. Also, at § 483.95(g)(3), we proposed to add to the existing requirement that the in-service training address areas of weakness as determined by a facility's assessment at § 483.70(e). In addition, current regulations at § 483.75(q) require facilities to only employ as a paid feeding assistant those individuals who have successfully completed a state approved training program, as specified in § 483.160. We proposed to relocate this provision without change to proposed § 483.95(h).

Lastly, we proposed at § 483.95(i) to require that facilities provide behavioral health training to its entire staff, based on the facility assessment at § 483.70(e). As required at § 483.70(e), we proposed that the facility be responsible for using their facility assessment to determine the behavioral health related needs of their residents. Then the facility must ensure that their staff is provided with behavioral health training that correlates with the needs of their residents.

Comment: Many commenters applauded the addition of the training section and the inclusion of the various required topics of training. Commenters noted that all trainings should be conducted in an environment that encourages participation and open discussion with the freedom to ask questions.

Response: We appreciate the feedback from commenters. We believe that requiring facilities to develop, implement, and maintain an effective training program for staff will help to prepare staff and improve outcomes. In addition, we believe that appropriately training staff can improve resident safety, create a more person-centered environment, and reduce the number of adverse events or other resident complications. We agree that training activities should encourage participation and allow for open dialogue among participants in order to

be productive. We encourage facilities to allow for this type of interaction and anticipate that the interpretive guidance to this regulation will further provide ideas and best practices for how to implement these training requirements.

Comment: While commenters supported the training topics named in the proposed rule, many commenters provided suggestions for additional topics to be required for all facility staff members who provide services directly to residents. Suggested topics included advance care planning, cultural competence, end-of-life care, geriatrics and gerontology, working with young and middle-aged adults, grief and loss, interdisciplinary collaboration, person-centered care, specialized rehabilitative therapy, and intellectual disability. In addition, one commenter recommended that the training section be expanded to require training on additional CMS requirements, such as resident choice and quality of life and care. One commenter indicated that staff should be educated on the aging process and have an understanding of how human beings change as they grow older.

Response: We appreciate the feedback from commenters. Given the volume of the proposed requirements and the concerns raised by commenters regarding the time needed to implement all of the requirements, we believe it would be overly burdensome to increase the number of required training topics at this time. We will continue to evaluate each of the suggested topics raised by commenters and consider them for future rulemaking. In addition, we note that while the regulations require specific training topics, facilities have the flexibility to add more topics to their training programs, in accordance with their facility assessments.

Comment: A couple of commenters recommended that the requirement for communication training specifically address the content that should be discussed in the training. One of the commenters recommended that the content specifically address individuals with dementia, individuals who are non-verbal, and individuals with hearing and/or vision impairments. Another commenter indicated that the requirement for communication training should specify the number of hours required for the training. One commenter indicated that the regulations should specifically require staff to pass exams as part of their training program.

Response: We appreciate the recommendations from commenters, but ultimately we recognize that training needs are likely to change over time. We believe that it is necessary for facilities to have the flexibility to determine, based on its internal facility assessment and competencies and skill sets needed for employees, how to structure training to meet its specific needs. To ensure that the training provided is facility specific and most beneficial to the residents receiving care in the facility, we believe that it is best not to limit the training requirements to too many specifics. We expect that the surveyor guidance associated with this final rule will provide facilities with additional guidance for how to meet these requirements. In addition we encourage readers to refer to the proposed rule discussion (80 FR 42222) for resources available for providing effective communication training including the Agency for Healthcare Research and Quality's (AHRQ) Team STEPPS Long Term Care communication training for front line staff in LTC facilities (*http://www.ahrq.gov/qual/ptsafetyltc/index.html*).

Comment: Many commenters recommended that caring for residents with dementia should be highlighted as a training topic for all nurse staffing personnel, not just nurse aides. Commenters noted that there are an overwhelming number of individuals with a diagnosis of Alzheimer's or another dementia-related illness in LTC facilities and the use of interdisciplinary teams to deliver care is on the rise. One commenter indicated that simple ideas such as sensory stimulation be used for communicating with an individual who has dementia and that this type of care does not need to be the province of just one type of staff who is caring for the individual. Another commenter noted the CMS ''Hand in Hand'' curriculum (*http://www.cms-handinhandtoolkit.info/*) as an excellent resource and highlighted a report developed by the Dementia Action Alliance entitled, ''Living Fully with Dementia: Words Matter'' (*http://daanow.org/living-fully-with-dementia-words-matter/*) as an additional resource for interested parties.

Response: Given the encouragement from commenters to extend dementia management training beyond just NAs, we have revised our proposal in this final rule. We agree that expanding the requirement for dementia management training to all staff will only further improve the care that is provided. Therefore, at § 483.95(c) we are adding a provision to require that all new and existing staff, individuals providing services under a contractual arrangement, and volunteers receive dementia management and abuse prevention training, consistent with their roles in the facility. We are not proposing that facilities develop a separate training from that required for nurse aides and given that the dementia management training will already be developed, it will not be overly burdensome for facilities to expand the training to all staff. In addition, we encourage facilities to utilize the free training materials available to facilities, such as the CMS ''Hand in Hand'' curriculum as well as the additional resources highlighted by commenters.

Comment: One commenter recommended that the term dementia management be replaced with ''appropriate care of residents living with dementia'' to be more person-centered.

Response: We appreciate the recommendation; however, dementia management is the language used in the Affordable Care Act and at this time we are using the same term for consistency.

Comment: One commenter indicated that all or part of the abuse, neglect, and exploitation training should be performed by an individual or agency that is not associated with the LTC facility.

Response: The regulations do not specify that a member of the facility has to conduct the training activities and facilities have the flexibility to work with outside entities to provide the training. We encourage facilities to leverage any resources available to assist with developing and implementing their training program.

Comment: One commenter recommended that all staff be required to receive an orientation to the LTC facility within their first two weeks of employment that includes training in at least residents' rights, aging, dementia, abuse reporting requirements, emergency procedures, and the policies of the LTC facility.

Response: We agree that new staff members should also receive training and have specified at § 483.95 that training must be provided to both new and existing staff. As discussed in a previous comment, we believe it would be burdensome to require additional training topics at this time.

Comment: One commenter recommended that all staff be required to be certified as nursing assistants. The commenter indicated that all staff should be able to assist residents with all activities of daily living without having to wait for a CNA.

Response: We agree that all staff should be able to assist residents with activities of daily living. However, we do not believe that having this capability is dependent on being a nursing assistant and therefore do not believe that it is necessary to require all

staff to be certified as nursing assistants. Instead we believe that facilities should assess their resident population including, among other things, the care required by the resident population considering the overall acuity that are present within the population. We proposed at § 483.70(e) to require facilities to conduct an annual facility assessment that addresses the staff competencies that are necessary to provide the level and types of care needed for the resident population. We believe that facilities will be able to use this information to appropriately staff their facilities and provide residents with the care and attention that they need.

Comment: One commenter recommended that those facilities with residents diagnosed with dementia should be required to conduct an annual assessment of all direct care staff that includes observation, to ensure that staff are providing adequate dementia care and abuse prevention. The commenter recommends further that for those staff members who exhibit caregiver stress, the facility should be required to have a plan in place to identify and support these individuals.

Response: The in-service training requirement for nurse aides specifies that the training must be no less than 12 hours per year. Therefore, following the implementation of this final rule nurse aides who provide direct care to residents will be re-trained in dementia management, as proposed at § 483.95(g)(2), at least annually. In addition, we note that in response to comments in this final rule we are expanding the requirement for dementia management and abuse prevention training to all direct care staff. As discussed previously, by direct care staff we are referring to those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. While we appreciate that recommendation to provide staff members with support for caregiver stress, we believe that it would be overly burdensome to place this additional responsibility on facilities. We encourage those facilities that are capable to consider developing some type of employee assistance program that can be utilized by those staff members that may be exhibiting caregiver stress.

Comment: One commenter disliked the use of the phrase ''dementia management'' and suggested the use of the phrase ''dementia care'' indicating that this phrase is more person-centered.

Response: We appreciate the commenter's feedback, however dementia management is the phrase used in the statute and at this time we are aligning the terminology in our regulation with that of the statute for consistency.

Comment: A few commenters recommended increasing the number of on-going in-service training hours for nurse aides. Commenters provided various recommendations for the number of hours increased from 12 to 24 hours. Another commenter recommended that CMS evaluate the current in-service training provided to nurse aides in order to determine a minimum requirement for hours to enhance the continued competency of staff.

Response: We appreciate the feedback from commenters and agree that additional consideration should be given to increasing the number of in-service training hours required for nurse aides. We will continue to review the commenters and as recommended by commenters, review the current in-service training for nurse aides in order to determine a minimum number of training hours that will help to enhance the continued competency of staff.

Comment: One commenter recommended that the in-service training for nurse aides be expanded to include training in end-of-life care, teamwork, and problem solving. Another commenter recommended that nurse aides should also be trained to recognize situations where licensed nursing staff are needed and how to initiate immediate contact with them.

Response: We appreciate the feedback from commenters and believe that their concerns are already covered in the regulations. We proposed at § 483.95(a) to include effective communications as a required training topic for direct care personnel, which includes NAs. We believe that effective communication is important for reducing unnecessary hospitalizations as well as for improving a resident's overall quality of life and quality of care.

Comment: One commenter questioned whether employees of the LTC facility must develop the training materials. The commenter indicated that many facilities use consultants or contractors to develop training. In addition, a commenter indicated that the proposed rule did not clearly define the type of training that volunteers should receive. Also, the commenter indicated that the requirement for facilities to train all individuals under a contractual arrangement is unreasonable.

Response: Facilities have the flexibility to determine the materials to use for providing training and determining the appropriate individuals to be responsible for providing the training. In the proposed rule we indicated that training should be provided for new and existing staff, individuals providing services under a contractual arrangement, and volunteers consistent with their expected roles. We do not agree that requiring individuals under a contractual arrangement be trained is unreasonable. Facilities have a responsibility to ensure that the individuals they employ, whether directly or under contract, have their appropriate competencies and capabilities to provide services in their facility.

Comment: Commenters indicated concern regarding the financial and administrative burdens associated with requiring expansive training requirements. Commenters noted that it is already challenging to address the currently imposed training requirements. Also, commenters indicated that facilities need the flexibility to determine how to training staff on the proposed training topics. One commenter recommended that the proposed training topics be evaluated by a workgroup comprised of both CMS and providers and that any new training topics be implemented based on a 5 year phased-in schedule.

Response: We did not propose a specific training mechanism to meet the training requirements, therefore facilities have the flexibility to determine how to appropriately train staff. Given the overall comprehensive revision to the LTC requirements we are finalizing a phased in implementation schedule for this regulation. We defer readers to section II.B. Implementation for a detailed discussion regarding the implementation timeline for the training requirements, as well as the other requirements finalized in the rule.

Comment: One commenter noted that there are many ways to provide training such as computer based training, self-directed learning, mentoring and coaching.

Response: We appreciate the feedback from commenters and agree that there are many effective training mechanisms available to facilities to meet the training requirements including those recommended by the commenter.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- Adding a new requirement at § 483.95(c)(3) to require that staff

receive dementia management and abuse prevention training.

III. Provisions of the Final Regulations

In this final rule, we are adopting the provisions of the July 16, 2015 proposed rule with the following revisions:

- In § 483.5, we are revising the definition of ''abuse'' to ''the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.''
- In § 483.5, we are revising the definition of ''exploitation'' to ''taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.''
- In § 483.5, we are adding ''registered respiratory therapist or certified respiratory therapy technician'' to the definition of ''licensed health professional.''
- In § 483.5, we are adding a definition of ''mistreatment'' and define it as ''inappropriate treatment or exploitation of a resident.''
- In § 483.5, we are revising the definition of ''neglect'' to ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''
- In § 483.5, we are revising the definition of ''resident representative'' to (in accordance with 45 CFR 1324.1), ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (3) Legal representative, as used in section 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''
- In § 483.10, we have consolidated proposed § 483.10 and proposed § 483.11 into § 483.10, ''Resident rights'' and removed or updated all cross-references as appropriate.
- In § 483.10, we have replaced the term ''verbal'' with ''oral'' throughout this entire section.
- In § 483.10, we have moved introductory language from proposed § 483.10 and proposed § 483.11, as well as § 483.11(a)(2) to § 483.10(a) ''Resident Rights.''
- In § 483.10, we have consolidated proposed § 483.10(a)(1) through (5), and proposed § 483.11(a)(1), and (a)(3) through (5) into § 483.10(b), ''Exercise of rights.''
- In § 483.10, we have revised § 483.10(b)(3) to incorporate previously existing language clarifying that the provision applies to residents who have not been adjudged incompetent by a State court.
- In § 483.10, we have revised § 483.10(b)(7)(i) to clarify that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it.
- In § 483.10, we have consolidated proposed § 483.10(b) and proposed § 483.11(b) into § 483.10(c), ''Planning and implementing care.''
- In § 483.10, we have changed the term '' disciplines'' to ''the type of care giver or professional'' at § 483.10(c)(4).
- In § 483.10, we have clarified in § 483.10(c)(5) that the physician or other practitioner or professional informs the resident of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options.
- In § 483.10, we have consolidated § 483.10(b)(6) and § 483.11(b)(2) into § 483.10(c)(7) which now states ''The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.''
- In § 483.10, we have withdrawn proposed § 483.10(c)(2) to require that physician's meet facility credentialing requirements and consolidated § 483.10(c)(1) and (3), and § 483.11(c)(1) through (3) at § 483.10(d).
- In § 483.10, we have redesignated § 483.10(d) as § 483.10(e), revised paragraph (6) to specify that the resident has a right to receive written notice, including the reason for the change before the resident's room or roommate in the facility is changed and added a new paragraph (7)(iii) to clarify that a room change cannot be solely for the convenience of staff.
- In § 483.10, we have consolidated proposed § 483.10(e) and proposed § 483.11(d) at § 483.10(f), Self-determination.
- In § 483.10, we have added ''and other applicable provisions of this Part'' to § 483.10(f)(1).
- In § 483.10, we have consolidated § 483.10(e)(3) and § 483.11(d)(1) at § 483.10(f)(4), clarified that the resident's right to deny visitation is ''when applicable,'' clarified that a facility must have written policies and procedures for visitation that includes restrictions, when such limitation may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation, and clarified that the facility must inform each resident not only of any limitation, but also to whom the restrictions apply.
- In § 483.10, we have added at § 483.10(f)(5)(i) that a facility must take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.
- In § 483.10, we have added at paragraph (f)(5)(ii) ''or other guests'' to the list of individuals who may only attend a resident or family group meeting at the group's invitation.
- In § 483.10, we have consolidated proposed § 483.10(e)(8) and § 483.11(d)(4) into § 483.10(f)(9).
- In § 483.10, we have consolidated proposed § 483.10(e)(9) and § 483.11(d)(5) into § 483.10(f)(10).
- In § 483.10, we have changed ''may'' to ''must'' in § 483.10(f)(11)(i).
- In § 483.10, we have changed ''health care provider'' to ''physician, physician assistant, nurse practitioner, or clinical nurse specialist'' in § 483.10(f)(11)(ii)(L)(1).
- In § 483.10, we have consolidated proposed § 483.10(f) and (h) and § 483.11(e) into § 483.10(g).
- In § 483.10, we revised proposed § 483.10(g)(2) to include both personal and medical records.
- In § 483.10, we revised § 483.10(g)(2)(ii) to remove the requirement that a resident must inspect a medical record prior to requesting to purchase a copy.

• In § 483.10, we updated § 483.10(g)(3) to exclude from its requirements documents specified in (g)(2) and (g)(11). This reflects that we do not require facilities to translate or summarize personal and medical records and survey reports.

• In § 483.10, we added ''State Survey Agency'' to § 483.10(g)(4)(ii) and added ''any suspected violation of state or federal nursing facility regulations'' to paragraph (g)(4)(vi).

• In § 483.10, we added ''requests for information regarding returning to the community'' to paragraph (g)(5)(ii).

• In § 483.10, we require at paragraph (g)(9)(iii) that electronic communications under this section must comply with state and federal law.

• In § 483.10, we have revised § 483.10(g)(11) to reflect the stricter standard imposed by the statutory language in section 1919(c)(8) of the Act and to better reflect both sections 1819(d) and 1919(d) of the Act, retaining the addition of availability of any plan of correction in effect with respect to facility, as proposed, and including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

• In § 483.10, we have revised paragraph (g)(18)(v) to specify that any admission contract, whether the facility requires it or not, must not conflict with the requirements of these regulations.

• In § 483.10, we have consolidated proposed § 483.10(g) and § 483.11(f) into § 483.10(h), consolidating duplicative language in § 483.10(g)(2) and § 483.11(f)(1)(ii), consolidating proposed § 483.11(f)(1) and (f)(1)(i) into § 483.10(h)(2), and deleting § 483.11(f)(2) as an unnecessary cross-reference.

• In § 483.10, we have consolidated proposed § 483.10(i) and § 483.11(g) into § 483.10(i) ''Safe environment''.

• In § 483.10, we have added a new § 483.10(i)(1)(ii) to require that the facility exercise reasonable care for the protection of the resident's property from loss or theft.

• In § 483.10, we have consolidated proposed § 483.10(j) and § 483.11(h) into § 483.10(k).

• In § 483.10, we have revised § 483.10(j)(1) by adding ''the behavior of staff and of other residents; and other concerns regarding their LTC facility stay'' to the statement regarding what grievances may include.

• In § 483.10, we finalize, as proposed, § 483.11(i) at § 483.10(k).

• In § 483.12, we revised paragraphs (a)(3)(i), (ii), and (iii) to include ''exploitation.''

• In § 483.12(a)(3)(iii) we have revised the paragraph to read ''. . . Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, . . .''

• In § 483.12, we revised paragraph (b)(5)(i)(B) to read ''Each covered individual shall report immediately, but not later than 2 hours. . .''

• In § 483.12, we corrected paragraph (c)(4) to read ''Report the results of all investigations to the administrator or his or her designated representative and . . .''

• In § 483.15, we have withdrawn our proposal to rename § 483.15, ''Transitions of Care'' and add introductory language, and retain the current title ''Admission, transfer, and discharge rights'' without the introductory language.

• In § 483.15, we correct references to ''clinical record'' to ''medical record.''

• In § 483.15, we revised paragraph (a)(6) to require that a facility disclose and provide to a resident or potential resident, prior to admission, notice of special characteristics or service limitations of the facility.

• In § 483.15, we re-designated proposed paragraph (b)(1) as paragraph (b), and added a cross—reference to the definition of transfer and discharge in § 483.5 and a cross—reference to resident rights at § 483.10(a)(2).

• In § 483.15, we re-designated proposed (b) ''Transfer and discharge'' as (c), and renumbered paragraphs (c)(1)(ii) through (iii) to (c)(1)(i) through (ii).

• In § 483.15(c)(1)(i)(E), we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third-party payment or after the third-party payor denies the claim and the resident refuses to pay for his or her stay.

• In § 483.15, we have clarified that paragraph (c)(1)(ii) applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose.

• In § 483.15, we revised paragraph (c)(2)(ii) to clarify that the term ''documentation'' refers to the documentation specified in paragraph (2)(i).

• In § 483.15, we revised paragraph (c)(2)(iii) to reflect a more flexible list of elements to be documented in the resident's clinical record and communicated to the receiving health care institution or provider. The documentation must include: Contact information of the practitioner responsible for the care of the resident, resident representative information including contact information, advance directive information, all special instructions or precautions for ongoing care, as appropriate, the resident's comprehensive care plan goals, and all other necessary information, including a copy of the residents discharge summary, consistent with § 483.21(c)(2) as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

• In § 483.15, we removed the requirement for resident consent in paragraph (c)(3).

• In § 483.15, we revised paragraph (c)(5)(iii) to remove the phrase ''expected to be.''

• In § 483.15, we revised paragraph (c)(5)(iv) to require the discharge notice to include a statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request; and expanded paragraphs (vi) and (vii) to include individuals with related disabilities.

• In § 483.15, we revised paragraph (c)(8) by removing ''of the residents or other responsible parties.''

• In § 483.15, we revised ''readmissions'' to ''returns'' in paragraphs (d) and (e).

• In § 483.15, we revised proposed paragraph (c)(3) as paragraph (e). Paragraph (e)(1) is revised to state that ''a facility must establish . . .'' and (e)(1)(i)(B) is revised to read ''Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services'' and revised proposed paragraph (c)(3)(ii) as (e)(2)(ii) to state that if the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

• In § 483.20 we have removed the reference to ''direct access staff'' at paragraph (b)(1)(xviii).

• In § 483.21, we have clarified that the facility must implement the baseline care plan at paragraph (a).

• In § 483.21 we have added a requirement for facilities to provide residents and their representatives with a summary of their baseline care plan.

• In § 483.21, we have clarified that the facility must implement the comprehensive person-centered care plan at paragraph (b).

• In § 483.21, we have replaced the word ''timetables'' with ''timeframe'' at paragraph (b)(1).

• In § 483.21 we have removed the requirement at paragraph (b)(2)(E) for a social worker to participate on the IDT.

• In § 483.21 we have added at paragraph (c)(1) that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable. We have also removed the reference to ''post-SNF care'' to clarify that the discharge planning process applies to both SNFs and NFs.

• In § 483.21 we have removed the language ''his or her family'' at paragraph (c)(2)(iv) and replaced it with ''the resident representative (s).''In § 483.24, we have established § 483.24, ''Quality of life'', which contains proposed § 483.35(a), (b), and (c) re-designated as § 483.24(a), (b), and (c), respectively, and revised the introductory language to clarify that quality of life applies to all care and services provided to facility residents.

• In § 483.24, we have added an introductory statement to new paragraph § 483.24(b)

• In § 483.24, paragraph (b)(2), we have added the word ''walking.''

• In § 483.24, we have added ''related physician orders'' to paragraph (a)(3) regarding the provision of basic life support.

• In § 483.25, we have revised the title to read ''Quality of care,'' eliminated the modifier ''special care issues,'' revised the introductory to clarify that quality of care applies to all care and services provided by the facility, and re-designated proposed § 483.25(d)(3) through (5) as § 483.25(a) through (c), proposed § 483.25(d)(6) through (9) as § 483.25(e) through (h), proposed § 483.25(10) as § 483.25(d), and proposed § 483.25(d)(11) through (15) as § 483.25(i) through (m), respectively.

• In § 483.25, we removed paragraph (d)(1) relating to restraints and relocated the provision to § 483.12(a)(2).

• In § 483.25, we have re-designated proposed paragraph (2) bed rails as paragraph § 483.25(n), added an appropriateness qualifier to the regulatory text and reworded the provision about the bed's dimension for clarity.

• In § 483.25, we have re-designated paragraph (d)(6)(ii)(C) as (e)(2)(iii) and revised it to state ''restore continence to the extent possible.''

• In § 483.25, we have added language to § 483.25(f), (h), (i), (j), (k), and (l) to require that care be provided consistent with professional standards of practice applicable to that care as well as the comprehensive person-centered care plan, and the residents' goals and preferences.

• In § 483.25(g)(1), we have eliminated the reference to protein levels as a nutritional parameter and add reference to electrolyte balance.

• In § 483.30, we have withdrawn proposed § 483.30(e) and withdrawn our proposal to re-designate paragraphs (e) and (f) as paragraphs (f) and (g).

• In § 483.30, we have modified the regulatory text at § 483.30(e)(2) and § 483.30(e)(3), respectively, to specify that it is the attending physician who has the authority to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders, to the extent that these professionals are permitted to perform these tasks under state law.

• In § 483.45, we have add paragraph (c)(5) to require LTC facilities to develop and maintain policies and procedures for the monthly DRR, which include but are not limited to, timeframes for the various steps in the process and procedures a pharmacist must take when he or she believes immediate action is required to protect the resident.

• In § 483.45(c)(3), we have modified the definition of ''psychotropic drugs'' by removing paragraphs (v) and (vi).

• In § 483.45(e)(4), we have modified the limitation for PRN prescriptions of psychotropic drugs by extending the time for PRN prescriptions to 14 days.

• In § 483.45(e)(5), we have added a specific limitation of 14 days for PRN prescriptions for anti-psychotic drugs.

• In § 483.55 Dental Services, we have modified proposed paragraphs (a)(3) and (a)(5) relating to dental services in SNFs and proposed paragraphs (b)(3) and (b)(4) to specify that both SNFs and NFs must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility and must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

• In § 483.60, we have modified our definition of qualified dietitian or other clinically qualified nutrition professional at § 483.60(a)(1) to more closely align with statutory requirements.

• In § 483.60, we have clarified that an associate's or higher degree in hospitality must include food service or restaurant management in order to be accepted as an option for food services managers' qualifications in paragraph (2)(i)(D).

• In § 483.60, in paragraph (c)(1), we deleted the term ''industry standards'' from our proposal that menus must meet the nutritional needs of residents in accordance with established national guidelines.

• In § 483.60, in paragraph (d)(5), we have replaced the terms ''substitutes'' and ''alternative'' with the terms ''options'' and ''different meal choice.''

• In § 483.60, in paragraph (f)(2), we have withdrawn our proposal to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

• In § 483.65 we are removing the requirement at paragraph (a)(2) for outside resources to be Medicare and/or Medicaid providers of specialized rehabilitative services.

• In § 483.67, outpatient rehabilitative services, we are removing this section in its entirety.

• In § 483.70, we have added 45 CFR part 92 to the regulations specifically referenced in § 483.70(c) ''Relationship to other HHS regulations.''

• In § 483.70(d), we have withdrawn our proposal to delete the phrase ''where licensing is required'' from § 483.70(d)(2)(i).

• In § 483.70(n), we have modified paragraph (1) to prohibit the use of pre-dispute agreements for binding arbitration between any resident or their representative and the facility and allow post-dispute agreements for binding arbitration, if the facility complies with the requirements in this section.

• In § 483.75, we have modified paragraph (a)(2) to mirror the statutory language to indicate that the facility must present its QAPI plan to the State Survey Agency surveyor not later than one year after the date the regulation is issued.

• In § 483.75, we have moved the language at paragraphs (h)(2)(i) and (ii) regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated proposed paragraph (h)(2)(iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.''

• In § 483.75, we have added the term ''information'' in paragraphs (c)(2) and (f)(4).

• In § 483.75, we eliminated the parenthetical examples in paragraph (d)(2)(i).

• In § 483.75, in paragraph (e)(3), we have referenced performance improvement activities in the context of our PIP requirement.

• In § 483.80, we have modified paragraph (a)(1) by changing the reference from § 483.75(e) to § 483.70(e).

• In § 483.80, we have modified paragraph (a)(2)(iv) by inserting after, ''[w]hen and how isolation should be used for a resident,'' the following language, ''including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) a requirement that the isolation should be the least restrictive possible for the resident under the circumstances.''

• In § 483.80, we have modified paragraph (b) to change the infection prevention and control officer (IPCO) to an infection preventionist (IP).

• In § 483.80, we have modified paragraph (b) to allow LTC facilities to designate more than one IP.

• In § 483.80, we have modified paragraphs (b) to establish that IPs must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; be qualified by education, training, experience or certification; work at least part-time at the facility; and have completed specialized training in infection prevention and control.

• In 483.80, we have modified paragraph (b) by removing the requirement that the IPCP be a major responsibility for the IP.

• In § 483.90, we have modified our proposal at paragraph (e) to require that, for facilities that receive approval of construction or are newly certified after the effective date of this final rule, each resident room must have its own bathroom with at least a commode and a sink.

• In § 483.90, we have modified our proposal at paragraph (h)(5) to state that facilities must establish policies in accordance with applicable federal, state, and local laws and regulations regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

• In § 483.95 we have added a new requirement at paragraph (c)(3) that all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, receive dementia management and abuse prevention training consistent with their expected roles.

• Throughout the regulation, we have removed references to ''direct access'' staff, workers, or personnel.

Technical Corrections

In addition to the substantive revisions listed above we have also identified a few technical errors that were inadvertently made in the proposed. We identify the errors below and have made the corrections in the regulatory text.

• We have made conforming changes to revise cross-references to part 483 in title 42 found in § 488.301, § 489.52, and § 489.55 that were inadvertently not included in the proposed rule.

• We have modified the term ''mental illness'' by changing it to ''mental disorder'' throughout this rule to be consistent with current terminology.

IV. Long-Term Care Facilities Crosswalk

The table below shows the cross-references between the current sections to the proposed. We also note that we have made conforming changes that would revise any cross-references to part 483 in title 42 that change due to the reorganization of subpart B in this final rule.

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B

Existing CFR section	Title	Action	New CFR section
§ 483.1	Basis and Scope (a)	Revised	§ 483.1.
§ 483.5(a)–(c)	(a) *Facility defined* (b) *Distinct part* (c) *Composite distinct part*	Re-designated	§ 483.5 in alphabetical order.
§ 483.5(d)	(d) *Common area*	Re-designated & revised	§ 483.5 in alphabetical order.
§ 483.5(e)	(e) *Fully sprinklered* (f) *Major modification*	Re-designated	§ 483.5 in alphabetical order.
§ 483.10	Resident rights	Revised	§ 483.10.
§ 483.10(a)(1)	(a) *Exercise of rights*	No change	§ 483.10(b)(2).
§ 483.10(a)(2)	(a) *Exercise of rights*	Revised	§ 483.10(b)(2).
§ 483.10(a)(3)		Re-designated and revised	§ 483.10(b)(7).
§ 483.10(a)(4)		Re-designated and revised	§ 483.10(b)(3).
§ 483.10(b)(1)	(b) *Notice of rights and services*	Re-designated & revised	§ 483.10(g)(16).
§ 483.10(b)(2)		Re-designated & revised	§ 483.10(g)(2).
§ 483.10(b)(3)		Re-designated	§ 483.10(c)(1).
§ 483.10(b)(4)		Revised	§ 483.10(c)(6).
§ 483.10(b)(5)		Re-designated & revised	§ 483.10(g)(17).
§ 483.10(b)(6)		Re-designated & revised	§ 483.10(g)(18).
§ 483.10(b)(7)		Re-designated & revised	§ 483.10(g)(4)(i).
§ 483.10(b)(8)		Re-designated & revised	§ 483.10(g)(5)(i)–(v).
§ 483.10(b)(9)		Re-designated & revised	§ 483.10(d)(3).
§ 483.10(b)(10)		Re-designated & revised	§ 483.10(g)(13).
§ 483.10(b)(11)		Re-designated & revised	§ 483.10(g)(14).
§ 483.10(b)(12)		Re-designated	§ 483.10(g)(15).
§ 483.10(c)(1)	(c) *Protection of resident funds*	Re-designated & revised	§ 483.10(f)(10), § 483.10(f)(10)(i).
§ 483.10(c)(2)		Re-designated	§ 483.10(f)(10)(i).
§ 483.10(c)(3)		Re-designated & revised	§ 483.10(f)(10)(ii).
§ 483.10(c)(4)		Re-designated	§ 483.10(f)(10)(B)(iii)(A).
§ 483.10(c)(5)		Re-designated	§ 483.10(f)(10)(B)(iv).
§ 483.10(c)(6)		Re-designated & revised	§ 483.10(f)(10)(B)(v).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.10(c)(7)		Re-designated	§ 483.10(f)(10)(B)(vi).
§ 483.10(c)(8)		Re-designated & revised	§ 483.10(f)(11).
§ 483.10(d)	(d) *Free choice*	Re-designated & revised	§ 483.10(d).
§ 483.10(d)(1)		Re-designated & revised	§ 483.10(d).
§ 483.10(d)(2)		Re-designated & revised	§ 483.10(c).
§ 483.10(d)(3)		Re-designated & revised	§ 483.10(b)(7)(iii), § 483.10(c)(2).
§ 483.10(e)	(e) *Privacy and confidentiality*	Re-designated & revised	§ 483.10(h).
§ 483.10(e)(1)		Re-designated	§ 483.10(h)(1).
§ 483.10(e)(2)		Re-designated & revised	§ 483.10(h)(3)(i).
§ 483.10(e)(3)		Re-designated & revised	§ 483.10(h)(3)(i).
§ 483.10(e)(3)(i)		Re-designated & revised	§ 483.10(h)(3)(i).
§ 483.10(e)(3)(ii)		Re-designated & revised	§ 483.10(h)(3)(i).
§ 483.10(f)	(f) *Grievances*	Re-designated & revised	§ 483.10(j).
§ 483.10(f)(1)		Re-designated & revised	§ 483.10(j)(1).
§ 483.10(f)(2)		Re-designated & revised	§ 483.10(j)(2).
§ 483.10(g)	(g) *Examination of survey results*	Re-designated	§ 483.10(g)(10).
§ 483.10(g)(1)		Re-designated & revised	§ 483.10(g)(10)(i), § 483.10(g)(11)(ii).
§ 483.10(g)(2)		Re-designated	§ 483.10(g)(10)(ii).
§ 483.10(h)	(h) *Work*	Re-designated & revised	§ 483.10(f)(9).
§ 483.10(h)(1)		Re-designated & revised	§ 483.10(f)(9).
§ 483.10(h)(2)		Re-designated & revised	§ 483.10(f)(9), § 483.10(f)(9).
§ 483.10(h)(2)(i)–(iv)		Re-designated	§ 483.10(f)(9)(i)–(iv).
§ 483.10(i)	(i) *Mail*	Re-designated & revised	§ 483.10(h) &.
§ 483.10(i)(1)		Re-designated & revised	§ 483.10(h)(2), § 483.10(h)(2).
§ 483.10(i)(2)		Re-designated & revised	§ 483.10(g)(8)(ii), § 483.10(g)(8)(ii).
§ 483.10(j)(1)	(j) *Access and visitation rights*	Re-designated & revised	§ 483.10(f)(4), § 483.10(f)(4).
§ 483.10(j)(1)(i)–(vi)		Re-designated & revised	§ 483.10(f)(4)(i)(A)–(F).
§ 483.10(j)(1)(vii)		Re-designated & revised	§ 483.10(f)(4)(ii).
§ 483.10(j)(1)(viii)		Re-designated & revised	§ 483.10(f)(4)(iii).
§ 483.10(j)(2)		Re-designated	§ 483.10(f)(4)(iv).
§ 483.10(j)(3)		Re-designated & revised	§ 483.10(h)(3)(ii).
§ 483.10(k)	(k) *Telephone*	Re-designated & revised	§ 483.10(g)(6).
§ 483.10(l)	(l) *Personal property*	Re-designated & revised	§ 483.10(e)(2).
§ 483.10(m)	(m) *Married couples*	Re-designated	§ 483.10(e)(4).
§ 483.10(n)	(n) *Self-Administration of Drugs*	Re-designated & revised	§ 483.10(c)(7).
§ 483.10(o)(1)–(2)	(o) *Refusal of certain transfers*	Re-designated & revised	§ 483.10(e)(7)(i)–(ii), 483.10(e)(7)(i)–(ii).
§ 483.12(a)	Admission, transfer and discharge rights (a) *Transfer and discharge.*	Re-designated & revised	§ 483.15(c).
§ 483.12(a)(1)	(1) *Definition:*	Re-designated	§ 483.5.
§ 483.12(a)(2)		Re-designated & revised	§ 483.15(c)(1)(ii).
§ 483.12(a)(2)(i)–(vi)		Re-designated & revised	§ 483.15(c)(1)(i)(A)–(F).
§ 483.12(a)(3)		Re-designated & revised	§ 483.15(c)(2).
§ 483.12(a)(3)(i)		Re-designated & revised	§ 483.15(c)(2)(ii)(A).
§ 483.12(a)(3)(ii)		Re-designated & revised	§ 483.15(c)(2)(ii)(B).
§ 483.12(a)(4)(i)–(iii)		Re-designated & revised	§ 483.15(c)(3)(i)–(iii).
§ 483.12(a)(5)(i)		Re-designated & revised	§ 483.15(c)(4).
§ 483.12(a)(5)(ii)(A)–(E).		Re-designated & revised	§ 483.15(c)(4)(ii)(A)–(E).
§ 483.12(a)(6)(i)–(vii)		Re-designated & revised	§ 483.15(c)(5)(i)–(vii).
§ 483.12(a)(7)		Re-designated & revised	§ 483.15(c)(7).
§ 483.12(a)(8)		Re-designated & revised	§ 483.15(c)(8).
§ 483.12(a)(9)		Re-designated & revised	§ 483.15(c)(9).
§ 483.12(b)(1)(i)–(ii)	(b) *Notice of bed-hold policy and re-admission.*	Re-designated & revised	§ 483.15(d)(1)(i)–(iii).
§ 483.12(b)(2)		Re-designated & revised	§ 483.15(d)(2).
§ 483.12(b)(3)(i)–(ii)		Re-designated	§ 483.15(e)(1)(i)(A)–(B).
§ 483.12(b)(4)		Re-designated & revised	§ 483.15(e)(2).
§ 483.12(c)(1)	(c) *Equal access to quality care*	Re-designated & revised	§ 483.15(b)(1).
§ 483.12(c)(2)		Re-designated & revised	§ 483.15(b)(2).
§ 483.12(c)(3)		Re-designated	§ 483.15(b)(3).
§ 483.12(d)(1) (i)–(ii)	(d) *Admissions policy*	Re-designated & revised	§ 483.15(a)(2)(i)–(ii).
§ 483.12(d)(2)		Re-designated & revised	§ 483.15(a)(3).
§ 483.12(d)(3) (i)–(ii)		Re-designated	§ 483.15(a)(4)(i)–(ii).
§ 483.12(d)(4)		Re-designated	§ 483.15(a)(5).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.13(a)	Resident behavior and facility practices. (a) *Restraints.*	Re-designated & revised	§ 483.10(e), § 483.12, § 483.25(d)(1).
§ 483.13(b)	(b) *Abuse*	Re-designated & revised	§ 483.12.
§ 483.13(c)	(c) *Staff treatment of residents*	Re-designated & revised	§ 483.12(b).
§ 483.13(c)(1)		Re-designated	§ 483.12(a).
§ 483.13(c)(1)(i)		Re-designated	§ 483.12(a)(1).
§ 483.13(c)(1)(ii)		Re-designated & revised	§ 483.12(a)(3).
§ 483.13(c)(1)(ii)(A)		Re-designated & revised	§ 483.12(a)(3)(i).
§ 483.13(c)(1)(ii)(B)		Re-designated & revised	§ 483.12(a)(3)(ii).
§ 483.13(c)(1)(iii)		Re-designated & revised	§ 483.12(a)(4).
§ 483.13(c)(2)		Re-designated & revised	§ 483.12(c)(1).
§ 483.13(c)(3)		Re-designated & revised	§ 483.12(c)(2)–(3).
§ 483.13(c)(4)		Re-designated & revised	§ 483.12(c)(4).
§ 483.15	Quality of life	Re-designated & revised	§ 483.24.
§ 483.15(a)	(a) *Dignity*	Re-designated & revised	§ 483.24.
§ 483.15(b)	(b) *Self-determination and participation.*	Re-designated & revised	§ 483.10(f), § 483.10(f).
§ 483.15(b)(1)		Re-designated & revised	§ 483.10(f)(1).
§ 483.15(b)(2)		Re-designated & revised	§ 483.10(f)(3).
§ 483.15(b)(3)		Re-designated	§ 483.10(f)(2).
§ 483.15(c)(1)	(c) *Participation in resident and family groups* groups.	Re-designated & revised	§ 483.10(f)(5).
§ 483.15(c)(2)		Re-designated & revised	§ 483.10(f)(6)–(7).
§ 483.15(c)(3)		Re-designated	§ 483.10(f)(5)(i)).
§ 483.15(c)(4)–(6)		Re-designated & revised	§ 483.10(f)(5)(ii)–(iv).
§ 483.15(d)	(d) *Participation in other activities*	Re-designated& revised	§ 483.10(f)(8).
§ 483.15(e)	(e) *Accommodation of needs*	Re-designated & revised	§ 483.10(e).
§ 483.15(e)(1)		Re-designated & revised	§ 483.10(e)(3).
§ 483.15(e)(2)		Re-designated & revised	§ 483.10(e)(6).
§ 483.15(f)(1)	(f) *Activities*	Re-designated & revised	§ 483.24(c)(1).
§ 483.15(f)(2)		Re-designated & revised	§ 483.24(c)(2).
§ 483.15(f)(2)(i)		Re-designated & revised	§ 483.24(c)(2).
§ 483.15(f)(2)(i)(A)		Re-designated	§ 483.24(c)(2)(i).
§ 483.15(f)(2)(i)(B)		Re-designated & revised	§ 483.24(c)(2)(ii)(A).
§ 483.15 (f)(2)(ii)–(iv)		Re-designated & revised	§ 483.24(c)(2)(ii)(B)–(D).
§ 483.15(g)(1)	(g) *Social Services*	Re-designated & revised	§ 483.40(d).
§ 483.15(g)(2)		Re-designated & revised	§ 483.70(p).
§ 483.15(g)(3)(i)–(ii)	(3) *Qualifications of social worker*	Re-designated & revised	§ 483.70(p)(1)–(2).
§ 483.15(h)	(h) *Environment*	Re-designated & revised	§ 483.10(i).
§ 483.15(h)(1)		Re-designated & revised	§ 483.10(i)(1).
§ 483.15(h)(2)		Re-designated	§ 483.10(i)(2).
§ 483.15(h)(3)		Re-designated	§ 483.10(i)(3).
§ 483.15(h)(4)		Re-designated & revised	§ 483.10(i)(4).
§ 483.15(h)(5)		Re-designated	§ 483.10(i)(5).
§ 483.15(h)(6)		Re-designated	§ 483.10(i)(6).
§ 483.15(h)(7)		Re-designated	§ 483.10(i)(7).
§ 483.20	Resident Assessment	No change	§ 483.20.
§ 483.20(a)	(a) *Admission orders*	No change	§ 483.20(a).
§ 483.20(b)	(b) *Comprehensive assessments*—(1) *Resident assessment instrument.*	Revised	§ 483.20(b).
§ 483.20(c)–(d)	(c) *Quarterly review assessment* (d) *Use*	No change	§ 483.20(c)–(d).
§ 483.20(e)	(e) *Coordination*	Revised	§ 483.20(e).
§ 483.20(f)–(j)	(f) *Automated data processing requirement.* (g) *Accuracy of assessments* (h) *Coordination* (i) *Certification* (j) *Penalty for falsification*	No change	§ 483.20(f)–(j).
§ 483.20(k)(1)	(k) *Comprehensive care plans*	Re-designated & revised	§ 483.21(b)(1).
§ 483.20(k)(2)		Re-designated	§ 483.21(b)(2).
§ 483.20(k)(2)(i)		Re-designated	§ 483.21(b)(2)(i).
§ 483.20(k)(2)(ii)		Re-designated & revised	§ 483.21(b)(2)(ii)(A)–(F).
§ 483.20(k)(2)(iii)		Re-designated & revised	§ 483.21(b)(2)(iii).
§ 483.20(k)(3)(i)–(ii)		Re-designated	§ 483.21(b)(3)(i)–(ii).
§ 483.20(l)	(l) *Discharge summary*	Re-designated & revised	§ 483.21(c)(2).
§ 483.20(l)(1)		Re-designated & revised	§ 483.21(c)(2)(i).
§ 483.20(l)(2)		Re-designated & revised	§ 483.21(c)(2)(ii).
§ 483.20(l)(3)		Re-designated & revised	§ 483.21(c)(2)(iv).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.20(m)	(m) *Preadmission screening for mentally ill individuals and individuals with mental retardation.*	Re-designated	§ 483.20(k)(1).
§ 483.20(m)(1)(i)–(ii)		Re-designated	§ 483.20(k)(1)(i)–(ii).
§ 483.20(m)(2)(i)–(ii)	(2) *Definition.* For purposes of this section—.	Re-designated & revised	§ 483.20(k)(3)(i)–(ii).
§ 483.25	Quality of care	Revised	§ 483.25.
§ 483.25(a)	(a) *Activities of daily living*	Re-designated & revised	§ 483.24(a).
§ 483.25(a)(1)		Re-designated and revised	§ 483.24(a),(b).
§ 483.25(a)(1)(i)		Re-designated and revised	§ 483.24(b)(1).
§ 483.25(a)(1)(ii)		Re-designated and revised	§ 483.24(b)(2).
§ 483.25(a)(1)(iii)		Re-designated and revised	§ 483.24(b)(3).
§ 483.25(a)(1)(iv)		Re-designated and revised	§ 483.24(b)(4).
§ 483.25(a)(1)(v)		Re-designated and revised	§ 483.24(b)(5).
§ 483.25(a)(2)		Re-designated and revised	§ 483.24(a)(1).
§ 483.25(a)(3)		Re-designated	§ 483.24(a)(2).
§ 483.25(b)	(b) *Vision and hearing*	Re-designated	§ 483.25(a).
§ 483.25(b)(1)		Re-designated	§ 483.25(a)(1).
§ 483.25(b)(2)		Re-designated	§ 483.25(a)(2).
§ 483.25(c)	(c) *Pressure sores*	Re-designated & revised	§ 483.25(b)(1).
§ 483.25(c)(1)		Re-designated & revised	§ 483.25(b)(1)(i).
§ 483.25(c)(2)		Re-designated & revised	§ 483.25(b)(1)(ii).
§ 483.25(d)	(d) *Urinary Incontinence*	Re-designated & revised	§ 483.25(e)(2).
§ 483.25(d)(1)		Re-designated	§ 483.25(e)(2)(i).
§ 483.25(d)(2)		Re-designated	§ 483.25(e)(2)(ii).
§ 483.25(e)	(e) *Range of motion*	Re-designated & revised	§ 483.25(c).
§ 483.25(e)(1)		Re-designated	§ 483.25(c)(1).
§ 483.25(e)(2)		Re-designated	§ 483.25(c)(2).
§ 483.25(f)	(f) *Mental and Psychosocial functioning.*	Re-designated & revised	§ 483.40(b).
§ 483.25(f)(1)		Re-designated & revised	§ 483.40(b)(1).
§ 483.25(f)(2)		Re-designated & revised	§ 483.40(b)(2).
§ 483.25(g)	(g) *Naso-gastric tubes*	Re-designated & revised	§ 483.25(g)(4).
§ 483.25(g)(1)		Re-designated & revised	§ 483.25(g)(4).
§ 483.25(g)(2)		Re-designated & revised	§ 483.25(g)(5).
§ 483.25(h)	(h) *Accidents*	Re-designated	§ 483.25(d).
§ 483.25(h)(1)		Re-designated	§ 483.25(d)(1).
§ 483.25(h)(2)		Re-designated	§ 483.25(d)(2).
§ 483.25(i)	(i) *Nutrition*	Re-designated & revised	§ 483.25(g).
§ 483.25(i)(1)		Re-designated & revised	§ 483.25(g)(1).
§ 483.25(i)(2)		Re-designated & revised	§ 483.25(g)(3).
§ 483.25(j)	(j) *Hydration*	Re-designated & revised	§ 483.25(g)(2).
§ 483.25(k)	(k) *Special needs*	Re-designated & revised	§ 483.25(d).
§ 483.25(k)(1)	(1) Injections;	Deleted	
§ 483.25(k)(2)	(2) Parenteral and enteral fluids;	Re-designated & revised	§ 483.25(h).
§ 483.25(k)(3)	(3) Colostomy, ureterostomy, or ileostomy care;.	Re-designated	§ 483.25(f).
§ 483.25(k)(4)	(4) Tracheostomy care;	Re-designated & revised	§ 483.25(i).
§ 483.25(k)(5)	(5) Tracheal suctioning;	Re-designated & revised	§ 483.25(i).
§ 483.25(k)(6)	(6) Respiratory care;	Re-designated & revised	§ 483.25(i).
§ 483.25(k)(7)	(7) Foot care; and	Re-designated & revised	§ 483.25(b)(2).
§ 483.25(k)(8)	(8) Prostheses	Re-designated	§ 483.25(j).
§ 483.25(l)	(l) *Unnecessary drugs*	Re-designated	§ 483.45(d).
§ 483.25(l)(1)(i)–(vi)		Re-designated	§ 483.45(d)(1)–(6).
§ 483.25(l)(2)(i)–(ii)	(2) *Antipsychotic Drugs*	Re-designated & revised	§ 483.45(e)(1)–(2).
§ 483.25(m)(1)–(2)	(m) *Medication Errors*	Re-designated & revised	§ 483.45(f)(1)–(2).
§ 483.25(n)	(n) *Influenza and pneumococcal immunizations.*	Re-designated	§ 483.80(d)(1).
§ 483.25(n)(1)(i)–(iv)		Re-designated & revised	§ 483.80(d)(1)(i)–(iv).
§ 483.25(n)(2)	(2) *Pneumococcal disease*	Re-designated	§ 483.80(d)(2).
§ 483.25(n)(2)(i)–(iv)		Re-designated & revised	§ 483.80(d)(2)(i)–(iv).
§ 483.25(n)(2)(v)	*Exception*	Deleted	
§ 483.30	Nursing services	Re-designated & revised	§ 483.35.
§ 483.30(a)	(a) *Sufficient staff*	Re-designated	§ 483.35(a).
§ 483.30(a)(1)(ii)		Re-designated & revised	§ 483.35(a)(1)(ii).
§ 483.30(a)(2)		Re-designated	§ 483.35(a)(2).
§ 483.30(b)(1)	(b) *Registered nurse*	Re-designated	§ 483.35(b)(1).
§ 483.30(b)(2)		Re-designated	§ 483.35(b)(2).
§ 483.30(b)(3)		Re-designated	§ 483.35(b)(3).
§ 483.30(c)	(c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.*	Re-designated	§ 483.35(e).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.30(c)(1)–(5)		Re-designated	§ 483.35(e)(1)–(5).
§ 483.30(c)(6)		Re-designated & revised	§ 483.35(e)(6).
§ 483.30(c)(7)		Re-designated & revised	§ 483.35(e)(7).
§ 483.30(d)(1)	(d) *SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.*	Re-designated	§ 483.35(f)(1).
§ 483.30(d)(1)(i)		Re-designated	§ 483.35(f)(1)(i).
§ 483.30(d)(1)(ii)		Re-designated	§ 483.35(f)(1)(ii).
§ 483.30(d)(1)(iii)		Re-designated	§ 483.35(f)(1)(iii).
§ 483.30(d)(1)(iii)(A)		Re-designated	§ 483.35(f)(1)(iii)(A).
§ 483.30(d)(1)(iii)(B)		Re-designated	§ 483.35(f)(1)(iii)(B).
§ 483.30(d)(1)(iv)		Re-designated & revised	§ 483.35(f)(1)(iv).
§ 483.30(d)(1)(v)		Re-designated & revised	§ 483.35(f)(1)(v).
§ 483.30(d)(2)		Re-designated	§ 483.35(f)(2).
§ 483.30(e)(1)(i)–(iv)	(e) *Nurse staffing information*	Re-designated	§ 483.35(g)(1)(i)–(iv).
§ 483.30(e)(2)(i)–(ii)		Re-designated	§ 483.35(g)(2)(i)–(ii).
§ 483.30(e)(3)		Re-designated	§ 483.35(g)(3).
§ 483.30(e)(4)		Re-designated	§ 483.35(g)(4).
§ 483.35	Dietary services	Re-designated & revised	§ 483.60.
§ 483.35(a)	(a) *Staffing*	Re-designated & revised	§ 483.60(a)(1).
§ 483.35(a)(1)		Re-designated & revised	§ 483.60(a)(2).
§ 483.35(a)(2)		Re-designated & revised	§ 483.60(a)(1)(i)–(iv).
§ 483.35(b)	(b) *Sufficient staff*	Re-designated & revised	§ 483.60(a)(3).
§ 483.35(c)	(c) *Menus and nutritional adequacy*	Re-designated	§ 483.60(c).
§ 483.35(c)(1)–(3)		Re-designated & revised	§ 483.60(c)(1)–(3).
§ 483.35(d)	(d) *Food*	Re-designated	§ 483.60(d).
§ 483.35(d)(1)		Re-designated	§ 483.60(d)(1).
§ 483.35(d)(2)		Re-designated & revised	§ 483.60(d)(2).
§ 483.35(d)(3)		Re-designated	§ 483.60(d)(3).
§ 483.35(d)(4)		Re-designated & revised	§ 483.60(d)(5).
§ 483.35(e)	(e) *Therapeutic diets*	Re-designated & revised	§ 483.60(e).
§ 483.35(f)(1)	(f) *Frequency of meals*	Re-designated & revised	§ 483.60(f)(1).
§ 483.35(f)(2)		Deleted	
§ 483.35(f)(3)		Re-designated	§ 483.60(f)(3).
§ 483.35(f)(4)		Deleted	
§ 483.35(g)	(g) *Assistive devices*	Re-designated & revised	§ 483.60(g).
§ 483.35(h)(1)	(h) *Paid feeding assistants*	Re-designated	§ 483.60(h)(1).
§ 483.35(h)(1)(i)–(ii)		Re-designated	§ 483.60(h)(1)(i)–(ii).
§ 483.35(h)(2)(i)		Re-designated	§ 483.60(h)(2)(i).
§ 483.35 (h)(2)(ii)		Re-designated & revised	§ 483.60(h)(2)(ii).
§ 483.35(h)(3)(i)–(ii)		Re-designated & revised	§ 483.60(h)(3)(i)–(ii).
§ 483.35(h)(3)(iii)		Re-designated & revised	§ 483.60(h)(3)(iii).
§ 483.35(i)	(i) *Sanitary conditions*	Re-designated & revised	§ 483.60(i).
§ 483.35(i)(1)		Re-designated & revised	§ 483.60(i)(1).
§ 483.35(i)(2)		Re-designated & revised	§ 483.60(i)(2).
§ 483.35(i)(3)		Re-designated	§ 483.60(i)(4).
§ 483.40	Physician services	Re-designated & revised	§ 483.30.
§ 483.40(a)	(a) *Physician supervision*	Re-designated	§ 483.30(a).
§ 483.40(a)(1)–(2)		Re-designated	§ 483.30(a)(1)–(2).
§ 483.40(b)	(b) *Physician visits*	Re-designated	§ 483.30(b).
§ 483.40(b)(1)		Re-designated	§ 483.30(b)(1).
§ 483.40(b)(2)		Re-designated	§ 483.30(b)(2).
§ 483.40(b)(3)		Re-designated & revised	§ 483.30(b)(3).
§ 483.40(c)(1)–(4)	(c) *Frequency of physician visits*	Re-designated	§ 483.30(c)(1)–(4).
§ 483.40(d)	(d) *Availability of physicians for emergency care.*	Re-designated	§ 483.30(d).
§ 483.40(e)(1)	(e) *Physician delegation of tasks in SNFs.*	Re-designated	§ 483.30(f)(1).
§ 483.40(e)(1)(i)–(iii)		Re-designated	§ 483.30(f)(1)(i)–(iii).
§ 483.40(e)(2)		Re-designated	§ 483.30(f)(4).
§ 483.40(f)	(f) *Performance of physician tasks in NFs.*	Re-designated	§ 483.30(g).
§ 483.45	Specialized rehabilitative services	Re-designated & revised	§ 483.65(a).
	(a) *Provision of services*		
§ 483.45(a)(1)–(2)		Re-designated & revised	§ 483.65(a)(1)–(2).
§ 483.45(b)	(b) *Qualifications*	Re-designated	§ 483.65(b).
§ 483.55	Dental services	No change	§ 483.55.
§ 483.55(a)(1)	(a) *Skilled nursing facilities*	Re-designated	§ 483.55(a)(1).
§ 483.55(a)(2)		Re-designated	§ 483.55(a)(2).
§ 483.55(a)(3)		Re-designated	§ 483.55(a)(4).
§ 483.55(a)(3)(i)		Re-designated	§ 483.55(a)(4)(i).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.55(a)(3)(ii)		Re-designated & revised	§ 483.55(a)(4)(ii).
§ 483.55(a)(4)		Re-designated & revised	§ 483.55(a)(5).
§ 483.55(b)	(b) *Nursing facilities*	Re-designated	§ 483.55(b).
§ 483.55(b)(1)(i)–(ii)		Re-designated& revised	§ 483.55(b)(1)(i)–(ii).
§ 483.55(b)(2)		Re-designated & revised	§ 483.55(b).
§ 483.55(b)(2)(i)–(ii)		Re-designated & revised	§ 483.55(b)(2)(i)–(ii).
§ 483.55(b)(3)		Re-designated & revised	§ 483.55(b)(3).
§ 483.60	Pharmacy services	Re-designated & revised	§ 483.45.
§ 483.60(a)	(a) *Procedures*	Re-designated	§ 483.45(a).
§ 483.60(b)	(b) *Service consultation*	Re-designated	§ 483.45(b).
§ 483.60(b)(1)–(3)		Re-designated	§ 483.45(b)(1)–(3).
§ 483.60(c)(1)	(c) *Drug regimen review*	Re-designated	§ 483.45(c)(1).
§ 483.60(c)(2)		Re-designated & revised	§ 483.45(c)(4).
§ 483.60(d)	(d) *Labeling of drugs and biologicals*	Re-designated	§ 483.45(g).
§ 483.60(e)(1–(2)	(e) *Storage of drugs and biologicals*	Re-designated	§ 483.45(h)(1)–(2).
§ 483.65	Infection control	Re-designated & revised	§ 483.80.
§ 483.65(a)(1)–(3)	(a) *Infection control program*	Re-designated & revised	§ 483.80(a)(1)–(3).
§ 483.65(b)(1)	(b) *Preventing spread of infection*	Re-designated & revised	§ 483.80(a)(2)(iv).
§ 483.65(b)(2)		Re-designated & revised	§ 483.80(a)(2)(v).
§ 483.65(b)(3)		Re-designated & revised	§ 483.80(a)(2)(vi).
§ 483.65(c)	(c) *Linens*	Re-designated	§ 483.80(e).
§ 483.70	Physical environment	Re-designated	§ 483.90.
§ 483.70(a)(1)–(8)	(a) *Life safety from fire*	Re-designated	§ 483.90(a)(1)–(8).
§ 483.70(b)(1)–(2)	(b) *Emergency power*	Re-designated	§ 483.90(b)(1)–(2).
§ 483.70(c)(1)–(2)	(c) *Space and equipment*	Re-designated & revised	§ 483.90(c)(1)–(2).
§ 483.70(d)	(d) *Resident rooms*	Re-designated	§ 483.90(d).
§ 483.70(d)(1)		Re-designated	§ 483.90(d)(1).
§ 483.70(d)(1)(i)		Re-designated & revised	§ 483.90(d)(1)(i).
§ 483.70(d)(1)(ii)–(vii).		Re-designated	§ 483.90(d)(1)(ii)–(vii).
§ 483.70(d)(2)		Re-designated	§ 483.90(d)(2).
§ 483.70(d)(2)(i)		Re-designated & revised	§ 483.90(d)(2)(i).
§ 483.70(d)(2)(ii)–(iv)		Re-designated	§ 483.90(d)(2)(ii)–(iv).
§ 483.70(d)(3)(i)–(ii)		Re-designated	§ 483.90(d)(3)(i)–(ii).
§ 483.70(e)	(e) *Toilet facilities*	Re-designated & revised	§ 483.90(e).
§ 483.70(f)(1)	(f) *Resident call system*	Re-designated & revised	§ 483.90(f)(1).
§ 483.70(f)(2)	(f) Resident call system	Re-designated	§ 483.90(f)(2).
§ 483.70(g)(1)	(g) *Dining and resident activities*	Re-designated	§ 483.90(g)(1).
§ 483.70(g)(2)		Re-designated & revised	§ 483.90(g)(2).
§ 483.70(g)(3)–(4)		Re-designated	§ 483.90(g)(3)–(4).
§ 483.70(h)(1)–(4)	(h) *Other environmental conditions*	Re-designated	§ 483.90(h)(1)–(4).
§ 483.75	Administration	Re-designated	§ 483.70.
§ 483.75(a)	(a) *Licensure*	Re-designated	§ 483.70(a).
§ 483.75(b)	(b) *Compliance with Federal, State, and local laws and professional standards.*	Re-designated	§ 483.70(b).
§ 483.75(c)	(c) *Relationship to other HHS regulations.*	Re-designated & revised	§ 483.70(c).
§ 483.75(d)(1)	(d) *Governing body*	Re-designated	§ 483.70(d)(1).
§ 483.75(d)(2)(i)–(ii)		Re-designated & revised	§ 483.70(d)(2)(i)–(ii).
§ 483.75(e)	(e) *Required training of nursing aides.*	Re-designated & revised	§ 483.95(g).
§ 483.75(e)(1)	(1) *Definitions. Licensed health professional.*	Re-designated & revised	§ 483.5.
§ 483.75(e)(1)	*Nurse aide*	Re-designated & revised	§ 483.5.
§ 483.75(e)(2)(i)–(ii)	(2) *General rule*	Re-designated & revised	§ 483.35(d)(1)(i)–(ii).
§ 483.75(e)(3)	(3) *Non-permanent employees*	Re-designated & revised	§ 483.35(d)(2).
§ 483.75(e)(4)(i)–(iii)	(4) *Competency*	Re-designated	§ 483.35(d)(3)(i)–(iii).
§ 483.75(e)(5)(i)–(ii)	(5) *Registry verification*	Re-designated	§ 483.35(d)(4)(i)–(ii).
§ 483.75(e)(6)	(6) *Multi-State registry verification*	Re-designated & revised	§ 483.35(d)(5).
§ 483.75(e)(7)	(7) *Required retraining*	Re-designated	§ 483.35(d)(6).
§ 483.75(e)(8)(i)–(iii)	(8) *Regular in-service education*	Re-designated & revised	§ 483.35(d)(7), § 483.95(g).
§ 483.75(f)	(f) *Proficiency of Nurse aides*	Re-designated	§ 483.35(c).
§ 483.75(g)(1)	(g) *Staff qualifications*	Re-designated	§ 483.70(f)(1).
§ 483.75(g)(2)		Re-designated	§ 483.70(f)(2).
§ 483.75(h)(1)	(h) *Use of outside resources*	Re-designated	§ 483.70(g)(1).
§ 483.75(h)(2)(i)–(ii)		Re-designated	§ 483.70(g)(2)(i)–(ii).
§ 483.75(i)(1)	(i) *Medical director*	Re-designated	§ 483.70(h)(1).
§ 483.75(i)(2)(i–ii)		Re-designated	§ 483.70(h)(2)(i)–(ii).
§ 483.75(j)(1)(i)–(iv)	(j) *Laboratory services*	Re-designated	§ 483.50(a)(1)(i)–(iv).
§ 483.75(j)(2)		Re-designated	§ 483.50(a)(2).

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR section	Title	Action	New CFR section
§ 483.75(j)(2)(i)–(iv)		Re-designated & Revised	§ 483.50(a)(2)(i)–(iv).
§ 483.75(k)	(k) *Radiology and other diagnostic services.*	Re-designated	§ 483.50(b).
§ 483.75(k)(1)		Re-designated	§ 483.50(b)(1).
§ 483.75(k)(2)		Re-designated & revised	§ 483.50(b)(2).
§ 483.75(l)(1)	(l) *Clinical records*	Re-designated & revised	§ 483.70(i)(1).
§ 483.75(l)(1)(i)–(iv)		Re-designated & revised	§ 483.70(i)(1)(i)–(iv).
§ 483.75(l)(2)		Re-designated & revised	§ 483.70(i)(4).
§ 483.75(l)(2)(i)		Re-designated	§ 483.70(i)(4)(i).
§ 483.75(l)(2)(ii)		Re-designated	§ 483.70(i)(4)(ii).
§ 483.75(l)(2)(iii)		Re-designated	§ 483.70(i)(4)(iii).
§ 483.75(l)(3)		Re-designated & revised	§ 483.70(i)(3).
§ 483.75(l)(4)(i)–(iv)		Re-designated & revised	§ 483.70(i)(2).
§ 483.75(l)(5)(i)–(v)		Re-designated & revised	§ 483.70(i)(5)(i)–(v).
§ 483.75(m)(1)	(m) *Disaster and emergency preparedness.*	*See Proposed Rule:* Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 FR 79081, December 27, 2013).	See 78 FR 79081.
§ 483.75(m)(2)		*See Proposed Rule:* Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 FR 79081, December 27, 2013).	See 78 FR 79081.
§ 483.75(n)(1)(i)–(ii)	(n) *Transfer agreement*	Re-designated & revised	§ 483.70(j)(1)(i)–(ii).
§ 483.75(n)(2)		Re-designated	§ 483.70(j)(2).
§ 483.75(o)(1)(i)–(iii)	(o) *Quality assessment and assurance.*	Re-designated & revised	§ 483.75(g)(1)(i)–(iv).
§ 483.75(o)(2)(i)–(ii)		Re-designated & revised	§ 483.75(g)(2)(i)–(iii).
§ 483.75(o)(3)		Re-designated & revised	§ 483.75(h)(1).
§ 483.75(o)(4)		Re-designated	§ 483.75(i).
§ 483.75(p)(1)	(p) *Disclosure of ownership*	Re-designated	§ 483.70(k)(1).
§ 483.75(p)(2)(i)–(iv)		Re-designated	§ 483.70(k)(2)(i)–(iv).
§ 483.75(p)(3)		Re-designated	§ 483.70(k)(3).
§ 483.75(q)	(q) *Required training of feeding assistants.*	Re-designated & revised	§ 483.95(h).
§ 483.75(r)(1)–(3)	(r) *Facility closure-Administrator*	Re-designated	§ 483.70(l)(1)–(3).
§ 483.75(s)	(s) *Facility closure*	Re-designated & revised	§ 483.70(m).
§ 483.75(t)	(t) *Hospice services*	Re-designated	§ 483.70(o).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information (COI) 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 document that contain information collection requirements (ICRs).

Omnibus Budget Reconciliation Act of 1987 Waiver

Ordinarily, we are required to estimate the public reporting burden for information collection requirements for these regulations in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act of 1987, Public Law 100–203 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for these regulations. We believe that this waiver still applies to those revisions and updates we made to existing requirements in part 483 subpart B. However, we provide burden estimates for the new information collection requirements finalized in this rule, specifically those requirements implemented as a result of the Affordable Care Act.

Comment: A few commenters raised concerns regarding the burden for information collection requirements for provisions covered under the waiver. Specifically, commenters indicated that the revised regulations will increase the amount of documentation that facilities must produce and maintain and these increases were not discussed in the COI

Response: We agree that under usual circumstances the paperwork burden related to documentation would be presented in the collection of information section; however in the proposed rule we indicated that sections 4204(b) and 4214(d) of OBRA '87 provide for a waiver of PRA requirements for these regulations. There have not been any amendments or other changes made by Congress to the PRA exemption regarding OBRA '87 provisions. Therefore, given that these regulations set forth requirements necessary to o implement sections 1819 and 1919 of the Act, we believe that the waiver still applies. We note that we specifically provided a discussion of the information collection actions for those requirements implemented through the Affordable Care Act because the Affordable Care Act did not provide PRA exemption for the added sections.

Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of the Medicare and Medicaid participating LTC facilities from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of May 1, 2016. We have not included data for nursing facilities that are not Medicare and/or Medicaid certified. Since the individual States periodically update the CASPER system, the number of SNFs and NFs may vary depending upon the date of the report. Thus, while number of facilities reflected in this final rule is accurate as of the date of the report, the actual number of facilities may be different as of the date of this final rule's publication.

Unless otherwise indicated, we obtained all salary information for the different positions identified in the following assessments from the US Bureau of Labor Statistics at *http://www.bls.gov/oes*. We calculated the estimated hourly rates based upon the national average salary for that particular position, including fringe benefits and overhead worth 100 percent of the base salary. Where we were able to identify positions linked to specific positions, we used that compensation information. However, in some instances, we used a general position description or we used information for comparable positions. For example, we were not able to locate specific information for LTC facility administrators and directors of nursing, so we used the average hourly wage for a medical and health services manager for these positions. Table 2 below summaries the various positions and salaries associated with the positions used in our analysis. We note that the same information has been used for our estimates in the impact analysis section.

TABLE 2—SOURCE INFORMATION USED FOR BURDEN ESTIMATES

[*Salaries include a 100 percent increase for fringe benefits and overhead]

Number of LTC Facilities	15,653
Number of Operating Organizations	7,314
Salary of a RN	$61
Salary of a Director of Nursing	$85
Salary of an Administrator	$85
Salary of a Nurse Aide	$25
Salary of a Social Worker	$47
Salary of an Office Assistant	$31
Salary of an Attorney	$131
Salary of a Physician	$185
Salary of a Facilities Manager	$37

In addition, in estimating the burden associated with this final rule we also took into consideration the many free or low cost resources LTC facilities have available to them. The following is a non-exhaustive list of some of the available resources:

- *http://www.nhqualitycampaign.org*
- *http://www.ascp.com*
- *http://www.amda.com*
- *http://www.ahcancal.org*
- *http://www.leadingage.org*
- *http://www.americangeriatrics.org*
- *http://www.ntocc.org*

A. ICRs Regarding Quality Assurance and Performance Improvement (§ 483.75)

Each facility is currently required to maintain a QAA committee consisting of the director of nursing services, a physician designated by the facility and at least three other members of the facility's staff. The committee must meet at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary. The committee is required to develop and implement appropriate plans of action to correct identified quality deficiencies. Based on our experience with facilities' compliance with QAA requirements, we anticipate that they already have some of the resources needed to develop and implement a proactive QAPI program. In addition, some ICRs will be met through the technical assistance provided to facilities by CMS on the development of best practices, as required by the Affordable Care Act.

We proposed at § 483.75 that a facility have a QAPI program. The burden associated with these requirements will be the time and effort necessary to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate the ongoing performance of the facility. The facility must establish a program to address the key components of the standards (program measures, program scope, and program activities). The existing regulations require that QAA committees identify and correct specific deficiencies. We believe facilities will use some of the resources they have to comply with the QAA requirements (such as collecting data), in the development of a QAPI-based, proactive approach to assessing services they provide (including those services furnished under contract or arrangement) and to improve the quality of care and quality of life provided to their residents.

Since the existing Interpretative Guidelines for facilities to comply with the Medicare regulations provide information on how to conduct quality improvement programs, we anticipate that some facilities are already utilizing the QAPI model. We also anticipate that facilities will use their existing resources to meet the requirements in this final rule. To the extent that facilities are utilizing a QAPI quality model and are proactively collecting data, evaluating their performance, and making and monitoring program improvements, they will be better prepared to comply with the QAPI requirements. However, for the purpose of this burden analysis, we assume that all facilities will need to develop a QAPI program.

Based on our experience with other Medicare providers that have developed QAPI programs, we estimate that, on average, it will take 56 hours for the facility to develop and document a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement.

We estimate that the facility administrator will be largely responsible for developing the overall QAPI program and will spend approximately 30 hours on this activity; the director of nursing and a registered nurse will each spend approximately 10 hours each to review and provide input on clinical services activities; a physician will spend approximately 4 hours to review the program plan and provide medical direction and input; and one office assistant will spend approximately 2 hours to prepare and distribute draft and final program plans. We estimate that this will require a total of 876,568 (56 hours × 15,653 facilities) burden hours for all LTC facilities to develop a QAPI program.

We estimate that the cost for the administrator will be $2,550 ($85 × 30 hours). We estimate the cost for the director of nursing will be $850 ($85 × 10 hours). We estimate that the cost for an RN would be $610 ($61 per hour × 10 hours). We estimate that the cost for the physician will be $740 ($185 × 4 hours). We estimate that the cost for an office assistant will be $62 ($31 × 2 hours). The estimated one-time cost for each facility will total $4,812. The total one-time cost for all LTC facilities will be $75,322,236.

We anticipate that the ongoing, annual burden for each facility to collect and analyze data for QAPI activities will be 20 hours. We also anticipate that to document the improvement activities will require 20 hours. We estimate the total annual burden hours for all LTC facilities will be 626,120 (40 hours × 15,653 facilities). We anticipate that the staff time will be distributed as follows:

Administrator: collect and analyze data: 10 hours; implement and document improvement projects: 4 hours. (Total cost of $1,190 ($85 × 14 burden hours)).

Director of Nursing: collect and analyze data: 4 hours; implement and document improvement projects: 10 hours. (Total cost of $1,190 ($85 × 14 burden hours)).

RN: collect and analyze data: 4 hours; implement and document improvement projects: 6 hours. (Total cost of $610 ($61 × 10 burden hours).

Physician: analyze data: 1 hours. (Total cost of $185).

Office Assistant: collect and analyze data: 1 hours. (Total cost of $29).

Therefore, we estimate that the on-going annual cost for each facility will be a total of $3,204. We estimate that the total on-going annual cost for all LTC facilities will be $50,152,212.

Comment: A few commenters indicated that we underestimated the amount of time and work it will take for facilities to come into compliance with our proposed QAPI requirements. One commenter provided a QAPI implementation task list including costs associated with each task. The commenter noted that the QAPI task list was based on an independently owned nursing center that cares for a little over 100 residents and highlighted that this center has already begun implementation of QAPI. The commenter indicated that specific to this nursing center it would cost them around $30,000 to develop a QAPI plan and an on-going annual cost of around $82,000.

The commenter noted further that the burden estimates provided in the proposed rule for developing a QAPI plan are flawed because unlike other Medicare and Medicaid providers/suppliers, LTC facilities have to meet Requirements for Participation, not Conditions of Participation. The commenter indicated that due to this, LTC facilities will spend greater time developing a plan because they are at greater risk for decertification (than other Medicare and Medicaid providers/suppliers) if noncompliance is determined by CMS.

Response: We appreciate the commenter's feedback and examples. We recognize that implementing a QAPI program can involve many tasks. However, we note that the specific tasks will be based on the individual needs of each facility. We provided a broad estimate of what facilities will need to do in order to develop a QAPI plan. Some facilities may view our estimates as an underestimate, while for some other facilities our estimates may prove to be an overestimate. We believe that our estimate provides all LTC facilities with a general idea of the burden and time that may be involved with developing a QAPI plan.

We note that these requirements build on the knowledge gained during the CMS QAPI demonstration in LTC facilities. We believe facilities are familiar with the principles that we proposed and expect that some facilities have or are in the process of developing QAPI programs using the materials developed during the demonstration. These materials were provided to LTC facilities on June 7, 2013 (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13–37.pdf*) and remain available on the CMS Web site (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html*). Nonetheless, we recognize the level of work it will take for facilities to come into compliance with these requirements. To address this concern, that facilities may need additional time to comply with these provisions, in this final rule we provide a phased in implementation of these QAPI requirements over 3 years (see Section. II.B. Implementation Date). We believe that this additional time, along with the resources provided through the CMS QAPI demonstration, will allow facilities the time necessary to allocate their resources and efficiently develop their QAPI program.

Lastly, we disagree with the commenter's assertion that LTC facilities will spend more time developing their plans because they are at greater risk for being decertified since they have to meet requirements for participation rather than conditions of participation. We provide a detailed discussion regarding this concern in the general comments section and encourage commenters to review that section.

B. ICRs Regarding Compliance and Ethics Program (§ 483.85)

Section 483.85 requires the operating organization for each SNF and NF to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and promoting quality of care. Each compliance and ethics program must contain at least the eight required elements in § 483.85(c). The operating organization for each facility must also review its compliance and ethics program annually, and revise its program, as needed. Furthermore, § 483.85(d) has additional requirements for operating organizations that operate five or more facilities.

For the purpose of determining a burden for this final rule, we have estimated a burden based on the number of SNF and NF operating organizations. We expect that the operating organization will develop the compliance and ethics program in collaboration with staff at their facilities and then share the implementation of the program with its operating facilities. Since it will be the individual facilities that will be surveyed and not the operating organization, operating organizations will need to ensure that the appropriate documentation is available at all of their individual facilities in order to demonstrate compliance with all of the relevant requirements in this final rule. Therefore, the burden we have assessed for the operating organization will encompass their working with staff at their individual facilities.

The current regulations for SNFs and NFs do not contain any requirements for a compliance and ethics program. However, SNFs and NFs, as well as all other health care facilities, must comply with all applicable statutes, regulations, and other mandatory guidance or face criminal, civil, or administrative sanctions. In addition, as discussed previously, the OIG had issued voluntary guidance about compliance and ethics programs for SNFs and NFs in 2000 and 2008. We also believe that it is standard practice for SNFs and NFs to have high-level personnel, such as the administrator, director of nursing, or the facilities director, be responsible for ensuring that the facility is in compliance with all of the applicable federal, state, and local laws. We believe that many, if not all, of the operating organizations for SNFs and NFs already have some type of compliance program in operation. Furthermore, since many of the proposed required components for the compliance and ethics programs are very similar to many of the listed elements for the programs in the OIG's voluntary guidance documents published in 2000 and 2008, we believe the compliance and ethics programs that are already being used by many facilities include many, if not all, of the components in this rule. However, since adherence to the OIG's guidance was voluntary and did not impose mandatory obligations, we also believe that some of these existing programs may not have all, or perhaps any, of the required components or may not be documented or included in the facility's standards, policies, or procedures. Therefore, we believe that all of the operating organizations for the SNFs

and NFs will need to review their current programs and possibly revise or, in some cases, develop new sections for their programs in order to comply with the requirements in this final rule.

Based on an analysis of the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and CASPER data, there are 9,200 SNFs and NFs that are part of a multi-facility operating organization (an operating organization with 2 or more facilities). Furthermore, based on PECOS and CASPER data, for purposes of this regulation, we estimate that there are 7,314 total operating organizations (395 operating organizations with 5 or more facilities, 419 operating organizations with 2 to 4 facilities, and 6,500 operating organizations with single facilities). Based on our experience with SNFs and NFs, we expect that the administrator and the director of nursing will primarily be involved in developing the operating organization's compliance and ethics program. Thus, in determining the burden for all of the requirements in § 483.85, except for § 483.85(d), we will analyze the burden based on an administrator and the director of nursing performing the necessary tasks and activities. If the operating organization has a designated compliance officer, we expect that he or she will take the lead in developing the entire program with the assistance of the administrator and the director of nursing as needed or when required. Since we have estimated that the compliance officer and the director of nursing will receive about the same amount of compensation, $85 an hour, and that the necessary activities will require about the same numbers of hours, we believe our estimates will be about the same regardless of whether these tasks and activities were performed by the administrator and the director of nursing or by the compliance officer with the assistance of the administrator and the director of nursing.

As described previously, LTC facilities must already ''be in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility'' (§ 483.85(b)). Thus, we expect that LTC facilities are already performing many of the tasks and activities necessary to a compliance program and spending hours of their time on compliance issues, especially the LTC facilities in multi-facility operating organizations. However, we are not certain that most LTC facilities have formal programs that comply with the requirements in this proposed rule. Thus, we believe that LTC facilities will sustain a burden associated with the requirement to develop a program that complied with this final rule from the resources needed for each facility to review, revise, and, if needed, develop new sections for the operating organization's compliance and ethics program.

We estimate that complying with this requirement will require 10 burden hours from the administrator and 10 burden hours from the director of nursing for a total of 20 burden hours from these individuals at an estimated cost of $1,700 (20 hours × $85 hourly wage). In addition, since we are requiring compliance and ethics programs to be mandatory, we expect that facilities will have an attorney review their programs to ensure they are in compliance with the requirements in this rule. The cost of having an attorney review the operating organization's program will vary depending on whether the operating organization has in-house counsel or has to hire an attorney at a law firm. For the purposes of determining the burden, we will assume that each operating organization has in-house counsel. We expect that an attorney will need to review the facility's compliance and ethics program, make recommendations, and approve the final program. We estimate this will require 4 burden hours at an estimated cost of $524 ($131 hourly wage × 4 hours).

Based on this data, we estimate it will require a total of 24 burden hours (10 hours for an administrator + 10 hours for the director of nursing + 4 hours for an attorney) for each operating organization to develop a compliance and ethics program that complied with the requirements in this final rule at a cost of $2,224 ($1,700 for the administrator and director of nursing + $524 for an attorney). Therefore, we estimate it will require 175,536 annual burden hours (24 burden hours for each operating organization × 7,314 operating organizations) at a cost of $16,266,336 ($2,224 for each operating organization × 7,314 operating organizations) for all facilities to comply with this requirement.

Each operating organization will also need to develop the policies and procedures necessary to implement the operating organization's compliance and ethics program. The burden associated with this requirement will be the resources needed to review and revise any existing policies and procedures and, if needed, develop new policies and procedures. Based on our experience with SNFs and NFs, we expect that the administrator, director of nursing, or perhaps both of these individuals will develop these policies and procedures. We estimate that it will require 10 burden hours for each operating organization to comply with this requirement at a cost of $850 ($85 hourly wage for a health services manager × 10 hours). Therefore, we estimate that for all 7,314 operating organizations to comply with this requirement, it will require 73,140 burden hours (10 burden hours for each operating organization × 7,314 operating organizations) at a cost of $6,216,900 ($850 per operating organization × 7,314 operating organizations).

In addition to developing the compliance and ethics program, each operating organization will be required to develop training materials and/or other publications to disseminate information about the program to its entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. As stated previously, we believe that facilities are already performing many of the tasks necessary for a compliance program and spending many hours on compliance issues. Thus, we expect that many operating organizations already have some of the materials and/or other publications that will be needed to comply with this requirement. The burden associated with this requirement will be the resources needed to review and revise any existing materials and, if needed, develop new materials to comply with this requirement. Based on our experience with operating organizations, we expect that the compliance liaison (nursing staffs) will be involved in these activities.

We believe that the compliance liaison will need 8 hours to develop these materials. Thus, we estimate it will require 8 burden hours for each operating organization to comply with this requirement at a cost of $488 ($61 hourly wage × 8 hours). Therefore, based on the previous estimate, for all 7,314 operating organizations to comply with this requirement it will require 58,512 burden hours (8 hours × 7,314 operating organizations) at a cost of $3,569,232 ($488 per operating organization × 7,314 operating organizations).

We also proposed in § 483.85(e) that the operating organization for each facility must review its compliance and ethics program annually, and revise its program, as needed. Thus, after LTC facilities develop their compliance and ethics programs, these facilities will need to review and revise their programs, as needed, in the subsequent

years. Based on our experience with other healthcare facilities, we expect that most facilities are already periodically reviewing their programs, policies, and procedures. However, since an effective compliance and ethics program requires that a facility stay up-to-date with all SNF and NF requirements to reduce the prospect of criminal, civil, and administrative violations and promote quality of care, we believe that the facility would require more time to review this program as compared to its other programs, policies, and procedures that it must periodically review. In addition, since it is common for there to be changes in laws, regulations, and other requirements, we expect that most SNFs and NFs will need to make at least some revisions annually. Even if there are no changes in the applicable laws, regulations, or other requirements, SNFs and NFs may need to make changes in their training materials or other publications.

We expect that the administrator or the director of nursing, or perhaps both, will be responsible for reviewing this program annually to ensure it was up-to-date and in compliance with all of the relevant federal and state laws, regulations, and other guidance. We expect that to comply with this requirement will require 5 hours from the administrator and 5 hours from the director of nursing for 10 burden hours at a cost of $850 ($85 hourly wage for administrator and director of nursing × 10 hours). Therefore, based on the previous estimate, for all 7,314 facilities to comply with this requirement will require 73,140 burden hours (10 hours × 7,314 operating organizations) at a cost of $6,216,900 ($850 per facility × 7,314 operating organizations).

Based upon the previous estimates, for the first year that this requirement is in effect, it will require 42 burden hours (24 hours for developing the program + 10 hours for developing policies and procedures + 8 hours for developing training materials, publication or both) at a cost of $3,562 ($2,224 for developing the program + $850 for developing policies and procedures + $488 for developing training materials, publication or both) for each operating organization to comply with this requirement. Based on the estimates shown previously in this section, for all 7,314 operating organizations to comply with these requirements it would require 307,188 burden hours (42 hours per operating organization × 7,314 operating organizations) at an estimated cost of $26,052,468 ($3,562 per operating organization × 7,314 operating organizations). For all subsequent years, we estimate to comply with the information collection will annually require 10 burden hours at a cost of $850. For all 7,314 operating organizations, it will require 73,140 (10 hours × 7,314 facilities) burden hours at an estimated cost of $6,216,900 ($850 per operating organization × 7,314 operating organizations).

Comment: One commenter disagreed with our estimate of costs to develop and implement a compliance program and indicated that the estimate of $139 million for the first year and $120 million for the second year is unrealistically low. The commenter noted that some of the large operating organizations budget over a million dollars annually to implement a compliance and ethics program and that significant funding is required to draft new policies and procedures, implement internal or external monitoring/auditing. The commenter also notes that developing a compliance and ethics program may require hiring additional staff or consultants to provide process and oversight guidance. The commenter indicated that the cost to annually review the program is very costly and may cost anywhere between $5,000 and $75,000 per year, depending on facility size. In summary, the commenter noted that the number of facilities with existing compliance and ethics programs will vary and recommended that all providers have at least two years to implement the compliance and ethics requirements.

Response: We understand that the actual cost to develop and implement a compliance and ethics program, as well as all of the other LTC facility requirements, will vary based on the individual characteristics of each LTC facility. We note that in the impact analysis for the proposed rule we allocated an estimated cost of $19,319,040 for operating organizations with five or more facilities to establish a compliance officer to carry out the program. We also allocated an estimated cost of $95,052,256 for operating organizations with less than five facilities to establish a compliance liaison to carry out the program. This information has been updated for the final rule and we encourage readers to review the impact analysis section collectively with the collection of information section. To alleviate some of the burden placed on LTC facilities we have provided a phased in implementation period of the proposed requirements over 3 years. Specifically, the compliance and ethics requirements will have a implementation timeframe of 3 years following the effective date of this final rule. We believe that this will provide all LTC facilities, regardless of size, a considerate amount of time to budget these costs into their financial plans. A detailed discussion regarding the implementation plan for this final rule can be found in Section II.B. Implementation.

C. ICRs Regarding Training Requirements (§ 483.95)

Each facility is already required to complete a performance review of every NA at least once every 12 months, and must provide in-service education based on the outcome of these reviews. At § 483.95(g)(2) facilities are required to include dementia management and abuse prevention in their regular in-service education for all NAs.

Existing regulations at § 483.75(e)(8)(iii) (relocated to § 483.95 in this final rule) already required that NAs who provide services to individuals with cognitive impairments receive in-service training to address the care of the cognitively impaired. Based on the existing requirements, facilities already conduct training for some NAs on caring for residents who are cognitively impaired. Additionally, the existing requirements at § 483.75(e)(8)(ii) (relocated to § 483.95 in this final rule) stated that NAs must receive in-service training that addresses areas of weakness as determined in their performance reviews and may address the special needs of residents, as determined by the facility staff. Thus NAs receive annual training in dementia management and abuse prevention only if the training is indicated by their performance reviews.

Because this final rule specifically requires facilities to provide dementia management and abuse prevention training to all NAs, each facility will need to review their training procedures and materials to ensure that they are complying with the new requirements. For example, facilities may currently provide the in-service training (as identified from the performance review) utilizing an individual, targeted approach. In this final rule, all NAs are required to receive this training annually, and the facility will need to evaluate whether another format might be more appropriate.

Since we are not increasing the time needed to provide this training, we are not adding additional burden for the staff to train the NAs, since the existing requirements for facilities require them to provide in-service training to all NAs at least once every 12 months. We estimate that the burden associated with complying with this requirement will be a one-time burden due to the resources required to review and, if necessary,

modify the existing training materials to apply to all NAs, regardless of identified performance weaknesses. We expect that these activities will require the involvement of a RN or a LPN. Based on our experience with facilities, we anticipate that it will take each facility 4 hours to review and modify their existing training materials. Based on an hourly rate of $61 for an RN, we estimate that this will require 62,612 burden hours (4 hours × 15,653 facilities) at a cost of $244 for each facility. The total cost for all LTC facilities is estimated to be $3,819,332 ($244 × 15,653 facilities).

Table 3 below summarizes the estimated annual reporting and recordkeeping burdens for this final rule.

TABLE 3—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 483.75(a)	0938—New	15,653	15,653	56	876,568	**	75,322,236	75,322,236
§ 483.75(b)(2)	0938—New	15,653	15,653	40	626,120	**	50,152,212	50,152,212
§ 483.85(b)	0938—New	7,314	7,314	24	175,536	**	16,266,336	16,266,336
§ 483.85(c)	0938—New	7,314	7,314	10	73,140	**	6,216,900	6,216,900
§ 483.85(d)(1)	0938—New	7,314	7,314	8	58,512	**	3,569,232	3,569,232
§ 483.85(e)	0938—New	7,314	7,314	10	73,140	**	6,216,900	6,216,900
§ 483.95	0938—New	15,653	15,653	4	62,612	**	3,819,332	3,819,332
Totals		22,967	76,215		1,945,628			161,563,148

** The hourly labor wages are discussed in detail earlier in this section.
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 3.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham, (CMS–3260–F), Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–3178–F, Fax (202) 395–6974.

VI. Regulatory Impact Analysis (RIA)

A. Statement of Need

CMS has not comprehensively reviewed the entire set of requirements for participation imposed on LTC facilities in many years. CMS staff conducted a review of the existing requirements as well as those issues identified by stakeholders as problematic over the years. Accordingly, the revisions to the requirements in this final rule will improve the quality of life, care, and services in facilities and optimize resident safety. In addition, the revisions in this final rule reflect current professional standards and improve the logical flow of the regulations.

B. 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), 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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 hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

C. Comments on the Initial Regulatory Impact Analysis

As discussed previously, we received nearly 10,000 public comments in response to the proposed rule. While many of those comments discussed the overall burden that the proposed requirements will place on facilities, few addressed the specifics of our preliminary regulatory impact analysis. We discuss those specific comments below. When possible, as discussed in our responses, we adjust our final analysis to take into account these comments.

Comment: Several commenters highlighted the decrease in Medicaid funding provided to LTC facilities and additional changes in the delivery of care and reimbursement for LTC facilities as challenges for meeting the financial costs associated with this final rule. Specifically, commenters noted several additional initiatives currently taking place within the LTC industry such as value-based purchasing (VBP), the advancement of accountable care organizations (ACOs), dual demo projects, and bundled payments.

Commenters noted that LTC facilities are already struggling, have limited resources and limited staff, and will have difficulty meeting the financial costs of this final rule. Commenters indicated that the majority of the residents in LTC facilities are Medicaid recipients, while one commenter in particular highlighted the impact of those facilities located in Wisconsin. The commenter indicated that in 2013–2014 Wisconsin LTC facilitys lost on average $52.11 per day for each Medicaid resident they served. The commenter noted further that 65 percent of the residents in Wisconsin LTC facilities are Medicaid recipients. In addition, the commenter notes a recent reduction in expenditures for SNFs by $14 billion through 2020 and a decrease in SNF reimbursement payments. Several commenters suggested that to avoid closures, staff cuts, or compromised care, CMS should pay for the proposed changes instead of placing the financial impact of this regulation on LTC facilities. Likewise, several commenters recognized that Medicaid is funded by states and suggested the CMS should implement a phased in implementation of the requirements and withdraw some of the proposed requirements to better allow facilities to meet the financial costs of this regulation.

Response: We appreciate the comments from commenters. We understand that for some facilities Medicaid reimbursement accounts for a large portion of its funding, however the specifics regarding Medicaid funding is regulated by the State and outside the scope of this regulation. We also recognize that there are additional initiatives taking place within the industry that fall outside the requirements in the regulation and will have an impact on LTC facilities including SNF reimbursement. However, as noted previously SNF PPS payment rates have increased steadily over recent years, due to market basket updates. In addition, the cost associated with operating a business that is in compliance with the requirements for LTC facilities is the responsibility of the facility.

In an effort to acknowledge the concerns raised by commenters and potentially reduce the immediate financial impact that this final rule will impose on facilities, we are finalizing a phased-in implementation of the requirements over 3 years. Readers should refer to Section B. ''Implementation'' for our discussion of the phased-in implementation deadlines. In response to public comments and in consideration of the burden imposed on facilities, we have also removed or made several revisions in this final rule to increase flexibility and avoid creating unintentional consequences for facilities. Readers should refer to Section III. ''Provisions of the Final Regulations'' for a detailed discussion of the changes from the proposed rule to the final rule.

Comment: Some commenters indicated that this regulation will increase the workload for both state mental health agencies and long-term care ombudsman programs. Specifically, the commenter noted that this proposed rule will increase the reporting by SNFs of patients and PASARR findings to the State Mental Health Authority. Commenters noted that the amount of information to be reported and investigated by the state Ombudsman will increase dramatically. One commenter requested that CMS conduct a cost analysis regarding these increases in workload, as well as a cost analysis of the impact on Federal and State Medicaid budgets.

Response: We recognize that these LTC facility requirements may have an indirect impact on additional entities. However, due to data limitations, we are unable to quantify with any degree of certainty the impact that these revisions will impose on these outside entities.

Comment: One commenter requested that we revisit the estimated impact that this regulation will place on federal, state, county, city and tribal budgets. The commenter indicated that approximately 912 SNFs are owned and operated by a federal agency, state, county or city governments as well as tribal authorities. Specific to the 912 SNFs, the commenter suggested that the proposed changes represent an unfunded mandate of $42 million that was not accounted for in the proposed rule impact analysis.

Response: In the proposed rule we indicated that there were 15,691 LTC facilities that participated in the Medicare and Medicaid program. The 15,691 LTC facilities accounted for in the proposed rule include those SNFs that are owned or operated by a federal agency, as well as tribal authorities. Therefore, we disagree with the commenter and believe that the cost estimates in the proposed rule, and subsequently this final rule, account for those cost placed on the 912 SNFs identified by the commenter.

Comment: Some commenters noted that the proposed changes will increase the survey workload for each State Survey Agency and will ultimately increase both federal and state budgets. The commenter indicated that the proposed rule did not calculate the cost impact to the state survey agencies.

Response: We analyzed the additional time that may be required for surveyors to conduct their surveys based on the changes and accounted for the increase in the cost estimate for federal costs. We believe that the revisions in this final rule will have only an incremental impact on the workload of surveyors that is outside of their normal scope of practice. As a result of any regulation that we issue the survey process will be reviewed and surveyors are updated and trained on the new guidance. This standard process is no different for these regulations.

Comment: One commenter indicated that our calculations that used minutes rounded down the time. The commenter noted that our calculations for 5 minutes used .08 instead of .0833 and our calculations for 2 minutes used .03 instead of .0333.

Response: We understand that the use of varying rounding methods to convert minutes to decimals will have an impact on the total cost calculations and that different rounding methods could be used. Therefore, in this final regulation we have revised our calculations for those estimates that use minutes. Specifically, we have revised the inputs for our calculations by using unrounded numbers. For example, our calculations in the final rule for 5 minutes uses the input 5/60 rather than .08.

Comment: One commenter indicated that our use of 1,382,201 as the number of Medicare beneficiaries in our calculations did not take into consideration the admissions from a hospital as well as the turnover of long stay residents during a year.

Response: We made our best effort to locate an adequate estimate for the number of Medicare beneficiaries. We recognize that this estimate will vary depending on the data collection, however we believe that the use of information from a National study of LTC providers is an adequate data source for our calculations (see Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014'' *http://www.cdc.gov/nchs/fastats/nursing-home-care.htm*). We note that the commenter did not suggest an alternative source.

Comment: Commenters indicated that our estimate for providing notices to residents regarding their Medicaid eligibility is too low. The commenters indicated that the regulation emphasizes the importance of meaningful communication and that providing such

communication frequently requires additional time.

Response: Based on commenter concerns, in our final rule estimate we have increased the amount of time anticipated for a social worker to provide a resident with a notice of their Medicaid eligibility.

Comment: A number of commenters indicated that we underestimated the cost of informing residents of the facility's grievance process. Commenters indicated that establishing a grievance process and designating a grievance official will be costly.

Response: We have reviewed the new requirements for establishing a grievance policy against the existing requirements that facilities must met regarding a grievance process. After further review, we agree with commenters and have assessed a cost to the requirement for facilities to establish a grievance process that is coordinated by a grievance official in the final rule RIA.

Comment: Most commenters objected our proposal for a physician to evaluate a resident prior to hospital transfer unless a delay in transfer places the resident at risk. Commenters indicated that the requirement would impose a large financial impact on facilities.

Response: Based on the concerns raised by commenters, we have withdrawn this proposal. Please see our detailed discussion in Section II. L. of this preamble, ''Physician Services''.

Comment: We proposed to require facilities that receive approval of construction or reconstruction from State and local authorities or are newly certified after the effective date of the final rule, to have resident rooms must with bathrooms that are equipped with at least a commode, sink, and shower. One commenter indicated that many LTC facilities, many of which were built in the 1960's and 70s, are currently undergoing reconstruction projects. Another commenter indicated that including a shower in each bathroom will be cost prohibitive. In addition, commenters pointed out the need for additional square footage and the cost of the additional plumbing needed for a shower.

Response: In response to public comments, we have modified this requirement to require that bathrooms at least include only a sink and commode. In addition, we note that this requirement applies to those facilities that receive approval of construction or are newly certified after the effective date of this final rule. These requirement will not apply to those facilities that are currently being constructed or received approval for construction before the effective date of this final rule. A detailed discussion regarding the changes in the final rule can be found in Section II. Y., ''Physical Environment.''

Comment: A few commenters indicated that the requirement for an infection control officer requires a person to spend more than half of their time in this role, however the salary estimate in the proposed rule assumed only 15 percent of a FTE to this function.

Response: In this final rule, we have modified our proposal to require each facility to designate one individual as the infection preventionist (IP) for whom the infection prevention and control program (IPCP) is a major responsibility. We have revised the requirement to specify that each facility may designate more than one person as the IP and the IPCP no longer has to be a major responsibility of the individual(s).

Comment: Many commenters requested that we re-analyze the overall cost that this regulation will impose on LTC facilities. Commenters provided several comments indicating that, in general, the proposed financial impact is underestimated and inaccurate. The vast majority of these comments generalized the overall cost of the regulations and did not provide specifics regarding the calculations presented in the proposed rule. One commenter highlighted concerns regarding the clinical and financial feasibility of some of the proposals and provided an individualized analysis of the impact analysis presented in the proposed rule.

Response: In section D. below we provide the anticipated costs of the final rule. Given the concerns raised by commenters and the lack of specifics, we have broadly reviewed the impact analysis section for accuracy and made general improvements where possible. In addition, in several instances we have revised our initial estimates to reflect specific concerns raised by commenters. For example, we have revised the analysis associated with the requirement for facilities to designate a grievance official.

Comment: One commenter indicated that the proposed impact analysis did not meet the statutory requirements of OBRA 87 to take into consideration the costs of complying with requirements for participation when computing payments to SNFs.

Response: Generally payment policy related to SNFs falls outside the scope of regulations for the requirements of participation for LTC facilities because payment policy is implemented under separate regulation. However, we acknowledge that the SNF value-based purchasing (VBP) program, which will take effect in FY 2019, is intended to tie SNF payments more closely to rewarding positive patient care outcomes. Under section 1888(h)(6) of the Act, the VBP incentive payments to the higher-performing SNFs are to be funded through a 2 percent reduction in the overall SNF PPS payment rates (again, effective in FY 2019); accordingly, under the terms of the VBP legislation, a SNF's successful performance in meeting the applicable quality measures can help mitigate the actual impact of the overall payment reduction. These payment changes were specifically mandated by Congress when it enacted the SNF VBP legislation in section 215 of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93). The requirements in this rulemaking share the VBP program's objective of improving the quality of care in the LTC setting. We note in addition that SNF PPS payment rates have increased steadily over recent years, due to market basket updates.

D. Anticipated Costs of the Final Rule

As of this final rule, there are about 15,653 SNFs and NFs that are certified by Medicare and Medicaid. We use the number of SNFs and NFs to estimate the potential impacts of the final rule. We have used the same data source for the RIA that we used to develop the PRA burden estimates. As stated in the COI section, we obtained all salary information from the May 2015 National Occupational Employment and Wage Estimates, United States by the BLS at *http://www.bls.gov/oes/current/oes_nat.htm* and all salary estimates include benefits and overhead package worth 100 percent of the base salary. The analysis below overlaps with the COI section for some requirements, therefore readers may wish to consult both sections on some topics.

This final rule will require facilities to review their current practices and make changes to be in compliance with the health and safety standards as set forth in this final rule. However, it is important to note that many of the changes to the requirements are only re-designations of existing requirements that have been imposed on LTC facilities since the implementation of OBRA 87. In these instances, where existing requirements have been relocated to improve the clarity of the regulations, we do not anticipate that facilities will undertake new actions or bear any additional costs in response to the issuance of this regulation. In addition, based on our experience with

health care providers, we expect that many of the requirements in this final rule are standard medical or business practices and as a result will not impose an additional burden or new cost to facilities. We have made several assumptions in order to assess the time that it will take for a facility to comply with the requirements and the associated costs of compliance. There are uncertainties about the magnitude of the discussed effects of this regulation, however we have based our overall assumptions on our ongoing experiences with LTC facilities. Table 4 below summarizes the source information used for the RIA.

TABLE 4—SUMMARY OF SOURCE INFORMATION USED FOR RIA

Number of LTC Facilities	* 15,653
Number of LTC Facilities	*15,653
Number of Operating Organizations with 5 or more facilities	395
Number of Operating Organizations with 5 or less facilities	6,919
Number of Medicare Beneficiaries	** 1,369,700
Hourly pay of a RN	$61
Hourly pay of a Director of Nursing	$85
Hourly pay of a LTC facility Administrator	$85
Hourly pay of a Nurse Aide	$25
Hourly pay of a Social Worker	$47
Hourly pay of an Office Assistant	$31

Note: Hourly pay include a 100% increase for fringe benefits and overhead.
* Source: CASPER Data as of May 1, 2016.
** Source: Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014'' *http://www.cdc.gov/nchs/fastats/nursing-home-care.htm*.

We have summarized the anticipated impact that this final rule will have on LTC facilities by regulatory section.

1. Resident Rights § 483.10

Notification of Changes to Care Plan (§ 483.10(c)(2))

Existing requirements require that a resident, to the extent practicable, participate in the development of his or her care plan and be informed of the need to significantly alter treatment. We believe that the involvement and notification will include an opportunity to see the care plan. Periodic review after development of the care plan is also already required. However, we require a new right for the resident, the right to sign the care plan. The intent is to ensure that the resident, to the extent practicable and consistent with the resident's choices, demonstrates his or her participation in and review of his or her care planning and that participation is evident to care-givers, surveyors, and other interested parties. We estimate that it will take a registered nurse, no more than an additional 2 minutes per resident, to obtain a resident signature. We estimate that this may occur up to four times per year per resident. Based on an estimated 1,369,700 residents per year, the resulting burden will be $11,140,227 for all LTC facilitys. ($61 hourly wage for a nurse × (2/60) hour per occurrence × 1,369,700 residents × 4 occurrences per year).

Notification of a Need To Select a New Physician (§ 483.10(d)(4)

In this final rule, we require facilities to inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to comply with regulatory requirements, discuss alternatives, and honor the resident's preferences. Under existing requirements, the facility is already required to ensure that the resident is informed of the name, specialty, and way of contacting the physician responsible for his or her care. We have no basis to quantify how often this occurs or how often a facility will need to obtain an alternate provider. We believe that these conversations will be accomplished, and in most cases already occur, in the course of routine communication between a resident and caregivers. Thus, we do not believe this creates any new burden.

Notification of Charges § 483.10(f)(11)(iii)

We specify that if a resident requests an item or service for which the facility will charge, the facility must inform the resident both orally and in writing of the charge. Existing provisions require that facilities only ''inform'' the resident. We expect that ''informing'' has typically been accomplished orally; therefore the additional cost to facilities is associated with providing the written information at the time the oral information is given. We anticipate that this written information will most often be in the form of a list of standard charges for frequently requested items and the cost will be the cost of photocopying or printing the list. In infrequent cases, an individualized cost page may be needed. We estimate that a facility will spend no more than $50 per year on average to print the notices. We estimate the cost of a notice to be $0.10/page (based on the per page photocopying cost established at 45 CFR 5.43(c) for FOIA requests) with no more than 500 notices required per facility per year for a total estimated cost of $782,650 ($50 printing cost × 15,653 facilities) annually for all facilities.

Internet Access (§ 483.10(g)(9))

Section 483.10(g)(9) requires that a resident has the right to reasonable access and privacy for electronic communications such as email and video communications and internet research. This provision does not require that the facility provide internet access to any greater extent than the facility already has internet access (that is, a facility that has no internet access due to logistical deterrents is not required to overcome those obstacles based on this requirement) and the facility is allowed to transfer any additional expense to the resident if any additional expense is incurred. The facility is not obligated to provide each resident an individual means of access (that is, a personal computer or tablet). A community computer with associated rules for sharing, such as is commonly done in public libraries, may be an appropriate model. While we allow the facility to pass additional costs to the resident, we anticipate that some facilities may incur an initial hardware cost that is not attributable to an individual resident. In addition, we expect there will be minimal ongoing maintenance/replacement costs for the shared devices. We do not believe this requirement will add to the supervision burden for facility staff, as appropriate resident supervision is already required,

but it may require a director of nursing (DoN) or nursing home administrator (NHA) to establish rules for use. We estimate this will require quarter of an hour of DoN or NHA time to develop in those facilities that do not already have a policy established. Furthermore, we estimate that up to ten percent of facilities will need to develop an internet policy. Based on this information, we estimate that this requirement will impose a one-time cost of $33,263 on facilities (($85 hourly wage for a DoN or NHA × .25 hours) × (0.10 × 15,653 facilities)). We note that to determine the hourly wage for a DON or NHA, we used the salary information for a medical and health services manager within the SNF and NF industry from BLS data (as detailed previously).

Resident Groups in the Facility(§ 483.10(f)(5)(iii))

Facilities are currently required to provide a designated staff person to participate in resident and family groups. The revised requirement adds that the designated staff person must be approved by the resident or family group. We anticipate that the DoN will select a representative and obtain group agreement by providing a name or names to the group and the group will respond. We estimate that this will generally consume no more than an additional 15 minutes of the DoNs time in most cases. We believe some facilities already have such mutually agreed upon representatives. However, for we estimate that this additional requirement will cost facilities $332,626 ((.25 (15 minutes) × $85 (hourly wage for DoN)) × 15,653 LTC facilities).

Updating of Notices

We are finalizing provisions that will require facilities to review and update their existing notices of rights and services and inform residents of these updates. First, at § 483.10(f)(4)(vi)), we are finalizing our provision to require facilities to inform each resident of their visitation rights. Second, at § 483.10(g)(5) we have added additional state regulatory and information agencies that facilities must post the contact information for to be available to residents.

When assessing the burden of these requirements we make a few assumptions. First, we believe that notices regarding facility practices are periodically reviewed and updated as a standard business practice. In addition, we believe that a facility's visitation policy is already addressed in their notices of rights and services that must be provided to a resident regarding the rules and regulations that govern resident conduct and responsibilities during their stay in the facility.

Based on these assumptions, we expect that facilities will need to review and update their notices of rights and services on a one-time basis to specifically include the new visitation requirements, additional contact information, and grievance requirements. We believe that an office assistant may be tasked with updating the notices and distributing or posting, as appropriate, the updated information. We estimate that it will require an office assistant no more than 1 hour to make any necessary updates the notice at a total one-time cost to facilities of $485,243 (1 burden hours × $31 (hourly wage of office assistant) × 15,653 LTC facilities).

Medicaid Eligibility (§ 483.10(g)(17))

Current regulations facilities to provide notice to a resident of their Medicaid eligibility. We have revised the requirement so that those residents who are not eligible for Medicaid at admission will receive an additional notice when they do become eligible. This means some residents will require both a notice at admission and a second notice. As the notice of Medicaid eligibility is already required once, the new cost is associated with providing the notice an additional time. We anticipate that this will affect only a subset of residents (those eligible but not yet receiving Medicaid). Thus, based on a data analysis by AHCA, approximately 64 percent of LTC facility residents are already Medicaid recipients (that is, Medicaid is the payor of record), 14 percent are covered by Medicare, and 22 percent have another payor. Of those, only the 36 percent who are not receiving Medicaid may require the second notice of Medicaid eligibility. We assume that a portion of those will require ongoing care and become eligible for Medicaid. We also assume that some of those residents will apply for Medicaid at or shortly after admission or as a result of the first notice and not require the second notice. Based on these assumptions, we estimate that 20 percent of LTC facility residents (slightly more than half of those not already receiving Medicaid) will actually require a second notice of Medicaid eligibility. We anticipate that a social worker will track a resident's status of Medicaid eligibility and provide the notice. In the proposed rule, we estimated that it would take a social worker 3 minutes per resident to provide the notice. Based on public comments, for the final rule analysis we have added an additional 2 minutes to allow for proper communication, for a total of 5 minutes per resident. We estimate that it will cost $3.92 per resident who requires the additional notice or $1,072,932 to provide these notices to the applicable residents across all 15,653 facilities (($47 hourly wage for social worker × (5/60) of an hour) × (.20 estimate percent of all LTC facility residents who will require a second notice × 1,369,700 LTC facility residents)). We note that the actual per facility cost will vary significantly according to facility size and resident mix.

Grievances (§ 483.10(j))

We are finalizing our proposal to require facilities to establish a grievance policy and identify a grievance official who is responsible for overseeing the grievance process. Existing regulations provide residents with the right to voice grievances without discrimination or reprisal and require facilities to promptly resolve grievance. Based on these existing regulations, we expect that most facilities already have process for residents to file a grievance and a process in which they will investigate and respond. Therefore, the cost associated with establishing a grievance policy will be associated with designating an individual as the grievance official who is responsible for overseeing the grievance process. We do not specify who has to be the grievance official, but for purposes of estimating the cost we believe that an average facility will designate a social worker to be the grievance official and that individual will need to commit about 10 percent of a FTE to his or her responsibilities for overseeing the grievance process. We estimate that this will cost $153,023,728 for all LTC facilities to comply with requirement (10 percent of a social worker FTE × $47 hourly wage for a social worker × 2,080 hours (40 hours a week × 52 weeks = 2,080 hours) × 15,653 facilities).

2. Admission, Transfer, and Discharge Rights (§ 483.15)

Notice of Transfer (§ 483.15(c)(4))

Existing regulations require facilities to notify the resident and a representative of the resident before a facility transfers or discharges the resident. These final regulations add that a facility must also send notice to the Office of the State Long-Term Care Ombudsman. The notice is already created for the resident; this requirement poses an additional burden of printing a copy of the notice and sending it to the Office of the State Long-Term Care Ombudsman or, if a

secure means of electronic transmission is available, sending a notice electronically. We estimate the burden of this requirement to be $.10 per notice to make a copy, and $.58 for a single pre-stamped first class envelope (USPS retail) plus 5 minutes for an office assistant to address and mail the notice. This will apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. We estimate this notice may need to be sent to the Office of the State Long-Term Care Ombudsman for one third of all LTC facility residents, resulting in a cost of $1,340,936 (($.10 + $.58 + ($31 hourly wage for an office assistant × .(5/60) of an hour)) × (.3 percentage of LTC facility residents for whom a copy of a transfer notice needs sent to the Office of the State Long-Term Care Ombudsman × 1,369,700 LTC facility residents)) for all facilities. We note that the per-facility cost will vary significantly according to facility size and number of transfers out of each facility.

Update Transfer Notices (§ 483.15(c)(6))

We are finalizing our proposal to add a requirement for facilities to update a transfer notice if the information changes and provide the updated information to the recipients of the notice as soon as practicable once the updated information is available. We believe that updates regarding any changes are already occurring in facilities informally. Based on this assumption we estimate that updating the notice and providing it to the resident will require a social worker an additional 5 minutes per notice. In addition, we believe that this requirement will apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. We estimate this notice may need to be updated once for up to one third of LTC facility residents who are transferred. The resulting cost is $1,609,398 (($47 hourly wage for a social worker × (5/60) of an hour) × (.3 percent of nursing facility residents × 1,369,700 nursing facility residents)) for all facilities. We note that the per-facility cost will vary significantly according to facility size and number of transfers out of each facility.

3. Comprehensive Resident Centered Care Planning (§ 483.21)

Additional Members of the IDT (§ 483.21(b)(2)(ii))

We are finalizing our proposal to require that a nurse aide and member of nutrition services participate on the IDT. We note that based on concerns raised by commenters, we have removed our requirement for a social worker to participate on the IDT. We believe that this requirement will add to the current duties of each of these staff members and therefore would be a new economic cost to each facility. Communications about the status of a resident are a part of standard job duties. We envision that these staff members are already regularly discussing resident's needs and their plans of care. When assessing the amount of burden associated with this requirement, we believe that this requirement will produce an incremental increase in the staff time necessary to participate on the IDT. In addition, we do not specify the type of communication the IDT must use. IDT members may use electronic communication as well as informal discussions to participate in IDT meetings. We estimate that participation on the IDT will add an additional one hour of staff time to the duties of a NA and member of food services. While we do not require that a dietitian participate on the IDT, for purposes of estimating the cost we use the salary of a dietitian to represent the participation of a member of food services. We estimate that this requirement will cost $65,116,480 for all LTC facilities (($25 NA hourly wage + $55 dietitian hourly wage) × 52 hours (1hour per week × 52 weeks) × 15,653 facilities).

Discharge Planning (§ 483.21(c)(1)(vii))

We require that, for residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, facilities assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use. The facility also must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences. We believe that a social worker will be responsible for compiling the standardized data, reviewing the resident's preferences/goals, and pulling data that applies to these preferences/goals. We estimate that it will take a social worker approximately one hour of staff time to compile and review the data in order to align the data with each resident's preferences/goals. This staff time will only be required for those residents who are transferred to another SNF or discharged from the LTC facility. We are unable to determine the average number of residents who are transferred to another SNF or discharged from a LTC facility annually. We believe that a conservative estimate is that if there are an estimated 1,369,700 residents per year in LTC facilities, possibly a third of these residents are discharged or transferred to another SNF on an annual basis. Therefore, we estimate that this requirement will cost $21,244,047 ($47 social worker hourly wage × 1 hour staff time × 452,001 residents discharged or transferred to another SNF annually).

4. Nursing Services (§ 483.35)

We are finalizing our proposal to require facilities to ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments and care plans. This will require facilities to identify, document, and maintain any training, certification, and similar records in an existing personnel file or training record for direct care personnel. This specifically includes nursing services and food and nutrition services but may apply to any direct care provider. We anticipate that any initial competency requirements will be identified by the facility assessment with documentation of individual accomplishments managed by an administrative position, likely an office assistant, as an addition to existing documentation. We believe that this will impose an incremental burden of 8 hours per year per facility to identify and add the additional information to existing files (paper or electronic). We estimate that this requirement will cost $3,881,944 for all LTC facilities ($31 office assistant hourly wage × 8 hours per facility × 15,653 facilities).

5. Food and Nutrition (§ 483.60)

Requirements for Food Service Directors (§ 483.60(a)(2))

We are finalizing our provision to establish requirements for directors of food and nutrition services hired before or after the effective date of these requirements. We require that the director of food and nutrition services be certified as a certified dietary manager, certified food service manager or similar national certification for food service management and safety from a national certifying body; or has an

associate's or higher degree in food service management or hospitality from an accredited institution of higher learning, or meets established state requirements. Many states already establish additional staff qualifications for food service directors and we expect that most facilities already hire food service directors that meet these requirements. In addition, we note that if the facility choses to designate their current food service manager as their director of food and nutrition services, the final rule allows 5 years following the effective date of this final rule for these individuals to comply with these requirements. We do not anticipate that many hiring officials will spend additional time recruiting other appropriate candidates, however we can assume that a small percentage will pursue additional candidates and spend time verifying credentials. For purposes of calculating the anticipated cost, we estimate that 10 percent of facilities will need to hire a director of food and nutrition services after the effective date of this final rule and this will require an additional hour of the NHA's time beyond their current duties related to hiring staff. Based on this information, we estimate that it will cost $133,051 for facilities to comply with this requirement. (($85 NHA hourly wage × 1 hour) × (.1 percentage of affected facilities × 15,653 facilities)).

Menu Options (§ 483.60(c)(4))

We are finalizing our proposal to require facilities to have menus that reflect the cultural and ethnic needs of residents. We expect that facilities will have their menus updated by a qualified dietitian or other clinically qualified nutrition professional in the course of routine reviews and updates. Additional time will include the dietitian or other clinically qualified nutrition professional reviewing the facility assessment for pertinent factors and reviewing and updating the menus. We anticipate this will require 1 to 4 hours, on average 2 hours, depending on the size of the facility and complexity of resident needs. Based on this information, we estimate that it will cost $1,721,830 ($56 dietitian hourly wage × 2 hours × 15,653 facilities) for all LTC facilities to comply with this requirement.

6. QAPI (§ 483.75)

We are finalizing the requirement for facilities to develop a QAPI program. In addition to the QAPI requirement related ICR costs discussed in the COI section, we expect that facilities will incur additional costs that will be dependent upon the projects they selected for their quality improvement activities. In turn, the projects will be dependent upon resident needs, and the type, complexity, and quality of services already provided by the facility. Facilities have the flexibility to determine their quality performance improvement activities based on their assessment of needs of their residents and their prioritized performance improvement projects. For example, a facility that chose, as one of its projects, to improve residents' nutritional status and satisfaction with the facility's food services could incur costs for higher quality, more palatable food. A facility that chose, as one of its projects, to improve nurse aides' interactions with residents suffering from dementia could incur costs for nurse aide training and/or additional nurse aide staffing. A facility that chose, as one of its projects, to improve residents' psychosocial well-being could incur costs for conversion of double rooms to single rooms, and additional social worker, and/or increased social activities for residents. Because the number, degree, and costs of these activities are difficult, if not impossible, to quantify, we have calculated only the cost of the QAPI ICRs ($125,474,448 upfront) that will be associated with the QAPI requirements (discussed in the COI section of the preamble). We estimate that the ongoing annual cost for each facility to comply with the QAPI requirements will be $3,204 for each facility and for all facilities will be $50,152,212 ($3,204 × 15,653). (This discussion is detailed in the COI section.)

7. Infection Control (§ 483.80)

Facilities and their staffs are currently required to have an infection control program (§ 483.65). In this final rule, we have modified our proposal to require each facility to designate one individual as the infection preventionist (IP) for whom the infection prevention and control program (IPCP) is a major responsibility. We have revised the requirement to specify that each facility may designate more than one person as the IP and the IPCP no longer has to be a major responsibility of the individual(s). The IP is responsible for assessing the current program, making any changes to the IPCP necessary to comply with the program's requirements, and implementing and managing the IPCP. This individual will also be required to be a member of the facility's QAA committee. The percentage of a full time equivalent position (FTE) that will be required at each facility will vary greatly. We believe that each facility will have to determine the appropriate percentage based upon it facility assessment, especially its assessment of the acuity of its resident population. A facility with a generally healthy population of elderly individual will likely require many fewer hours than a facility with a large percentage of sub-acute residents or residents that are on ventilators. For the purposes of determining an estimate, we believe that the average facility will designate a RN to be the IP and that individual will need to commit about 15 percent of a FTE to his or her responsibilities under the IPCP. We estimate that this will require 15 percent of one RN FTE for each of the 15,653 facilities for a total cost of $297,907,896 (15% of an RN FTE × $61 average hourly wage for an RN × 2,080 hours (40 hours a week × 52 weeks = 2,080 hours) × 15,653 facilities).

8. Compliance and Ethics Program (§ 483.85)

Compliance Officer and Compliance Liaison Activities

We are finalizing our proposal to require facilities to develop a compliance and ethics program. As discussed in the COI section, we estimate the ICR burden associated with developing this program to be $26,052,468. We estimate that in carrying out this program the compliance officer (similar to an administrator) in each of the 395 organizations operating 5 or more facilities will commit 30 percent of a full time equivalent (FTE) in the compliance program operation, for a total cost of $20,950,800 (30% of FTE × 2080 × $85 × 395). We also estimate that in carrying out this program the compliance liaison (nursing staffs) in each of 6,919 facilities will commit 10 percent of an FTE, at a total cost of $87,788,272 (10% of FTE × 2080 × $61 × 6,919).

Annual Review of Program (483.85(e))

As detailed in the COI section, facilities are required to review their compliance and ethics program annually. Therefore, for subsequent years we estimate to comply with the ICR requirement to review and, if necessary, revise the operating organization's program annually will cost an estimated $6,216,900.

9. Physical Environment (§ 483.90)

Resident Rooms (§ 483.90(d)(1)(i))

For facilities that receive approval of construction or reconstruction plans by state and local authorities or are newly certified or undergoing reconstruction after the effective date of this final rule, we are finalizing our proposal to require

that resident rooms accommodate no more than two residents. A review of CASPER data on the number of new providers per fiscal year from 2008 to 2013 reveals an annually declining number of new facilities, down from 225 new providers in 2008 to 172 in 2012, with only 144 new providers as of August 2013. Of those, the majority were for-profit facilities of 99 beds or less. We further note the overall number of facilities has also declined slightly (by less than 2 percent) but steadily over the same period. A number of states already have similar requirements and represent an average of 7 percent of new providers for the years we reviewed. Therefore, we expect that these requirements will affect fewer than 140 facilities annually. We do not have statistics on the number of providers per year who undertake reconstruction. While we expect that semi-private rooms will increase constructions costs, we are unable to find data regarding the incremental increased cost to the facility of semi-private rooms versus configurations that accommodate up to four residents.

Toilet facilities (§ 483.90(e))

In this final rule, we have removed our proposal to require that for resident rooms newly constructed or undergoing reconstruction, each room must have its own bathroom equipped with at least a commode, sink and shower. We have revised the proposal to require that for newly constructed or newly certified facilities, each bathroom must be equipped with at least a commode and sink. A review of CASPER data on the number of new providers per fiscal year from 2008 to 2013 reveals an annually declining number of new facilities, down from 225 new providers in 2008 to 172 in 2012, with only 144 new providers as of August 2013. Of those, the majority were for-profit facilities of 99 beds or less. We further note the overall number of facilities has also declined slightly (by less than 2 percent) but steadily over the same period. In addition, several states require direct access and limit the number of rooms or residents who may be served by a toilet, lavatory (sink), and/or shower or bath. Given the decline in new facilities and the impact of state regulation, we estimate that this provision will impact fewer than 150 providers per year. While we are aware that ensuring each resident bedroom has an adjacent bathroom may increase construction costs, we were unable to find data regarding neither the number of facilities that do not currently have bathrooms adjacent to each resident room nor the incremental cost of adding bathrooms adjacent to each resident room in new construction.

10. Training Requirements (§ 483.95)

General Training Topics (§ 483.95a)

We are finalizing our proposal to require facilities to develop and/or update training materials to include topics on communication, resident rights, facility obligations, abuse, neglect, exploitation, infection control, and its QAPI program. We require that these training topics be provided for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles and that they be able to demonstrate competency in these topic areas. We also expect each facility to keep a record of these trainings. To reduce regulatory burden and create a reasonable requirement we have not specified the amount or types of training that a facility must provide. There are various free online training tools and resources that facilities can use to assist them in complying with this requirement. For example, the Agency for Healthcare Research and Quality (AHRQ) released a set of training modules to help educate LTC facility staff on key patient safety concepts to improve the safety of LTC facility residents (*http://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/*). In addition to the web based materials, instructor and student handbooks can be sent to facilities at no additional cost. Therefore, we believe that the cost associated with this requirement will be limited to the staff time required to review and update their current training materials.

Based on our experience with facilities, we expect that all facilities have some type of training program. However, we expect that each facility will need to compare their training programs to their facilities assessments as required at § 483.70(e) and ensure they cover the above training topics. We expect that complying with this requirement will require the involvement of a RN and the infection control and prevention officer (ICPO). We expect that a RN will spend more time reviewing, revising and/or developing new sections for the training program. The IP will need to weigh in on the infection control training related topics. We estimate that it will require 8 (6 for the RN ($61/hour) and 2 for the IP ($61/hour)) burden hours for each facility to develop a training program at a cost of $488. Thus, for all facilities to comply, it will cost an estimated $7,638,664 ($488 estimated cost for each facility × 15,653 facilities). We believe that the training will be considered part of regular ongoing training for the staff of each facility.

Compliance and Ethics Program Training (§ 483.95(f))

We require that SNF and NF operating organizations include as part of their compliance and ethics program an effective way to communicate their program's standards, policies, and procedures. We believe that all operating organizations would need to develop training materials and/or other publications to comply with the training requirement. This regulation requires higher standards for organizations operating 5 or more facilities, therefore for the purposes of the RIA our cost estimates differentiate by organization size. We estimate that training staff in organizations operating 1 to 4 facilities will mainly require the duties of a RN at a cost of $900,740 for all 7,765 facilities (6,621 single facilities operating organizations + 1,144 facilities in operating organizations with 2 to 4 facilities = 7,765 facilities) × 2 hours × $61 average hourly wage for a RN = $900,740). For the training in operating organizations with 1 to 4 facilities, we expect that operating organizations will be able to minimize these training costs by including the training on their compliance and ethics program with any current trainings or in-services that they already conduct for their staff. In addition, these facilities could also include this information in publication, print or electronic, that are available to their staff.

We estimate that training staff in organizations operating five or more facilities will require 2 hours of time of a compliance officer (similar to an administrator) conducting the training at the organizational level (387 organizations) at a cost of $61,920 (387 × 2 × $85 = $61,920) and 2 hours of time of a compliance liaison (similar to an RN) at the facility level (7,879 facilities × 2 × $61 = $913,964), for a total cost of $975,884 ($61,920 + $913,964 = $975,884).

Dementia Management and Abuse Prevention Training § 483.95(g)

This final rule will implement section 6121 of the Affordable Care Act which requires dementia management and abuse prevention training to be included in the current mandatory on-going training requirements for nurse aides. In addition, we have also extended this requirement to all direct care staff. Facilities will have the flexibility to determine the length of the training and the format of the training. Since we have

not increased the minimum hours for training, we anticipate that facilitates will maximize their on-going training efforts to improve outcomes through a more efficient training program by modifying their current training program to ensure that all NAs receive annual training in dementia management and abuse prevention. In addition, we believe that the majority of facilities will need to acquire training materials to either update or supplement what they are currently using to train staff. There are numerous online tools available to facilities at no cost. For the sole purpose of complying with section 6121 of the Affordable Care Act and ensuring that nurse aides receive regular training on caring for residents with dementia and on preventing abuse. CMS has published an online hand in hand tool kit that provides a detailed training series for LTC facilities on dementia education and abuse prevention (*http://www.cms-handinhandtoolkit.info/*). CMS, supported by a team of training developers and subject matter experts, created this training to address the need for nurse aides' annual in-service training on these important topics. The mission of the hand in hand training is to provide LTC facilities with a high-quality training program that emphasizes person-centered care in the care of persons with dementia and the prevention of abuse. Given the availability of these materials, we have not assessed a cost burden associated with acquiring training materials for this requirement, however, as discussed in the COI section, we estimate that it will cost facilities an estimated $3,819,332 to review and update their current in-service training material.

11. Administration § 483.70(e)

We are finalizing our requirement for facilities to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. LTC facilities must already determine and plan for what staffing they will need, as well as the other resources that will be required to care for their residents and operate their facilities. Thus, we believe that conducting and documenting a facility assessment is a standard business practice and do not include a burden for this requirement in the impact analysis.

E. Summary of Impacts

We estimate the total projected cost of this final rule will be about $831 million in the first year and $736 million per year for subsequent years. While this is a large amount in total, the average cost per facility is estimated to be approximately $62,900 in the first year and $55,000 in subsequent years. Although the overall magnitude of cost related to this regulation is economically significant, we note that these costs are significantly less than the amount of Medicare and Medicaid spending for LTC services. According to the 2015 Annual Report of the Medicare Trustees, payments for SNF services from Medicare Part A were $29.92 billion for fiscal year 2015 and payments for NF services were $50.6 billion for fiscal year 2013 (see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/2015.html*). Table 5 below presents a summary of the section by section estimated costs to comply with the requirements of this final rule.

TABLE 5—SECTION BY SECTION SUMMARY OF ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS FINAL RULE

Regulatory section	Number of affected entities	Total 1st year cost to all LTC facilities ($ millions)	Total recurring annual cost to all LTC facilities ($ millions)	Estimated recurring annual cost per facility (rounded to the nearest $)
Resident Rights (§ 483.10)	15,653	$166.87	$166.35	$10,627
Admission, Discharge, and Transfer Rights (§ 483.15)	15,653	2.95	2.95	188
Comprehensive Resident Centered Care Planning (§ 483.21)	15,653	86.36	86.36	5,517
Nursing Services (§ 483.35)	15,653	3.88	3.88	248
Food and Nutrition Services (§ 483.60)	15,653	1.85	1.85	118
QAPI (§ 483.75)	15,653	125.47	50.15	3,204
Infection Control (§ 483.80)	15,653	297.91	297.91	19,032
Compliance and Ethics Program	7,314 (operating organizations).	134.79	114.98	15,721
Training (§ 483.95)	15,653	11.46	11.46	732
Total		831.35	735.90	55,388

F. Cost to the Federal Government

As a result of this final rule, CMS will update the interpretive guidance, update the survey process, and make IT systems changes. We anticipate the majority of the system costs will be incurred between FY17 and FY18. In order to implement these new standards, we anticipate initial federal start-up costs between $15 and $20 million. Once implemented, improved surveys to review the new requirements will require an estimated $15 to $20 million annually in federal costs.

G. Benefits of Final Rule

This final rule will implement comprehensive changes intended to update the current requirements for LTC facilities and create new efficiencies and flexibilities for facilities. In addition, these changes will support improved resident quality of life and quality of care. Quality of life in particular can be difficult to translate into dollars saved. However, there is a body of evidence suggesting the factors that improve quality of life may also increase the rate of improvement in quality and can have positive business benefits for facilities. Many of the quality of life improvements changes in this final rule are grounded in the concepts of person-centered care and culture change. These changes not only result in improved quality of life for the resident, they can result in improvements in the caregiver's quality of work life and in savings to the facility. Savings can be accrued through reduced turnover, decreased use of agency labor and decreased worker compensation costs. Although these savings are difficult to

quantify, we believe that they must be lower in magnitude than the costs borne by facilities; otherwise, facilities will change their policies even in the absence of this rulemaking.

In addition to finalizing changes that are likely to have long-term positive impacts on quality of life and quality of care, we have finalized several changes that may mitigate the costs associated with implementing some of our requirements. For example, including the use of electronic health records in these regulations may reduce the burden on facilities when providing a resident with a copy of his or her clinical record. We believe that the option to provide an electronic copy of the record may reduce the amount of time a staff person is taken away from other duties to copy the medical records. To increase access and reduce burden, this final rule allows physicians to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing diet, including therapeutic diets, to the extent allowed by state law. We do not currently have data to estimate the savings that this will produce in SNFs and NFs, however we believe that it will allow for better use of both physician and dietitian time. Likewise, we also allow physicians to delegate to qualified therapists the task of prescribing physical, occupational, speech language, or respiratory therapies, but as with dietitians, we have no empirical evidence with which to quantify a cost savings. Again, however, we believe that this allows better use of both physician and therapist time.

With respect to dental services, we modified the language relating to dental services to remove references to a dentist's office and replace these references to 'dental services location.' This more explicitly accommodates options for dental care such as dental schools or provision of dental hygiene services on site at a facility. Based on the literature we reviewed, improved dental health as a result of improved access to dental care is highly likely to result in improved health and well-being of facility residents, including potentially fewer hospitalizations and less unanticipated weight loss. We have no definitive data on the direct reduction in hospitalizations and other complications stemming from or exacerbated by poor dental care and poor dental hygiene, but given the relationship of poor dental care and poor dental hygiene to other illnesses, savings are quite possible.

We have also made a number of changes in the area of food and nutrition services. These changes are expected to have multiple impacts, ranging from the improved nutritional status of residents to reduced food waste by the facility, to reductions in the incidence of food-borne illness. In FY 2012, there were over 9,000 deficiency citations associated with food and nutrition services. The most commonly cited deficiency in this grouping was, by far, associated with food sanitation. Out of 6,828 surveys, there were 5,490 citations for deficiencies in food procurement, storage, preparation, and service-sanitary, affecting 31.80 percent of providers. The improvements in food and nutrition services from this final rule have the potential to improve resident quality of life while also resulting in a reduced incidence of food-borne illness.[5]

We have also finalized revisions to strengthen requirements related to infection control. While a reduction in the incidence of healthcare associated infections will likely impact hospitalization of residents, as discussed below, it will also impact the care required for residents who remain in the facility. An effective infection prevention and control program can, among other benefits, identify infections early and prevent their spread. Several illness-causing organisms are of particular concern in LTC facilities. For example, Norovirus may cause illness following a very low infection dose. The illness is characterized by nausea, sudden onset of projectile vomiting (particularly in children), watery, non-bloody diarrhea, abdominal cramping, chills, body aches and fatigue. Dehydration is a common complication, especially in the elderly. The illness usually lasts 2 to 3 days. Outbreaks can impact residents and/or staff and cause significant inconvenience and cost. (Overview of the management of norovirus outbreaks in hospitals and nursing homes, compiled by the Wisconsin Division of Public Health, Bureau of Communicable Diseases, Communicable Disease Epidemiology Section, February 2004. Retrieved from *http://www.publichealthmdc.com/environmental/food/documents/ManagementofNorovirusInfectionOutbreaksinHospitalsandNursingHomes.pdf*). These illnesses can result in higher acuity of residents and increased care needs as well as increased use of either overtime or temporary staff to replace ill staff. Improved prevention, detection, and mitigation of illnesses can result in substantial savings to a facility. Unfortunately, specific rates of infection and the associated cost to treat residents or to replace absent staff have not been clearly quantified in available literature or data.

We note that the revisions in this final rule also target reducing avoidable or unnecessary hospitalizations. We are finalizing revisions regarding improved communication of critical information, competency-based care assignments, training, and systemic quality improvement. We believe that even a small reduction in the number of unnecessary hospitalizations could result in substantial savings.

Overall, we believe that this final rule will address a number of the shortcomings of the existing LTC requirements identified by stakeholders and experts. Unfortunately, without a predicted change in behavior or outcomes, we are unable to quantify the benefits of the final rule.

H. Alternatives Considered

As discussed previously, some of these provisions are mandated under the Affordable Care Act and the IMPACT Act, therefore, no major alternatives were considered. We could have finalized only those requirements that are required by statute, which would be a less burdensome approach on the LTC community. However despite the many changes in the delivery of health care services, the requirements for LTC care facilities have not been comprehensively updated in many years and our revisions address several issues, such as avoidable hospitalizations, staffing concerns, infection control, and behavioral health. In addition, we believe that it is necessary to modernize the regulations to reflect advances such as electronic communications and health information technology. Overall, we believe that finalizing a general reorganization and comprehensive revision will ensure that the requirements are consistent with current standards of practice and continue to meet statutory obligations, while also assisting individuals who are less familiar with these regulations to find information within the requirements. Therefore, we determined

[5] It is logical to assume that the requirement for nursing, food service and other competency either necessitates hiring more competent staff who command a higher wage—the cost of which would be included in the cost section—or the competency provision is essentially unnecessary because staff are already competent—in which case, there would be no benefits to facilities or their residents. As regards the menu options provision, the cost section mentions two hours of effort per facility. It might be plausible that a two-hour review would be sufficient to confirm that there is nothing in need of revision (in which case there are no benefits). However, if a review uncovers that there is potential for benefits due to menu revisions, then there will be further costs, such as training for food service workers or higher costs of raw ingredients.

it is most effective to make comprehensive changes at this time.

We considered alternatives to competency-based staffing requirement and looked closely at suggestions from commenters to establish and require minimum staffing levels and a RN 24 hours a day, 7 days a week in the nursing facility. We have begun voluntary payroll-based collection of staffing information from LTC facilities, and are preparing to begin mandatory collection of payroll-based staffing information from LTC facilities. The staff covered includes registered nurses, licensed practical or vocational nurses, certified nursing assistants, or other types of medical personnel as specified by CMS, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day. Ultimately, we believe this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue and have decided not to pursue staffing minimums at this time. We also considered modifying, rather than removing, our proposal to require an in-person evaluation by a physician before a resident is transferred to a hospital by indicating that a RN, in consultation with a physician, could perform the evaluation. However, based on the concerns raised by commenters regarding access to physicians and emergency situations, we determined it was best to withdraw the proposal.

For all provisions, we extensively reviewed the public comments and made revisions where possible to improve readability, provide clarity, increase flexibility, and reduce burden by avoiding any unnecessarily costly requirements.

I. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/omb/circulars_a004_a-4*), we have prepared an accounting statement.

TABLE 6—ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Benefits:				
Qualitative	Improve in quality of life and quality of care.			
Costs:				
Annualized Monetized ($million/year)	758	2015	7	2016–2020.
	756	2015	3	2016–2020.
Qualitative	Unquantified possible cost associated with the bathroom requirement.			

Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most LTC facilities are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of nursing and residential care facilities are small entities; either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business having revenues of less than $25.5 million in any 1 year (see the SBA's Web site at *http://www.sba.gov/content/small-business-size-standards*). As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because the impact associated with the provision will be less than 1 percent of the revenue of the nursing facilities. According to a report by Kaiser Family Foundation published in 2015, the annual national spending on nursing facilities across all payers totaled $155.8 billion in 2013 (*http://kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-introduction/*). With the number of nursing facilities around 15,600, the average annual revenue of a nursing facility is about $10 million. The annual impact on a nursing facility would be around $63,000 in year 1 and $55,000 in year 2 and thereafter (see Table 5 of this section), so the average impact on the facility is less than 1 percent of revenue. Therefore, we have determined and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. We note that the proposed rule, see 80 FR 42168 (July 16, 2015), incorrectly identified that the proposed rule would have a significant economic impact on a substantial number of small entities. The inclusion of this statement was an oversight.

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 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. This final rule pertains solely to SNFs and NFs. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Unfunded Mandates Reform Act

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 2016, that is approximately $146 million. This final rule contains mandates that will impose a one-time cost of about $831 million. Thus, we have assessed the various costs and benefits of this final rule. This final rule will not mandate any new requirements for state, local or tribal governments. For the private sector facilities, the regulatory impact section, together with the remainder of the preamble, constitutes the analysis required under UMRA.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have Federalism implications as defined in the Executive Order 13132 and, consequently, a Federalism summary impact statement is not required.

Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

K. Conclusion

The requirements in this final rule will update the existing requirements for long-term care facilities to reflect current standards of practice. In addition, the revisions will provide added flexibility to providers, potentially improve efficiency and effectiveness, potentially enhance resident quality of care and quality of life, and potentially improve clinical outcomes. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

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

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 405.926 [Amended]

■ 2. In § 405.926, amend paragraph (f) by removing the reference ''§ 483.12'' and add in its place, the reference ''§§ 483.5(n) and 483.15''.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 3. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

§ 431.206 [Amended]

■ 4. In § 431.206, amend paragraph (c)(3) by removing the reference ''§ 483.12'' and adding in its place the reference ''§ 483.15''.

§ 431.213 [Amended]

■ 5. In § 431.213, amend paragraph (h) by removing reference ''§ 483.12 (a)(5)(ii)'' and adding in its place the reference ''§ 483.15(b)(4)(ii) and (b)(8)'' and by removing the reference ''§ 483.12 (a)(5)(i)'' and adding in its place the reference ''§ 483.15(b)(4)(i) of this chapter''.

PART 447—PAYMENTS FOR SERVICES

■ 6. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 447.253 [Amended]

■ 7. In § 447.253, amend paragraph (b)(1)(iii)(B) by removing the reference ''§ 483.30(c)'' and adding in its place the reference ''§ 483.35(e)''.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 8. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 9. In § 482.58, paragraphs (b)(1) through (8) are revised to read as follows:

§ 482.58 Special requirements for hospital providers of long-term care services (''swing-beds'').

* * * * *

(b) * * *

(1) Resident rights (§ 483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), (f)(4)(i), (f)(4)(iii), (f)(9), (h)(2), and (h)(3) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.15(c), § 483.15(c)(1), (c)(2), (c)(3)(i) through (iii), (c)(4), (c)(5)(i) through (vii), and (c)(7) of this chapter).

(3) Freedom from abuse, neglect and exploitation (§ 483.12 of this chapter).

(4) Patient activities (§ 483.24(c) of this chapter).

(5) Social services (§ 483.40(d) and § 483.70(p) of this chapter).

(6) Discharge planning (§ 483.21 of this chapter).

(7) Specialized rehabilitative services (§ 483.65 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 10. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 11. Section 483.1 is amended by revising paragraphs (a)(1) introductory text, (a)(3), and (b) and adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 483.1 Basis and scope.

(a) * * *

(1) Sections 1819(a), (b), (c), (d), and (f) of the Act provide that—

* * * * *

(3) Sections 1919(a), (b), (c), (d), and (f) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(4) Sections 1128I(b) and (c) require that—

(i) Skilled nursing facilities or nursing facility have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.

(ii) The Secretary establish and implement a quality assurance and performance improvement program for facilities, including multi-unit chains of facilities.

(5) Section 1150B establishes requirements for reporting to law enforcement crimes occurring in federally funded LTC facilities.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

■ 12. Section 483.5 is amended by—

■ a. Removing the paragraph designations for paragraphs (a), (b), (c), (d), (e), and (f) and placing the definitions in alphabetical order.

■ b. Adding introductory text.

■ c. Revising the definition of ''common area''.

■ d. Amending the definition of ''Composite distinct part'' by adding paragraph (2)(v).

■ e. Amending the definition of ''Facility'' by removing the italicized word ''*defined*''.

■ f. Adding the new definitions of ''Abuse'', ''Adverse event'', ''Exploitation'', ''Licensed health professional'', ''Misappropriation of resident property'', ''Mistreatment'', ''Neglect'', ''Nurse aide'', ''Person-centered care'', ''Resident representative'', ''Sexual abuse'', and ''Transfer and discharge'' in alphabetical order.

The revisions and additions read as follows:

§ 483.5 Definitions.

As used in this subpart, the following definitions apply:

Abuse. Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful,* as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

Adverse event. An adverse event is an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

Common area. Common areas are areas in the facility where residents may gather together with other residents, visitors, and staff or engage in individual pursuits, apart from their residential rooms. This includes but is not limited to living rooms, dining rooms, activity rooms, outdoor areas, and meeting rooms where residents are located on a regular basis.

Composite distinct part. * * *

(2) * * *

(v) Use of composite distinct parts to segregate residents by payment source or on a basis other than care needs is prohibited.

* * * * *

Exploitation. Exploitation means taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.

* * * * *

Licensed health professional. A licensed health professional is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.

* * * * *

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.

Mistreatment means inappropriate treatment or exploitation of a resident.

Neglect is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

Nurse aide. A nurse aide is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

Person-centered care. For purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.

Resident representative. For purposes of this subpart, the term resident representative means any of the following:

(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(3) Legal representative, as used in section 712 of the Older Americans Act; or.

(4) The court-appointed guardian or conservator of a resident.

(5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.

Sexual abuse is non-consensual sexual contact of any type with a resident.

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed

is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

■ 13. Section 483.10 is revised to read as follows:

§ 483.10 Resident rights.

(a) *Residents Rights.* The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility, including those specified in this section.

(1) A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life, recognizing each resident's individuality. The facility must protect and promote the rights of the resident.

(2) The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source.

(b) *Exercise of rights.* The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(1) The facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart.

(3) In the case of a resident who has not been adjudged incompetent by the state court, the resident has the right to designate a representative, in accordance with State law and any legal surrogate so designated may exercise the resident's rights to the extent provided by state law. The same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.

(i) The resident representative has the right to exercise the resident's rights to the extent those rights are delegated to the resident representative.

(ii) The resident retains the right to exercise those rights not delegated to a resident representative, including the right to revoke a delegation of rights, except as limited by State law.

(4) The facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law.

(5) The facility shall not extend the resident representative the right to make decisions on behalf of the resident beyond the extent required by the court or delegated by the resident, in accordance with applicable law.

(6) If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law.

(7) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law

(i) In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

(ii) The resident's wishes and preferences must be considered in the exercise of rights by the representative.

(iii) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.

(c) *Planning and implementing care.* The resident has the right to be informed of, and participate in, his or her treatment, including:

(1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

(2) The right to participate in the development and implementation of his or her person-centered plan of care, including but not limited to:

(i) The right to participate in the planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care.

(ii) The right to participate in establishing the expected goals and outcomes of care, the type, amount, frequency, and duration of care, and any other factors related to the effectiveness of the plan of care.

(iii) The right to be informed, in advance, of changes to the plan of care.

(iv) The right to receive the services and/or items included in the plan of care.

(v) The right to see the care plan, including the right to sign after significant changes to the plan of care.

(3) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right. The planning process must—

(i) Facilitate the inclusion of the resident and/or resident representative.

(ii) Include an assessment of the resident's strengths and needs.

(iii) Incorporate the resident's personal and cultural preferences in developing goals of care.

(4) The right to be informed, in advance, of the care to be furnished and the type of care giver or professional that will furnish care.

(5) The right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers.

(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.

(7) The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.

(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate.

(d) *Choice of attending physician.* The resident has the right to choose his or her attending physician.

(1) The physician must be licensed to practice, and

(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

(3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet

requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

(e) *Respect and dignity.* The resident has a right to be treated with respect and dignity, including:

(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with § 483.12(a)(2).

(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(3) The right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents.

(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(5) The right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement.

(6) The right to receive written notice, including the reason for the change, before the resident's room or roommate in the facility is changed.

(7) The right to refuse to transfer to another room in the facility, if the purpose of the transfer is:

(i) To relocate a resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) to relocate a resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(iii) solely for the convenience of staff.

(8) A resident's exercise of the right to refuse transfer does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.

(f) *Self-determination.* The resident has the right to and the facility must promote and facilitate resident self-determination through support of resident choice, including but not limited to the rights specified in paragraphs (f)(1) through (11) of this section.

(1) The resident has a right to choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, plan of care and other applicable provisions of this part.

(2) The resident has the right to make choices about aspects of his or her life in the facility that are significant to the resident.

(3) The resident has a right to interact with members of the community and participate in community activities both inside and outside the facility.

(4) The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.

(i) The facility must provide immediate access to any resident by—

(A) Any representative of the Secretary,

(B) Any representative of the State,

(C) Any representative of the Office of the State long term care ombudsman, (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*),

(D) The resident's individual physician,

(E) Any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*),

(F) Any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), and

(G) The resident representative.

(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;

(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;

(iv) The facility must provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and

(v) The facility must have written policies and procedures regarding the visitation rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation, when such limitations may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation.

(vi) A facility must meet the following requirements:

(A) Inform each resident (or resident representative, where appropriate) of his or her visitation rights and related facility policy and procedures, including any clinical or safety restriction or limitation on such rights, consistent with the requirements of this subpart, the reasons for the restriction or limitation, and to whom the restrictions apply, when he or she is informed of his or her other rights under this section.

(B) Inform each resident of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse (including a same-sex spouse), a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(C) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(D) Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.

(5) The resident has a right to organize and participate in resident groups in the facility.

(i) The facility must provide a resident or family group, if one exists, with private space; and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.

(ii) Staff, visitors, or other guests may attend resident group or family group meetings only at the respective group's invitation.

(iii) The facility must provide a designated staff person who is approved by the resident or family group and the facility and who is responsible for providing assistance and responding to written requests that result from group meetings.

(iv) The facility must consider the views of a resident or family group and act promptly upon the grievances and

recommendations of such groups concerning issues of resident care and life in the facility.

(A) The facility must be able to demonstrate their response and rationale for such response.

(B) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

(6) The resident has a right to participate in family groups.

(7) The resident has a right to have family member(s) or other resident representative(s) meet in the facility with the families or resident representative(s) of other residents in the facility.

(8) The resident has a right to participate in other activities, including social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(9) The resident has a right to choose to or refuse to perform services for the facility and the facility must not require a resident to perform services for the facility. The resident may perform services for the facility, if he or she chooses, when—

(i) The facility has documented the resident's need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(10) The resident has a right to manage his or her financial affairs. This includes the right to know, in advance, what charges a facility may impose against a resident's personal funds.

(i) The facility must not require residents to deposit their personal funds with the facility. If a resident chooses to deposit personal funds with the facility, upon written authorization of a resident, the facility must act as a fiduciary of the resident's funds and hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in this section.

(ii) *Deposit of funds.* (A) In general: Except as set out in paragraph (f)(10)(ii)(B) of this section, the facility must deposit any residents' personal funds in excess of $100 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain a resident's personal funds that do not exceed $100 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(B) Residents whose care is funded by Medicaid: The facility must deposit the residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(iii) *Accounting and records.* (A) The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(B) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(C) The individual financial record must be available to the resident through quarterly statements and upon request.

(iv) *Notice of certain balances.* The facility must notify each resident that receives Medicaid benefits—

(A) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(B) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(v) Conveyance upon discharge, eviction, or death. Upon the discharge, eviction, or death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the resident, or in the case of death, the individual or probate jurisdiction administering the resident's estate, in accordance with State law.

(vi) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(11) The facility must not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with § 489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See § 447.15 of this chapter, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities must not charge a resident for the following categories of items and services:

(A) Nursing services as required at § 483.35.

(B) Food and Nutrition services as required at § 483.60.

(C) An activities program as required at § 483.24(c).

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing assistance, and basic personal laundry.

(F) Medically-related social services as required at § 483.40(d).

(G) Hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan.

(ii) *Items and services that may be charged to residents' funds.* Paragraphs (f)(11)(ii)(A) through (L) of this section are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if they are not required to achieve the goals stated in the resident's care plan, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone, including a cellular phone.

(B) Television/radio, personal computer or other electronic device for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Cost to participate in social events and entertainment outside the scope of the activities program, provided under § 483.24(c).

(J) Non-covered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Except as provided in (e)(11)(ii)(L)(*1*) and (2) of this section, specially prepared or alternative food requested instead of the food and meals generally prepared by the facility, as required by § 483.60.

(*1*) The facility may not charge for special foods and meals, including medically prescribed dietary supplements, ordered by the resident's physician, physician assistant, nurse practitioner, or clinical nurse specialist, as these are included in accordance with § 483.60.

(*2*) In accordance with § 483.60(c) through (f), when preparing foods and meals, a facility must take into consideration residents' needs and preferences and the overall cultural and religious make-up of the facility's population.

(iii) *Requests for items and services.* (A) The facility can only charge a resident for any non-covered item or service if such item or service is specifically requested by the resident.

(B) The facility must not require a resident to request any item or service as a condition of admission or continued stay.

(C) The facility must inform, orally and in writing, the resident requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

(g) *Information and communication.* (1) The resident has the right to be informed of his or her rights and of all rules and regulations governing resident conduct and responsibilities during his or her stay in the facility.

(2) The resident has the right to access personal and medical records pertaining to him or herself.

(i) The facility must provide the resident with access to personal and medical records pertaining to him or herself, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, within 24 hours (excluding weekends and holidays); and

(ii) The facility must allow the resident to obtain a copy of the records or any portions thereof (including in an electronic form or format when such records are maintained electronically) upon request and 2 working days advance notice to the facility. The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:

(A) Labor for copying the records requested by the individual, whether in paper or electronic form;

(B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C) Postage, when the individual has requested the copy be mailed.

(3) With the exception of information described in paragraphs (g)(2) and (g)(11) of this section, the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (g)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.

(4) The resident has the right to receive notices orally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including;

(i) *Required notices as specified in this section.* The facility must furnish to each resident a written description of legal rights which includes—

(A) A description of the manner of protecting personal funds, under paragraph (f)(10) of this section;

(B) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment of resources under section 1924(c) of the Social Security Act.

(C) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State regulatory and informational agencies, resident advocacy groups such as the State Survey Agency, the State licensure office, the State Long-Term Care Ombudsman program, the protection and advocacy agency, adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community and the Medicaid Fraud Control Unit; and

(D) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(ii) Information and contact information for State and local advocacy organizations, including but not limited to the State Survey Agency, the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*);

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program

(v) Contact information for the Medicaid Fraud Control Unit; and

(vi) Information and contact information for filing grievances or complaints concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(5) The facility must post, in a form and manner accessible and understandable to residents, and resident representatives:

(i) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State agencies and advocacy groups, such as the State Survey Agency, the State licensure office, adult protective services where state law provides for jurisdiction in long-term care facilities, the Office of the State Long-Term Care Ombudsman program, the protection and advocacy

network, home and community based service programs, and the Medicaid Fraud Control Unit; and

(ii) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements (42 CFR part 489 subpart I) and requests for information regarding returning to the community.

(6) The resident has the right to have reasonable access to the use of a telephone, including TTY and TDD services, and a place in the facility where calls can be made without being overheard. This includes the right to retain and use a cellular phone at the resident's own expense.

(7) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, including reasonable access to:

(i) A telephone, including TTY and TDD services;

(ii) The internet, to the extent available to the facility; and

(iii) Stationery, postage, writing implements and the ability to send mail.

(8) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

(9) The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for Internet research.

(i) If the access is available to the facility

(ii) At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

(iii) Such use must comply with state and federal law.

(10) The resident has the right to—

(i) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility; and

(ii) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(11) The facility must—

(i) Post in a place readily accessible to residents, and family members and legal representatives of residents, the results of the most recent survey of the facility.

(ii) Have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years, and any plan of correction in effect with respect to the facility, available for any individual to review upon request; and

(iii) Post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

(iv) The facility shall not make available identifying information about complainants or residents.

(12) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives).

(i) These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the resident's option, formulate an advance directive.

(ii) This includes a written description of the facility's policies to implement advance directives and applicable State law.

(iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.

(iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law.

(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(13) The facility must display in the facility written information, and provide to residents and applicants for admission, oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(14) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s), when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (that is, a need to discontinue or change an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.15(c)(1)(ii).

(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in § 483.15(c)(2) is available and provided upon request to the physician.

(iii) The facility must also promptly notify the resident and the resident representative, if any, when there is—

(A) A change in room or roommate assignment as specified in § 483.10(e)(6); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section.

(iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s).

(15) *Admission to a composite distinct part.* A facility that is a composite distinct part (as defined in § 483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under § 483.15(c)(9).

(16) The facility must provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay.

(i) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.

(ii) The facility must also provide the resident with the State-developed notice of Medicaid rights and obligations, if any.

(iii) Receipt of such information, and any amendments to it, must be acknowledged in writing;

(17) The facility must—

(i) Inform each Medicaid-eligible resident, in writing, at the time of

admission to the nursing facility and when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in § 483.10(g)(17)(i)(A) and (B) of this section.

(18) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible.

(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.

(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.

(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility.

(v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.

(h) *Privacy and confidentiality.* The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

(2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

(3) The resident has a right to secure and confidential personal and medical records.

(i) The resident has the right to refuse the release of personal and medical records except as provided at § 483.70(i)(2) or other applicable federal or state laws.

(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

(i) *Safe environment.* The resident has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatment and supports for daily living safely. The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible.

(i) This includes ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk.

(ii) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.90(d)(2)(iv);

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71 to 81 °F; and

(7) For the maintenance of comfortable sound levels.

(j) *Grievances.* (1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay.

(2) The resident has the right to and the facility must make prompt efforts by the facility to resolve grievances the resident may have, in accordance with this paragraph.

(3) The facility must make information on how to file a grievance or complaint available to the resident.

(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in this paragraph. Upon request, the provider must give a copy of the grievance policy to the resident. The grievance policy must include:

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

(ii) Identifying a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through to their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations;

(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;

(iv) Consistent with § 483.12(c)(1), immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services

on behalf of the provider, to the administrator of the provider; and as required by State law;

(v) Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued;

(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State Survey Agency, Quality Improvement Organization, or local law enforcement agency confirms a violation of any of these residents' rights within its area of responsibility; and

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than 3 years from the issuance of the grievance decision.

(k) *Contact with external entities.* A facility must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman, and any representative of the agency responsible for the protection and advocacy system for individuals with mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

■ 14. Section 483.12 is revised to read as follows:

§ 483.12 Freedom from abuse, neglect, and exploitation.

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

(a) The facility must—

(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

(3) Not employ or otherwise engage individuals who—

(i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

(ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property; or

(iii) Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.

(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations, and

(3) Include training as required at paragraph § 483.95.

(4) Establish coordination with the QAPI program required under § 483.75.

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

§ 483.13 [Removed]

■ 15. Remove § 483.13.

■ 16. Section 483.15 is revised to read as follows:

§ 483.15 Admission, transfer, and discharge rights.

(a) *Admissions policy.* (1) The facility must establish and implement an admissions policy.

(2) The facility must—

(i) Not request or require residents or potential residents to waive their rights as set forth in this subpart and in applicable state, federal or local licensing or certification laws, including but not limited to their rights to Medicare or Medicaid; and

(ii) Not request or require oral or written assurance that residents or potential residents are not eligible for,

or will not apply for, Medicare or Medicaid benefits.

(iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property

(3) The facility must not request or require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may request and require a resident representative who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(4) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term ''nursing facility services'' so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(5) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

(6) A nursing facility must disclose and provide to a resident or potential resident prior to time of admission, notice of special characteristics or service limitations of the facility.

(7) A nursing facility that is a composite distinct part as defined in § 483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (b)(10) of this section.

(b) *Equal access to quality care.* (1) A facility must establish, maintain and implement identical policies and practices regarding transfer and discharge, as defined in § 483.5 and the provision of services for all individuals regardless of source of payment, consistent with § 483.10(a)(2); (2) The facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law and consistent with the notice requirement in § 483.10(g)(3) and (g)(4)(i) describing the charges; and

(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(c) *Transfer and discharge*—(1) *Facility requirements*—

(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

(D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

(2) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (b)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the residents discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

(3) *Notice before transfer.* Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

(ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

(iii) Include in the notice the items described in paragraph (b)(5) of this section.

(4) *Timing of the notice.* (i) Except as specified in paragraphs (b)(4)(ii) and (b)(8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice must be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered under paragraph (b)(1)(ii)(C) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (b)(1)(ii)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (b)(1)(ii)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (b)(1)(ii)(A) of this section; or

(E) A resident has not resided in the facility for 30 days.

(5) *Contents of the notice.* The written notice specified in paragraph (b)(3) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

(v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

(vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106–402, codified at 42 U.S.C. 15001 *et seq.*); and

(vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

(6) *Changes to the notice.* If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

(7) *Orientation for transfer or discharge.* A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

(8) *Notice in advance of facility closure.* In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(l).

(9) *Room changes in a composite distinct part.* Room changes in a facility that is a composite distinct part (as defined in § 483.5) are subject to the requirements of § 483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

(d) *Notice of bed-hold policy and return*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave, the nursing facility must provide written information to the resident or resident representative that specifies—

(i) The duration of the state bed-hold policy, if any, during which the resident is permitted to return and resume residence in the nursing facility;

(ii) The reserve bed payment policy in the state plan, under § 447.40 of this chapter, if any;

(iii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (c)(3) of this section, permitting a resident to return; and

(iv) The information specified in paragraph (c)(3) of this section.

(2) *Bed-hold notice upon transfer.* At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and the resident representative written notice which specifies the duration of the bed-hold policy described in paragraph (c)(1) of this section.

(e)(1) *Permitting residents to return to facility.* A facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.

(i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, returns to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident

(A) Requires the services provided by the facility; and

(B) Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.

(ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

(2) *Readmission to a composite distinct part.* When the facility to which a resident returns is a composite distinct part (as defined in § 483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of return, the resident must be given the option to return to that location upon the first availability of a bed there.

§ 483.20 [Amended]

■ 17. In § 483.20—

■ a. Revise paragraph (b)(1) introductory text.

■ b. Revise paragraphs (b)(1)(xvi) and (xviii).

■ c. Revise paragraph (e).

■ d. Remove paragraphs (k) and (l).

■ e. Redesignate paragraph (m) as paragraph (k).

■ f. Revise newly designated paragraph (k).

The revisions read as follows:

§ 483.20 Resident assessment.

* * * * *

(b) * * *

(1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:

* * * * *

(xvi) Discharge planning.

* * * * *

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as

well as communication with licensed and nonlicensed direct care staff members on all shifts.

* * * * *

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes—

(1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

(2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

* * * * *

(k) *Preadmission screening for individuals with a mental disorder and individuals with intellectual disability.* (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental disorder as defined in paragraph (k)(3)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Intellectual disability, as defined in paragraph (k)(3)(ii) of this section, unless the State intellectual disability or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

(2) *Exceptions.* For purposes of this section—

(i) The preadmission screening program under paragraph (k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under paragraph (k)(1) of this section to the admission to a nursing facility of an individual—

(A) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,

(B) Who requires nursing facility services for the condition for which the individual received care in the hospital, and

(C) Whose attending physician has certified, before admission to the facility that the individual is likely to require less than 30 days of nursing facility services.

(3) *Definition.* For purposes of this section—

(i) An individual is considered to have a mental disorder if the individual has a serious mental disorder as defined in § 483.102(b)(1).

(ii) An individual is considered to have an intellectual disability if the individual has an intellectual disability as defined in § 483.102(b)(3) or is a person with a related condition as described in § 435.1010 of this chapter.

(4) A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has a mental disorder or intellectual disability for resident review.

■ 18. Section 483.21 is added to read as follows:

§ 483.21 Comprehensive person-centered care planning.

(a) *Baseline care plans.* (1) The facility must develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care. The baseline care plan must—

(i) Be developed within 48 hours of a resident's admission.

(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to:

(A) Initial goals based on admission orders.

(B) Physician orders.

(C) Dietary orders.

(D) Therapy services.

(E) Social services.

(F) PASARR recommendation, if applicable.

(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan—

(i) Is developed within 48 hours of the resident's admission.

(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

(3) The facility must provide the resident and their representative with a summary of the baseline care plan that includes but is not limited to:

(i) The initial goals of the resident.

(ii) A summary of the resident's medications and dietary instructions.

(iii) Any services and treatments to be administered by the facility and personnel acting on behalf of the facility.

(iv) Any updated information based on the details of the comprehensive care plan, as necessary.

(b) *Comprehensive care plans.* (1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at § 483.10(c)(2) and § 483.10(c)(3, that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following:

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 483.24, § 483.25, or § 483.40; and

(ii) Any services that would otherwise be required under § 483.24, § 483.25, or § 483.40 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(c)(6).

(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(iv) In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to—

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

(i) Meet professional standards of quality.

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be culturally-competent and trauma–informed.

(c) *Discharge planning*—(1) *Discharge planning process.* The facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must be consistent with the discharge rights set forth at § 483.15(b) as applicable and—

(i) Ensure that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident.

(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(iii) Involve the interdisciplinary team, as defined by § 483.21(b)(2)(ii), in the ongoing process of developing the discharge plan.

(iv) Consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs.

(v) Involve the resident and resident representative in the development of the discharge plan and inform the resident and resident representative of the final plan.

(vi) Address the resident's goals of care and treatment preferences.

(vii) Document that a resident has been asked about their interest in receiving information regarding returning to the community.

(A) If the resident indicates an interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose.

(B) Facilities must update a resident's comprehensive care plan and discharge plan, as appropriate, in response to information received from referrals to local contact agencies or other appropriate entities.

(C) If discharge to the community is determined to not be feasible, the facility must document who made the determination and why.

(viii) For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available. The facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences.

(ix) Document, complete on a timely basis based on the resident's needs, and include in the clinical record, the evaluation of the resident's discharge needs and discharge plan. The results of the evaluation must be discussed with the resident or resident's representative. All relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

(2) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

(ii) A final summary of the resident's status to include items in paragraph (b)(1) of § 483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

■ 19. Section 483.24 is added to read as follows:

§ 483.24 Quality of life.

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

(a) Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes the facility ensuring that:

(1) A resident is given the appropriate treatment and services to maintain or improve his or her ability to carry out the activities of daily living, including those specified in paragraph (b) of this section,

(2) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene, and

(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives.

(b) *Activities of daily living.* The facility must provide care and services in accordance with paragraph (a) of this section for the following activities of daily living:

(1) Hygiene—bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation, including walking,

(3) Elimination—toileting,

(4) Dining—eating, including meals and snacks,

(5) Communication, including

(i) Speech,

(ii) Language,

(iii) Other functional communication systems.

(c) *Activities.* (1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.

(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—

(i) Is licensed or registered, if applicable, by the State in which practicing; and

(ii) Is:

(A) Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(B) Has 2 years of experience in a social or recreational program within the last 5 years, one of which was full-time in a therapeutic activities program; or

(C) Is a qualified occupational therapist or occupational therapy assistant; or

(D) Has completed a training course approved by the State.

■ 20. Section 483.25 is revised to read as follows:

§ 483.25 Quality of care.

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following:

(a) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(b) *Skin integrity*—(1) *Pressure ulcers.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

(ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

(2) *Foot care.* To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must—

(i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

(c) *Mobility.* (1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.

(d) *Accidents.*The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(e) *Incontinence.* (1) The facility must ensure that a resident who is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.

(2) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—

(i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary, and

(iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible.

(3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

(f) *Colostomy, urostomy, or ileostomy care.* The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(g) *Assisted nutrition and hydration.* (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

(2) Is offered sufficient fluid intake to maintain proper hydration and health; and

(3) Is offered a therapeutic diet when there is a nutritional problem and the

health care provider orders a therapeutic diet.

(4) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and

(5) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

(h) *Parenteral fluids.* Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

(i) *Respiratory care, including tracheostomy care and tracheal suctioning.* The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and § 483.65 of this subpart.

(j) *Prostheses.* The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences, to wear and be able to use the prosthetic device.

(k) *Pain management.* The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(l) *Dialysis.* The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(m) *Trauma-informed care.* The facility must ensure that residents who are trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.

(n) *Bed rails.* The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

(1) Assess the resident for risk of entrapment from bed rails prior to installation.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

■ 21. In the table below, each section indicated in the first column is re-designated as the section indicated in the second column:

Existing CFR section	New CFR section
§ 483.30	§ 483.35
§ 483.35	§ 483.60
§ 483.40	§ 483.30
§ 483.45	§ 483.65
§ 483.60	§ 483.45
§ 483.65	§ 483.80
§ 483.70	§ 483.90
§ 483.75	§ 483.70

■ 22. In newly redesignated § 483.30—
■ a. Revise the introductory text.
■ b. Revise paragraph (b)(3).
■ c. Amend paragraph (e)(1) introductory text by removing the reference ''paragraph (e)(2)'' and adding in its place the reference ''paragraph (e)(4)''.
■ d. Resignate paragraph (e)(2) as paragraph (e)(4).
■ e. Add new paragraphs (e)(2) and (e)(3).

The revisions and additions read as follows:

§ 483.30 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

* * * * *

(b) * * *

(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

* * * * *

(e) * * *

(2) A resident's attending physician may delegate the task of writing dietary orders, consistent with § 483.60, to a qualified dietitian or other clinically qualified nutrition professional who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

(3) A resident's attending physician may delegate the task of writing therapy orders, consistent with § 483.65, to a qualified therapist who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

* * * * *

■ 23. In newly redesignated § 483.35—
■ a. Revise the introductory text.
■ b. Amend paragraph (a)(1)(i) by removing the reference ''paragraph (c)'' and adding in its place the reference ''paragraph (e)''.
■ c. Revise paragraph (a)(1)(ii).
■ d. Add paragraphs (a)(3) and (4).
■ e. Amend paragraphs (b)(1) and (b)(2) by removing the reference ''paragraph (c) or (d)'' and adding in its place the reference ''paragraph (e) or (f)''.
■ f. Redesignate paragraphs (c), (d) and (e) as paragraphs (e), (f), and (g), respectively.
■ g. Add new paragraphs (c) and (d).
■ h. Revise newly redesignated paragraphs (e)(6) and (7).
■ i. Revise newly redesignated paragraphs (f)(1)(iv) and (v).

The revisions and additions read as follows:

§ 483.35 Nursing services.

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e).

(a) * * *

(1) * * *

(ii) Other nursing personnel, including but not limited to nurse aides.

* * * * *

(3) The facility must ensure that licensed nurses have the specific

competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.

* * * * *

(c) *Proficiency of nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(d) *Requirements for facility hiring and use of nursing aides* —(1) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless—

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154; or

(B) That individual has been deemed or determined competent as provided in § 483.150(a) and (b).

(2) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (d)(1) (i) and (ii) of this section.

(3) *Minimum competency.* A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in § 483.150(a) and (b).

(4) *Registry verification.* Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(5) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

(6) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(7) *Regular in-service education.* The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. In-service training must comply with the requirements of § 483.95(g).

(e) * * *

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

(f) * * *

(1) * * *

(iv) The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental disorders; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

* * * * *

■ 24. A new § 483.40 is added to read as follows:

§ 483.40 Behavioral health services.

Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with § 483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to § 483.70(e), and

(2) Implementing non-pharmacological interventions.

(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays or is diagnosed with mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being;

(2) A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable; and

(3) A resident who displays or is diagnosed with dementia, receives the

appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services, including specialized rehabilitation services as required in § 483.65; or

(2) Obtain the required services from an outside resource (in accordance with § 483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

■ 25. In newly redesignated § 483.45—

■ a. Amend the introductory text by removing the reference ''§ 483.75(h) of this part'' and add in its place the reference ''§ 483.70(g)''.

■ b. Redesignate paragraph (c)(2) as paragraph (c)(4).

■ c. Add new paragraphs (c)(2) and (3).

■ d. Revise newly designated paragraph (c)(4).

■ e. Redesignate paragraphs (d) and (e) as paragraphs (g) and (h), respectively.

■ f. Add new paragraphs (d), (e), and (f).

The additions and revisions read as follows:

§ 483.45 Pharmacy services.

* * * * *

(c) * * *

(2) This review must include a review of the resident's medical chart.

(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety; and

(iv) Hypnotic.

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

(d) *Unnecessary drugs—General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

(1) In excessive dose (including duplicate drug therapy); or

(2) For excessive duration; or

(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or

(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

(e) *Psychotropic drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

(f) *Medication errors.* The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors.

* * * * *

■ 26. Add § 483.50 to read as follows:

§ 483.50 Laboratory, radiology, and other diagnostic services.

(a) *Laboratory services.* (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

(2) The facility must:

(i) Provide or obtain laboratory services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of laboratory results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs asistance; and

(iv) File in the resident's clinical record laboratory reports that are dated

and contain the name and address of the testing laboratory.

(b) *Radiology and other diagnostic services.* (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in § 482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must:

(i) Provide or obtain radiology and other diagnostic services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

■ 27. Section 483.55 is amended by—

■ a. Amending paragraph (a)(1) by removing the reference ''§ 483.75(h) of this part'' and adding in its place the reference ''§ 483.70(g)''.

■ b. Redesignating paragraph (a)(3) and (4) as paragraphs (a)(4) and (5), respectively.

■ c. Adding a new paragraph (a)(3).

■ d. Revising newly redesignated paragraph (a)(4) introductory text and (a)(4)(ii).

■ e. Revising newly redesignated paragraph (a)(5).

■ f. Amending paragraph (b)(1) introductory text by removing the reference ''§ 483.75(h) of this part'' and adding in its place the reference ''§ 483.70(g)''.

■ g. Revising paragraph (b)(2) introductory text, (b)(2)(ii), and (b)(3).

■ h. Adding paragraphs (b)(4) and (5).

The revisions and additions read as follows:

§ 483.55 Dental services.

* * * * *

(a) * * *

(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

* * * * *

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) * * *

(2) Must, if necessary or if requested, assist the resident—

* * * * *

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

■ 28. Newly redesignated § 483.60 is revised to read as follows:

§ 483.60 Food and nutrition services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident.

(a) *Staffing.* The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e). This includes:

(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.

(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services who—

(i) For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:

(A) A certified dietary manager; or

(B) A certified food service manager, or

(C) Has similar national certification for food service management and safety from a national certifying body; or

(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and

(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

(3) *Support staff.* The facility must provide sufficient support personnel to safely and effectively carry out the functions of the food and nutrition service.

(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in § 483.21(b)(2)(ii).

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with established national guidelines.;

(2) Be prepared in advance;

(3) Be followed;

(4) Reflect, based on a facility's reasonable efforts, the religious, cultural, and ethnic needs of the resident population, as well as input received from residents and resident groups;

(5) Be updated periodically;

(6) Be reviewed by the facility's dietitian or other clinically qualified nutrition professional for nutritional adequacy; and

(7) Nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices.

(d) *Food and drink.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food and drink that is palatable, attractive, and at a safe and appetizing temperature;

(3) Food prepared in a form designed to meet individual needs;

(4) Food that accommodates resident allergies, intolerances, and preferences;

(5) Appealing options of similar nutritive value to residents who choose not to eat food that is initially served or who request a different meal choice; and

(6) Drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.

(e) *Therapeutic diets.* (1) Therapeutic diets must be prescribed by the attending physician. (2) The attending physician may delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by State law.

(f) *Frequency of meals.* (1) Each resident must receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community or in accordance with resident needs, preferences, requests, and plan of care.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a nourishing snack is served at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span.

(3) Suitable, nourishing alternative meals and snacks must be provided to residents who want to eat at non-traditional times or outside of scheduled meal service times, consistent with the resident plan of care.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.

(h) *Paid feeding assistants*—(1) *State-approved training course.* A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of § 483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) *Supervision.* (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help.

(3) *Resident selection criteria.* (i) A facility must ensure that a feeding assistant provides dining assistance only for residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the interdisciplinary team's assessment and the resident's latest assessment and plan of care. Appropriateness for this program should be reflected in the comprehensive care plan.

(i) *Food safety requirements.* The facility must—

(1) Procure food from sources approved or considered satisfactory by federal, state, or local authorities;

(i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.

(ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.

(iii) This provision does not preclude residents from consuming foods not procured by the facility.

(2) Store, prepare, distribute, and serve food in accordance with professional standards for food service safety.

(3) Have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption, and

(4) Dispose of garbage and refuse properly.

■ 29. In newly redesignated § 483.65, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 483.65 Specialized rehabilitative services.

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at § 483.120(c), are required in the resident's comprehensive plan of care, the facility must—

* * * * *

(2) In accordance with § 483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

* * * * *

■ 30. In newly redesignated § 483.70—

■ a. Revise paragraph (c).

■ b. Revise paragraph (d)(2).

■ c. Add paragraph (d)(3).

■ d. Revise paragraph (e).

■ e. Remove paragraphs (f), (j), (k), (m), (o), and (q).

■ f. Redesignate paragraphs (g), (h), (i), (l), (n), (p), (r), (s), (t), and (u) as paragraphs (f), (g), (h), (i), (j), (k), (l), (m), (o), and (q), respectively.

■ g. Revise newly redesignated paragraphs (i)(1) introductory text, and (i)(2), (3), (4), and (5).

■ h. Revise newly redesignated paragraphs (j)(1)(i) and (ii).

■ i. Revise newly redesignated paragraph (m).

■ j. Add new paragraph (n).

■ k. Add new paragraph (p).

■ l. In the table below, for each newly redesignated paragraph indicated in the

first column, remove the reference indicated in the second column and add the reference indicated in the third column.

Paragraphs	Remove	Add
(g)(1)	(h)(2)	(g)(2).
(k)(3)	(p)(2)	(k)(2).
(m)	(r)	(l).
(o)(2) introductory text.	(t)(1)(i)	(o)(1)(i).

The revisions and additions read as follows:

§ 483.70 Administration.

* * * * *

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); nondiscrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). Violations of such other provisions may result in a finding of non-compliance with this paragraph.

(d) * * *

(2) The governing body appoints the administrator who is—

(i) Licensed by the State, where licensing is required;

(ii) Responsible for management of the facility; and

(iii) Reports to and is accountable to the governing body.

(3) The governing body is responsible and accountable for the QAPI program, in accordance with § 483.75(f).

(e) *Facility assessment.* The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

* * * * *

(i) *Medical records.* (1) In accordance with accepted professional standards and practices, the facility must maintain medical records on each resident that are—

* * *

(2) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is—

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;

(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512.

(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use;

(4) Medical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, 3 years after a resident reaches legal age under State law.

(5) The medical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The comprehensive plan of care and services provided;

(iv) The results of any preadmission screening and resident review evaluations and determinations conducted by the State;

(v) Physician's, nurse's, and other licensed professional's progress notes; and

(vi) Laboratory, radiology and other diagnostic services reports as required under § 483.50.

(j) * * *

(1) * * *

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician or, in an emergency situation, by another practitioner in accordance with facility policy and consistent with state law; and

(ii) Medical and other information needed for care and treatment of residents and, when the transferring facility deems it appropriate, for determining whether such residents can receive appropriate services or receive services in a less restrictive setting than either the facility or the hospital, or reintegrated into the community, will be exchanged between the providers, including but not limited to the information required under § 483.15(c)(2)(iii).

* * * * *

(m) Facility closure. The facility must have in place policies and procedures to

ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure, as required at paragraph (l) of this section.

(n) *Binding arbitration agreements.* (1) A facility must not enter into a pre-dispute agreement for binding arbitration with any resident or resident's representative nor require that a resident sign an arbitration agreement as a condition of admission to the LTC facility.

(2) If, after a dispute between the facility and a resident arises, and a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.

(i) The facility must ensure that:

(A) The agreement is explained to the resident and their representative in a form and manner that he or she understands, including in a language the resident and their representative understands, and

(B) The resident acknowledges that he or she understands the agreement.

(ii) The agreement must:

(A) Be entered into by the resident voluntarily.

(B) Provide for the selection of a neutral arbitrator agreed upon by both parties.

(C) Provide for selection of a venue convenient to both parties.

(iii) A resident's continuing right to remain in the facility must not be contingent upon the resident or the resident's representative signing a binding arbitration agreement.

(iv) The agreement must not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

(v) The agreement may be signed by another individual if:

(A) Allowed by state law;

(B) All of the requirements in this section are met; and

(C) That individual has no interest in the facility.

(vi) When the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee.

* * * * *

(p) *Social worker.* Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:

(1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and

(2) One year of supervised social work experience in a health care setting working directly with individuals.

* * * * *

■ 31. A new § 483.75 is added to read as follows:

§ 483.75 Quality assurance and performance improvement.

(a) *Quality assurance and performance improvement (QAPI) program.* Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must—

(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

(b) *Program design and scope.* A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

(1) Address all systems of care and management practices;

(2) Include clinical care, quality of life, and resident choice;

(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

(4) Reflect the complexities, unique care, and services that the facility provides.

(c) *Program feedback, data systems and monitoring.* A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:

(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at § 483.70(e) and including how such information will be used to develop and monitor performance indicators.

(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

(d) *Program systematic analysis and systemic action.* (1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

(2) The facility will develop and implement policies addressing:

(i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;

(ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems ; and

(iii) How the facility will monitor the effectiveness of its performance

improvement activities to ensure that improvements are sustained.

(e) *Program activities.* (1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

(3) As a part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at § 483.70(e). Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

(f) *Governance and leadership.* The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that—

(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

(2) The QAPI program is sustained during transitions in leadership and staffing;

(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to resident based on performance indicator data, and resident and staff input, and other information.

(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

(6) Clear expectations are set around safety, quality, rights, choice, and respect.

(g) *Quality assessment and assurance.* (1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:

(i) The director of nursing services;

(ii) The Medical Director or his or her designee;

(iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and

(iv) The infection control and prevention officer.

(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

(i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary; and

(ii) Develop and implement appropriate plans of action to correct identified quality deficiencies; and

(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

(h) *Disclosure of information.* A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(i) *Sanctions.* Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

■ 32. Newly redesignated § 483.80 is revised to read as follows:

§ 483.80 Infection control.

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

(a) *Infection prevention and control program.* The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to § 483.70(e) and following accepted national standards;

(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.

(v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(b) *Infection preventionist.* The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

(2) Be qualified by education, training, experience or certification;

(3) Work at least part-time at the facility; and

(4) Have completed specialized training in infection prevention and control.

(c) *IP participation on quality assessment and assurance committee.* The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

(d) *Influenza and pneumococcal immunizations*—(1) *Influenza.* The

facility must develop policies and procedures to ensure that—

(i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) *Pneumococcal disease.* The facility must develop policies and procedures to ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(e) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(f) *Annual review.* The facility will conduct an annual review of its IPCP and update their program, as necessary.

■ 33. Section 483.85 is added to read as follows:

§ 483.85 Compliance and ethics program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.

Operating organization means the individual(s) or entity that operates a facility.

(b) *General rule.* Beginning on November 28, 2017, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) *Required components for all facilities.* The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to

prevent and detect criminal, civil, and administrative violations under the Act.

(d) *Additional required components for operating organizations with five or more facilities.* In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in § 483.95(f).

(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

(3) Designated compliance liaisons located at each of the operating organization's facilities.

(e) *Annual review.* The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.

■ 34. In newly redesignated § 483.90—

■ a. Revise paragraph (c).

■ b. Revise paragraphs (e)(1)(i) and (e)(2)(i).

■ c. Revise paragraph (f).

■ d. Revise paragraph (g) introductory text and (g)(1).

■ e. Revise paragraph (h)(2).

■ f. Add paragraph (i)(5).

The revisions and additions read as follows:

§ 483.90 Physical environment.

* * * * *

(c) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care; and

(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition.

(3) Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.

(e) * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after November 28, 2016, bedrooms must accommodate no more than two residents.

* * * * *

(2) * * *

(i) A separate bed of proper size and height for the safety and convenience of the resident;

* * * * *

(f) *Bathroom facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction from State and local authorities or are newly certified after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink.

(g) *Resident call system.* The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from—

(1) Each resident's bedside; and

* * * * *

(h) * * *

(2) Be well ventilated;

* * * * *

(i) * * *

(5) Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

■ 35. Section 483.95 is added to subpart B to read as follows:

§ 483.95 Training requirements.

A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e). Training topics must include but are not limited to—

(a) *Communication.* A facility must include effective communications as mandatory training for direct care staff.

(b) *Resident's rights and facility responsibilities.* A facility must ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth at § 483.10, respectively.

(c) *Abuse, neglect, and exploitation.* In addition to the freedom from abuse, neglect, and exploitation requirements in § 483.12, facilities must also provide training to their staff that at a minimum educates staff on—

(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at § 483.12.

(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

(3) Dementia management and resident abuse prevention.

(d) *Quality assurance and performance improvement.* A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.

(e) *Infection control.* A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at § 483.80(a)(2).

(f) *Compliance and ethics.* The operating organization for each facility must include as part of its compliance and ethics program, as set forth at § 483.85—

(1) An effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

(2) Annual training if the operating organization operates five or more facilities.

(g) *Required in-service training for nurse aides.* In-service training must—

(1) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.

(2) Include dementia management training and resident abuse prevention training.

(3) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at § 483.70(e) and may address the special needs of residents as determined by the facility staff.

(4) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(h) *Required training of feeding assistants.* A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in § 483.160.

(i) *Behavioral health.* A facility must provide behavioral health training consistent with the requirements at § 483.40 and as determined by the facility assessment at § 483.70(e).

§ 483.118 [Amended]

■ 36. In § 483.118, amend paragraphs (b)(1) and (c)(2)(i) by removing the reference ''§ 483.12(a)'' and adding in its place the reference ''§ 483.15(b)''.

§ 483.130 [Amended]

■ 37. In § 483.130, amend paragraphs (m)(5) and (m)(6) by removing the reference ''§ 483.12(a)'' and adding in its place the reference § 483.15(b)''.

§ 483.138 [Amended]

■ 38. In § 483.138, amend paragraphs (a) introductory text and (b)(1) by removing the reference ''§ 483.12(a)'' and adding in its place the reference ''§ 483.15(b)''.

§ 483.151 [Amended]

■ 39. In § 483.151, amend paragraph (a)(3) by removing the reference ''§ 483.75(e)'' and adding in its place the reference ''§ 483.35(c) and (d) and § 483.95(g)''.

§ 483.204 [Amended]

■ 40. In § 483.204, amend paragraph (b) by removing the reference ''§ 483.12 of this part'' and adding in its place the reference ''§ 483.15(h)''.

§ 483.206 [Amended]

■ 41. In § 483.206, amend paragraph (a) by removing the reference ''(See § 483.5 and § 483.12(a)(1))'' and adding in its place the reference ''(See § 483.5)''.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 42. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.635 [Amended]

■ 43. In § 485.635, amend paragraph (a)(3)(vii) by removing the reference ''§ 483.25(i)'' and adding in its place the reference ''§ 483.25(d)(8)''.

■ 44. In § 485.645, paragraphs (d)(1) through (9) are revised and paragraph (d)(10) is added to read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'')

* * * * *

(d) * * *

(1) Resident rights (§ 483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), and (h)(3) of this chapter).

(2) Facility responsibilities (§ 483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i) of this chapter).

(3) Admission, transfer, and discharge rights (§ 483.5(n), § 483.15(b)(1), (b)(2), (b)(3)(i) through (iii), (b)(4), (b)(5)(i) through (vii), and (b)(7) of this chapter).

(4) Freedom from abuse, neglect and exploitation (§ 483.12 of this chapter).

(5) Patient activities (§ 483.25(c) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.25(c)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(6) Social services (§ 483.40(d) and § 483.75(p) of this chapter).

(7) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), and § 483.21(b) and (c) of this chapter), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

(8) Specialized rehabilitative services (§ 483.65 of this chapter).

(9) Dental services (§ 483.55 of this chapter).

(10) Nutrition (§ 483.25(d)(8) of this chapter).

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 45. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, and 1395hh); Pub. L. 110–149, 121 Stat. 1819. Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 488.56 [Amended]

■ 46. In § 488.56, paragraph (a) introductory text is amended by removing the reference ''§ 483.30'' and adding in its place the reference ''§ 483.35''.

■ 47. Section 488.301 is amended by revising the definitions of ''Abuse'', ''Neglect'', ''Nurse aide'', ''Paid feeding assistant'', and ''Substandard quality of care'' to read as follows:

§ 488.301 Definitions.

* * * * *

Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful,* as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

* * * * *

Neglect is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

* * * * *

Nurse aide means an individual, as defined in § 483.5 of this chapter.

* * * * *

Paid feeding assistant means an individual who meets the requirements specified in § 483.60(h)(1) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

* * * * *

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.10 ''Resident rights'', paragraphs (a)(1) through (a)(2), (b)(1) through (b)(2), (e) (except for (e)(2), (e)(7), and (e)(8)), (f)(1) through (f)(3), (f)(5) through (f)(8), and (i) of this chapter; § 483.12 of this chapter ''Freedom from abuse, neglect, and exploitation''; § 483.24 of this chapter ''Quality of life''; § 483.25 of this chapter ''Quality of care''; § 483.40 ''Behavioral health services'', paragraphs (b) and (d) of this chapter; § 483.45 ''Pharmacy services'', paragraphs (d), (e), and (f) of this chapter; § 483.70 ''Administration'', paragraph (p) of this chapter, and § 483.80 ''Infection control'', paragraph (d) of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or

widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

* * * * *

§ 488.426 [Amended]

■ 48. In § 488.426, paragraph (b) is amended by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)'' and paragraph (c) is amended by removing the reference ''§ 483.75(r)(1)(ii)'' and adding in its place the reference ''§ 483.70(l)''.

§ 488.446 [Amended]

■ 49. In § 488.446, the introductory text is amended by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 50. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 489.52 [Amended]

■ 51. In § 489.52, amend paragraph (a)(2) by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

§ 489.55 [Amended]

■ 52. In § 489.55, amend paragraph (b) by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

Dated: September 1, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 19, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–23503 Filed 9–28–16; 5:10 pm]

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Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 32
2016–2017 Refuge-Specific Hunting and Sport Fishing Regulations; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

[Docket No. FWS–HQ–NWRS–2016–0007; FXRS12650900000–167–FF09R26000]

RIN 1018–BB31

2016–2017 Refuge-Specific Hunting and Sport Fishing Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, add 1 national wildlife refuge (NWR or refuge) to the list of areas open for hunting, increase the hunting activities available at 12 other NWRs, open 1 refuge to fishing for the first time, and add pertinent refuge-specific regulations for other NWRs that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing for the 2016–2017 season.

DATES: This rule is effective October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Jillian Cohen, (703) 358–1764.

SUPPLEMENTARY INFORMATION: The National Wildlife Refuge System Administration Act of 1966 closes NWRs in all States except Alaska to all uses until opened. The Secretary of the Interior (Secretary) may open refuge areas to any use, including hunting and/or sport fishing, upon a determination that the use is compatible with the purposes of the refuge and National Wildlife Refuge System mission. The action also must be in accordance with provisions of all laws applicable to the areas, developed in coordination with the appropriate State fish and wildlife agency(ies), consistent with the principles of sound fish and wildlife management and administration, and otherwise in the public interest. These requirements ensure that we maintain the biological integrity, diversity, and environmental health of the Refuge System for the benefit of present and future generations of Americans.

We annually review refuge hunting and sport fishing programs to determine whether to include additional refuges or whether individual refuge regulations governing existing programs need modifications. Changing environmental conditions, State and Federal regulations, and other factors affecting fish and wildlife populations and habitat may warrant modifications to refuge-specific regulations to ensure the continued compatibility of hunting and sport fishing programs and to ensure that these programs will not materially interfere with or detract from the fulfillment of refuge purposes or the Refuge System's mission.

Provisions governing hunting and sport fishing on refuges are in title 50 of the Code of Federal Regulations in part 32 (50 CFR part 32). We regulate hunting and sport fishing on refuges to:

- Ensure compatibility with refuge purpose(s);
- Properly manage fish and wildlife resource(s);
- Protect other refuge values;
- Ensure refuge visitor safety; and
- Provide opportunities for quality fish- and wildlife-dependent recreation.

On many refuges where we decide to allow hunting and sport fishing, our general policy of adopting regulations identical to State hunting and sport fishing regulations is adequate in meeting these objectives. On other refuges, we must supplement State regulations with more-restrictive Federal regulations to ensure that we meet our management responsibilities, as outlined in the Statutory Authority section, below. We issue refuge-specific hunting and sport fishing regulations when we open wildlife refuges to migratory game bird hunting, upland game hunting, big game hunting, or sport fishing. These regulations may list the wildlife species that you may hunt or fish, seasons, bag or creel (container for carrying fish) limits, methods of hunting or sport fishing, descriptions of areas open to hunting or sport fishing, and other provisions as appropriate. You may find previously issued refuge-specific regulations for hunting and sport fishing in 50 CFR part 32. In this rulemaking, we are also standardizing and clarifying the language of existing regulations.

Statutory Authority

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee, as amended by the National Wildlife Refuge System Improvement Act of 1997 [Improvement Act]) (Administration Act), and the Refuge Recreation Act of 1962 (16 U.S.C. 460k–460k–4) (Recreation Act) govern the administration and public use of refuges.

Amendments enacted by the Improvement Act built upon the Administration Act in a manner that provides an ''organic act'' for the Refuge System, similar to organic acts that exist for other public Federal lands. The Improvement Act serves to ensure that we effectively manage the Refuge System as a national network of lands, waters, and interests for the protection and conservation of our Nation's wildlife resources. The Administration Act states first and foremost that we focus our Refuge System mission on conservation of fish, wildlife, and plant resources and their habitats. The Improvement Act requires the Secretary, before allowing a new use of a refuge, or before expanding, renewing, or extending an existing use of a refuge, to determine that the use is compatible with the purpose for which the refuge was established and the mission of the Refuge System. The Improvement Act established as the policy of the United States that wildlife-dependent recreation, when compatible, is a legitimate and appropriate public use of the Refuge System, through which the American public can develop an appreciation for fish and wildlife. The Improvement Act established six wildlife-dependent recreational uses as the priority general public uses of the Refuge System. These uses are: Hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

The Recreation Act authorizes the Secretary to administer areas within the Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that doing so is practicable and not inconsistent with the primary purpose(s) for which Congress and the Service established the areas. The Recreation Act requires that any recreational use of refuge lands be compatible with the primary purpose(s) for which we established the refuge and not inconsistent with other previously authorized operations.

The Administration Act and Recreation Act also authorize the Secretary to issue regulations to carry out the purposes of the Acts and regulate uses.

We develop specific management plans for each refuge prior to opening it to hunting or sport fishing. In many cases, we develop refuge-specific regulations to ensure the compatibility of the programs with the purpose(s) for which we established the refuge and the Refuge System mission. We ensure initial compliance with the Administration Act and the Recreation Act for hunting and sport fishing on newly acquired refuges through an interim determination of compatibility made at or near the time of acquisition. These regulations ensure that we make the determinations required by these acts prior to adding refuges to the lists of areas open to hunting and sport fishing in 50 CFR part 32. We ensure continued compliance by the development of comprehensive conservation plans, specific plans, and

by annual review of hunting and sport fishing programs and regulations.

Summary of Comments and Responses

On July 14, 2016, we published a proposed rule (81 FR 45790) to add 1 refuge to the list of areas open for hunting, increase the hunting activities available at 12 other refuges, open 1 refuge to fishing for the first time, and add pertinent refuge-specific regulations for other refuges that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing for the 2016–2017 season. We accepted public comments on the proposed rule for 30 days, ending August 15, 2016. By that date, we received 601 comments. Below, we discuss the comments we received by topic.

Comment (1): Many commenters expressed general opposition to any hunting or fishing in the National Wildlife Refuge System (NWRS). In many cases, commenters stated that hunting was antithetical to the purposes of a ''refuge,'' which, in their opinion, should serve as an inviolate sanctuary for all wildlife.

Our Response: The Administration Act, as amended, stipulates that hunting (along with fishing, wildlife observation and photography, and environmental education and interpretation), if found to be compatible, is a legitimate and priority general public use of a refuge and should be facilitated. The Service has adopted policies and regulations implementing the requirements of the Administration Act that refuge managers comply with when considering hunting and fishing programs.

We allow hunting of resident wildlife on NWRs only if such activity has been determined compatible with the established purpose(s) of the refuge and the mission of the Refuge System as required by the Administration Act. Hunting of resident wildlife on NWRs generally occurs consistent with State regulations, including seasons and bag limits. Refuge-specific hunting regulations can be more restrictive (but not more liberal) than State regulations and often are more restrictive in order to help meet specific refuge objectives. These objectives include resident wildlife population and habitat objectives, minimizing disturbance impacts to wildlife, maintaining high-quality opportunities for hunting and other wildlife-dependent recreation, eliminating or minimizing conflicts with other public uses and/or refuge management activities, and protecting public safety.

Each refuge manager makes a decision regarding hunting on that particular refuge only after rigorous examination of the available information. Developing or referencing a comprehensive conservation plan (CCP), a 15-year plan for the refuge, is generally the first step a refuge manager takes. Our policy for managing units of the Refuge System is that we will manage all refuges in accordance with an approved CCP, which, when implemented, will achieve refuge purposes; help fulfill the Refuge System mission; maintain and, where appropriate, restore the ecological integrity of each refuge and the Refuge System; help achieve the goals of the National Wilderness Preservation System; and meet other mandates. The CCP will guide management decisions and set forth goals, objectives, and strategies to accomplish these ends. The next step for refuge managers is developing or referencing step-down plans, of which a hunting plan would be one. Part of the process for opening a refuge to hunting after completing the step-down plan would be appropriate compliance with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), such as conducting an environmental assessment accompanied by the appropriate decision documentation (record of decision, finding of no significant impact, or environmental action memorandum or statement). The rest of the elements in the opening package are an evaluation of section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), copies of letters requesting State and/or tribal involvement, and draft refuge-specific regulatory language. We make available the CCP, hunt plan, and NEPA documents and request public comments on them, as well as on any proposed rule, before we allow hunting on a refuge.

In sum, this illustrates that the decision to allow hunting on an NWR is not a quick or simple process. It is full of deliberation and discussion, including review of all available data to determine the relative health of a population before we allow it to be hunted.

The word ''refuge'' includes the idea of providing a haven of safety for wildlife, and as such, hunting might seem an inconsistent use of the NWRS. But again, the Administration Act stipulates that hunting, if found compatible, is a legitimate and priority general public use of a refuge. Furthermore, we manage refuges to support healthy wildlife populations that in many cases produce harvestable surpluses that are a renewable resource. As practiced on refuges, hunting and fishing do not pose a threat to wildlife populations. It is important to note that taking certain individuals through hunting does not necessarily reduce a population overall, as hunting can simply replace other types of mortality. In some cases, however, we use hunting as a management tool with the explicit goal of reducing a population; this is often the case with exotic and/or invasive species that threaten ecosystem stability. Therefore, facilitating hunting opportunities is an important aspect of the Service's roles and responsibilities as outlined in the legislation establishing the NWRS, and the Service will continue to facilitate these opportunities where compatible with the purpose of the specific refuge and the mission of the NWRS.

Note that not all refuges are inviolate sanctuaries. If we acquired a refuge as an inviolate sanctuary, we may open up to 40 percent of that refuge's area for hunting of migratory game birds (16 U.S.C. 668dd(d)(1)(A)). However, if we acquired a refuge without the stipulation that it be an inviolate sanctuary, we may open 100 percent of the refuge's area for hunting.

The Fish and Wildlife Improvement Act of 1978 (Pub. L. 95–616) amended section 6 of the Administration Act to provide for the opening of all or any portion of an inviolate sanctuary to the taking of migratory birds if taking is determined to be beneficial to the species. Such opening of more than 40 percent of the refuge to hunting is determined by species. This amendment refers to inviolate sanctuaries created in the past or to be created in the future. It has no application to areas acquired for other management purposes.

We did not make any changes to the rule as a result of these comments.

Comment (2): Many commenters expressed support for hunting and fishing expansions on NWRs. One commenter expressed support for the openings and expansions described in the proposed rule, but felt that the Service has not opened enough refuges to hunting or increased hunting at enough refuges. According to the commenter, more than 40 percent of the more than 562 NWRs still prohibit hunting; with the clear directives from the Executive and Legislative branches of the Federal Government to increase hunting activities, the Service must open refuges to hunting at a faster pace. The commenter also strongly recommended that the Service engage in discussions with State wildlife managers and with representatives of the hunting community, to facilitate and expedite these openings and make

certain that these and all NWRs become or remain open to hunting.

Our Response: As noted in our response to *Comment (1),* the Administration Act, as amended, establishes that the Refuge System was created to conserve fish, wildlife, plants, and their habitats and that the Service should facilitate opportunities for Americans to participate in compatible wildlife-dependent recreation, including hunting and fishing, on Refuge System lands and waters. Therefore, the Service will continue to facilitate hunting and fishing opportunities where doing so is compatible with the purpose of the specific refuge and the mission of the NWRS.

The Service continues to open and expand hunting opportunities across the NWRS, as evidenced by this final rule; however, as detailed in our response to *Comment (1),* above, the decision to allow hunting on a refuge is not a quick or simple process. Once the Service determines that a hunt can be carried out in a manner compatible with individual refuge purposes and the mission of the NWRS, we work expeditiously to open it. We did not make any changes to the rule as a result of these comments.

Comment (3): Many commenters stated that the majority of Americans do not hunt and were of the opinion that allowing hunting would impede ''non-consumptive'' uses of refuges, including photography and wildlife viewing. Several users claimed that hunting turns refuges into ''war zones'' unsuitable for wildlife viewing. One commenter said wolves at Yellowstone and Denali became harder to observe after hunting was allowed, asserting that hunting would diminish the quality of wildlife viewing for non-hunters.

Our Response: Congress, through the Administration Act, as amended, envisioned that hunting, fishing, wildlife observation and photography, and environmental education and interpretation would all be treated as priority public uses of the NWRS. Therefore, the Service facilitates all of these uses on refuges, as long as they are found compatible with the purposes of the specific refuge and the mission of the NWRS. For this rulemaking, we analyzed impacts of the proposed changes to hunting programs at each refuge through the NEPA process, which included analyzing impacts to other wildlife-dependent uses. Ten refuges completed environmental assessments (EAs), while Alamosa, Baca, and Monte Vista NWRs, as part of the San Luis Valley National Wildlife Refuge Complex, completed a combined environmental impact statement (EIS). We also provided opportunities for the public to comment on the proposed hunt opening and expansions when we developed the CCP, hunt plan, and compatibility determination, and through the NEPA process. When looking at the 10 EAs and one EIS completed for this specific rulemaking, collectively with the refuges that already allow for hunting, the Service has determined that there are no significant impacts to other wildlife-dependent recreation opportunities.

The refuges in this rulemaking use a variety of techniques to reduce user conflict, such as specific hunt seasons, limited hunting hours, restricting which parts of the refuge are open to hunting, and restricting the number of hunters. Refuge managers also use public outreach tools, such as signs and brochures, to make users aware of hunting and their options for minimizing conflict. Most refuges have refuge-specific regulations to improve the quality of the hunting experience as well as provide for quality wildlife-dependent experiences for other users. The Service is aware of several studies showing a correlation between increased hunting and decreased wildlife sightings, which underscores the importance of using the aforementioned techniques, particularly time and space zoning of hunting, to ensure a quality experience for all refuge visitors. We also note that Denali and Yellowstone are part of the National Park System, not the NWRS. More information on how a specific refuge facilitates various wildlife-dependent recreation opportunities can be found in the refuge's CCP, hunt plan, and/or refuge-specific EA/EIS for this rule. The public may contact the specific refuge for any of these materials.

We did not make any changes to the rule as a result of these comments.

Comment (4): One commenter was of the opinion that hunting can disrupt the natural balance of the ecosystem that people enjoy and can deter people from going to visit areas even at times when there are not people actively hunting wildlife.

Our Response: We do not allow hunting on a refuge if it is found incompatible with that individual refuge's purposes or with the mission of the NWRS. In addition, the Service's Biological Integrity, Diversity, and Environmental Health (BIDEH) policy (601 FW 3) guides decisionmaking with respect to management of activities on refuges, including hunting. Service biologists and wildlife professionals, in consultation with the State, determine the optimal number of each game animal that should reside in an ecosystem and then establish hunt parameters (*e.g.,* bag limits, sex ratios) based on those analyses. We carefully consider how a proposed hunt fits with individual refuge goals, objectives, and strategies before allowing the hunt. None of the known, estimated, or projected harvests of migratory game birds, upland game, or big game species in this rulemaking is expected to have significant adverse direct, indirect, or cumulative impacts to hunted populations, non-hunted wildlife, endangered or threatened species, plant or habitat resources, wildlife-dependent recreation, prescribed fire, air, soil, water, cultural resources, refuge facilities, solitude, or socio-economics. Further, we address the relationship between hunting and wildlife sightings in our response to *Comment (3).* We did not make any changes to the rule as a result of this comment.

Comment (5): Several commenters were of the opinion that expanding hunting on NWRs could cause refuge visitors to be accidentally shot or otherwise injured.

Our Response: The Service considers public safety to be a top priority. Hunting of resident wildlife on refuges generally occurs consistent with State regulations, which are designed to protect public safety. Refuges may also develop refuge-specific hunting regulations that are more restrictive than State regulations in order to help meet specific refuge objectives, including protecting public safety. Refuges use many techniques to ensure the safety of hunters and visitors, such as requiring hunters to wear blaze orange, controlling the density of hunters, limiting where firearms can be discharged (*e.g.,* not across roads, away from buildings), and using time and space zoning to limit conflicts between hunters and other visitors. It is worth noting that injuries and deaths related to hunting are extremely rare, both for hunters themselves and for the non-hunting public. We did not make any changes to the rule as a result of these comments.

Comment (6): Several commenters felt that expanding hunting on NWRs would increase the likelihood of wildlife being taken illegally (poaching). One commenter was of the opinion that no significant penalties or charges will be brought against individuals who illegally take wildlife on NWRs.

Our Response: Hunters on NWRs must comply with State regulations and any refuge-specific regulations, which would ban taking wildlife illegally (poaching). The Service takes poaching very seriously, as allowing poaching

would seriously undermine the conservation mission of the NWRS. Refuge managers use a variety of techniques to help ensure that hunters are aware of relevant laws and regulations, such as requiring hunters to carry a signed refuge hunt brochure at all times while in the field. Also, refuge managers may institute check stations when hunters leave the refuge. The priority for Federal Wildlife Officers and other refuge staff is to educate the public so that violations do not occur in the first place. In addition, our Federal Wildlife Officers routinely partner with State and other Federal law enforcement agents to coordinate efforts and share information to counter poaching. In 2013, the Strategic Wildlife Enforcement Program, an initiative that leverages funding for enforcement activities by partnering with State and local agencies, resulted in 1500 contacts, 149 warnings, and 127 violation notices. Some activities funded through this program include long-term surveillance to detect take violations at Willapa Bay, Lewis and Clark, and Ridgefield NWRs; patrolling waterways to conduct waterfowl compliance checks at Patoka River NWR; a deer decoy operation at Seney NWR; and checking deer harvests to ensure hunters complied with size limitations at Patuxent Research Refuge.

The commenter is incorrect in assuming that no significant fines or charges are associated with hunting violations. Penalties for illegally taking wildlife on a refuge can range as high as 1 year in jail and/or $100,000 in fines (16 U.S.C. 668dd(f)(1)). In some cases, felony provisions of the Lacey Act (16 U.S.C. 3371 *et seq.;* 18 U.S.C. 42–43) may be used to prosecute violators of wildlife laws; for example, see prosecution of poaching on Sherburne NWR at: *http://www.fws.gov/midwest/news/721.html.* Further, the Service may suspend a hunt at any time if there is evidence that the hunt is no longer meeting our objectives. We did not make any changes to the rule as a result of these comments.

Comment (7): One commenter said the Service should manage predators as a means to promote bird nesting success, small game opportunities, and other considerations appropriate to the mission of enhancing our wildlife populations and diversity. Conversely, one commenter was very opposed to hunting predators, including bears and cougars.

Our Response: Refuge managers consider predator management on a case-by-case basis. As with all species, a refuge manager makes a decision about allowing predatory species to be hunted only after careful examination to ensure the hunt would comply with relevant laws, policies, and directives. The Administration Act, as amended, directs the Service to manage refuges for ''biological integrity, diversity, and environmental health.'' Moreover, the Service manages refuges in accordance with the BIDEH policy described in our response to *Comment (4).* Predators play a critical role in the integrity, diversity, and overall health of ecosystems, so managing predators is not always appropriate. Before allowing predators to be hunted, a refuge manager would have to ensure that the hunt would not threaten the integrity, diversity, or health of the refuge ecosystem. The manager would also have to determine that the hunt was compatible with refuge purposes and was in keeping with the refuge's CCP and hunt plan. The Service manages all refuges in accordance with an approved CCP, which, when implemented, will achieve refuge purposes; help fulfill the Refuge System mission; maintain, and, where appropriate, restore the ecological integrity of each refuge and the Refuge System; help achieve the goals of the National Wilderness Preservation System; and meet other mandates. In addition, the refuge manager would have to analyze the impacts of the proposed hunt through the NEPA process, which would include the opportunity for public comment. Finally, the proposed hunt would be open to public comment through the rulemaking process. We did not make any changes to the rule as a result of these comments.

Comment (8): Some commenters were of the opinion that hunters target the strongest and healthiest animals in a population, thereby degrading the gene pool and putting the viability of the population at risk.

Our Response: We disagree with the above comment that hunters will have a significant enough impact to affect the gene pool of an entire population. We are not aware of any information that suggests hunting programs, as they are conducted on refuges, are shifting the genetic makeup of a population. In many cases, hunting is a tool used to manage populations and ensure a healthy ecosystem. If hunters are targeting older males in a way that threatens the viability of a population, as is sometimes the case with trophy hunting, refuge managers have several tools at their disposal to protect the population, such as limiting hunting days or only allowing hunters to take antlerless animals.

We considered the impacts of hunting on target and non-target populations through individual EAs or an EIS for each of the proposed hunting openings and expansions. We also consider the cumulative impacts of all proposed hunts in the 2016–2017 Cumulative Impacts Report accompanying the proposed rule. In each case, the number of animals to be taken is too small to shift the genetic makeup of the population in any significant way. We made no changes to the rule as a result of these comments.

Comment (9): One commenter asserted that we should prepare an EIS before proposing to expand hunting and fishing opportunities on many NWRs. According to the commenter, the proposed rule is of sufficient context and intensity to indicate that it is significant enough to warrant an EIS because refuges attract people from all across the country, and because of the severity of the impacts. Specifically, the commenter stated that the 13 refuges where we proposed to add or increase hunting activities represent ''unique geographic areas.'' According to the commenter, the hunting programs we proposed will likely last at least 10 years and set a precedent for continued management on NWRs.

Our Response: The Service disagrees with the assertion that we should prepare an EIS before proposing expanded hunting and fishing opportunities on NWRs. The Service's analysis of the impacts of the proposed rule demonstrated that the rule would not have significant impacts at the local, regional, or national level, and the commenter has provided no additional information that would change our analysis. As discussed above, we annually conduct refuge management activities on NWRs that minimize or offset impacts of hunting on physical and cultural resources, including establishing designated areas for hunting; restricting levels of use; confining access and travel to designated locations; providing education programs and materials for hunters, anglers, and other users; and conducting law enforcement activities.

The Service completed individual EAs for 10 refuges and one EIS for the San Luis Valley National Wildlife Refuge Complex (which includes Alamosa, Baca, and Monte Vista NWRs) in compliance with NEPA to evaluate the impacts of opening or expanding hunting opportunities on refuges in connection with this rulemaking. These EAs/EIS underwent regional and national review to address and consider these actions from a multi-State or flyway perspective, and to discuss the cumulative impacts from this larger geographical context. The 2016–2017 Cumulative Impacts Report supports

this finding, concluding that, after analyzing the impacts of these 10 EAs and EIS collectively with the refuges that already allow hunting, the proposed rule would not result in significant adverse impacts to the human environment. A court found that this approach was an appropriate way for the Service to analyze the impacts of the rule in compliance with NEPA (see *Fund for Animals* v. *Hall,* 777 F. Supp. 2d 92, 105 (D.D.C., 2011)). Therefore, we did not find that the impacts to the human environment were severe, as the commenter suggests.

As for the comment on precedential future refuge management, most of the activities that are part of this rulemaking are either expanding the areas for existing hunts or adding new species to existing hunts—species that are already hunted nearby off refuge. We also note that the Service annually conducts notice-and-comment rulemaking to revise the refuge-specific regulations at 50 CFR part 32; therefore, if, in the future, the Service obtained new information that changes our analysis of impacts either locally, regionally, or nationally, we would promptly undertake revisions to the regulations as needed. It is also worth noting that each refuge must revise its CCP every 15 years, which would include an evaluation of any hunting or fishing programs. Finally, as noted in our response to *Comment (6),* the Service may suspend a hunt at any time if there is evidence the hunt is no longer meeting our objectives. For these reasons, we made no changes to the rule as a result of this comment.

Comment (10): Many commenters were of the opinion that the proposed opening and expansions would turn refuges into ''danger zones'' for wildlife by interrupting migration, disrupting hibernation, and destroying wildlife families. Many also felt that the Service should consider the suffering of fish and other animals as a result of the proposed opening and expansions. One commenter stated that we fail to include a serious discussion of the ethical implications of the proposed action to expand hunting and fishing on multiple refuges and that we should prepare an EIS that includes a legitimate discussion of ethics and the rights of wildlife in order to assist the public and decision makers in fully considering the best alternative to choose.

Our Response: As detailed in our response to *Comment (1),* above, we do not take lightly the decision to allow hunting on a refuge, and we never allow hunting if there is evidence that it will impair the purposes of the refuge or the mission of the NWRS. Refuge managers use a variety of techniques to minimize disturbance to non-target species of wildlife, such as time and space zoning. In some cases, hunting may be part of a management program to reduce the population of nuisance species; otherwise, hunt programs are carefully designed and regulated so as not to affect the sustainability of wildlife populations. Refuge managers are authorized to suspend a hunt program at any time if it appears as though the hunt is causing unacceptable impacts to refuge values or resources.

The Service understands that some members of the public do not believe that hunting on refuges is ethical. However, the Administration Act, as amended, stipulates that hunting and fishing, if found to be compatible, are legitimate and priority public uses of a refuge and should be facilitated. As detailed above in our response to *Comment (1),* the decision to open a refuge to hunting must comply with all applicable laws, regulations, and policies; requires rigorous examination; and provides many opportunities for public comment, all to ensure that hunting is consistent with the purpose of the specific refuge and the mission of the NWRS. Specifically, each refuge complies with NEPA in keeping with procedures outlined in the Department of the Interior Manual (516 DM 1–7) and other appropriate policies and guidance.

We must base our decisions on the best available science, and commenters have not provided information that would change our analysis. Our hunting programs are consistent with State regulations and, where necessary, use more stringent refuge-specific regulations to ensure that hunting and fishing are carried out in a safe, responsible manner. We made no changes to the rule as a result of these comments.

Comment (11): A commenter asserted that our analysis of cumulative impacts in the Cumulative Impacts Report is vague and superficial, and fails to consider the cumulative impacts for expanding hunting and fishing on 13 refuges at the same time. The commenter further stated that we failed to consider how increased hunting will affect the distribution, migration patterns, and abundance of fish, wildlife, and plant populations across multiple refuges, and that while we claim that there will not be significant impacts due to certain mitigation measures, we fail to disclose where and how we will implement those mitigation measures. The commenter gives the example that, although we claim to conduct annual refuge management activities that minimize or offset the disturbance and impacts of hunting and/or fishing, such as the establishment of non-hunted sanctuary areas, we do not specify what, if any, areas have been established as non-hunted sanctuary areas or whether we will expand sanctuary areas to a sufficient degree to mitigate for expanded hunting and fishing. Thus, it is unclear to the commenter whether these activities are sufficient to mitigate the impacts of the proposed rule.

Our Response: The Service disagrees with the commenter that we have not considered how increased hunting will affect the distribution, migration patterns, and abundance of fish, wildlife, and plant populations across multiple refuges. As discussed in our response to *Comment (1),* the Service does a very rigorous analysis before opening or expanding hunting and fishing opportunities on refuges. The Service works very closely with the States to develop refuge-specific regulations consistent with State hunting programs that carefully consider the amount of hunting that can occur so as to not significantly affect the distribution, migration patterns, and abundance of fish and wildlife populations. Additionally, the refuge manager must determine that the hunting and fishing opportunities will meet both the purpose of the individual refuge and the mission of the NWRS, which is to conserve fish and wildlife populations and habitat. As part of this rulemaking, each individual refuge prepared an EA or EIS that analyzed the cumulative impacts of expanding or opening hunting on fish, wildlife, and plant populations at both a local and regional level, including the cumulative impacts of hunting across multiple refuges that are geographically connected. Finally, the 2016–2017 Cumulative Impacts Report looks at the refuge-specific EA/EISs collectively to determine the national cumulative impacts of the proposed rule on fish, wildlife, and plant populations. As discussed in our response to *Comment (9),* this method was approved by a Court.

Furthermore, the Service would like to address the comment about certain mitigation measures such as ''sanctuary areas.'' To the contrary, the 2016–2017 Cumulative Impacts Report concluded that none of the refuge-specific EAs found that there would be significant adverse cumulative impacts to wildlife populations. Additionally, when looking at the EA/EISs collectively with the refuges that already allow hunting, the Service concluded that the cumulative impacts on non-hunted wildlife populations would be

negligible. However, the Service does manage hunting on refuges to minimize any impacts to non-hunted wildlife populations by establishing non-hunted sanctuary areas, conducting habitat management and restoration activities, and minimizing illegal take through enforcement of applicable Federal, State, and refuge-specific regulations.

The Service is not required to mitigate for every impact from hunting. The Service will mitigate where there are:

- Population-level effects to non-sensitive wildlife, including game species, through future restrictions, such as smaller bag limits or season closures; or
- Potential impacts to sensitive wildlife, such as species listed as endangered or threatened under the Endangered Species Act.

The Service may close or alter hunts as needed.

The specific refuge makes all of these management decisions, and, therefore, we do not discuss them in detail in the 2016–2017 Cumulative Impacts Report. However, more information on a refuge-specific hunting plan, including the establishment of non-hunted sanctuary areas on a refuge, can be found in the refuge's CCP, hunt plan, and/or refuge-specific EA/EIS for this rulemaking. The public may contact the specific refuge for any of these materials.

Comment (12): Many commenters expressed concern that fishing paraphernalia would be tossed aside, injuring companion animals and non-target wildlife.

Our Response: It is illegal to abandon property or dispose of waste on a refuge (see 50 CFR 27.93 and 27.94), whether fishing-related or not. It is also illegal to disturb or injure any non-target plants or wildlife (see 50 CFR 27.51) on a refuge. Further, many refuges have specific regulations to guard against littering associated with fishing. We did not make any changes to the rule in response to these comments.

Comment (13): One commenter suggested that the Service use ''mammalian birth control'' as a management tool, rather than hunting.

Our Response: Under the Administration Act, as amended, hunting is a priority use of refuges, along with fishing, wildlife observation and photography, and environmental education and interpretation. The Administration Act directs the Service to facilitate priority uses as long as they are compatible with individual refuge mandates and purposes. In some cases, hunting may also function as a management tool, but this is not the primary justification for allowing hunting on refuges. We made no changes to the rule as a result of this comment.

Comment (14): Several commenters expressed concern over allowing lead ammunition to be used on refuges; some requested that the Service ban lead ammunition for all hunting. Some of these commenters specifically requested that we prohibit hunters from using lead ammunition when hunting elk at Alamosa, Baca, and Monte Vista NWRs. One commenter stated that lead-based ammunition could harm endangered and threatened species on refuges. Another commenter asserted that the Service did not adequately analyze the cumulative impacts of the regulations in the Cumulative Impacts Report because the analysis does not disclose or evaluate the cumulative impacts on non-target wildlife that will result from the regulations that continue to allow the use of toxic (lead) ammunition on some of the refuges for some types of hunting. One commenter felt that it is confusing that several refuges in California (Don Edwards, Salinas, and San Pablo NWRs) removed language requiring the use of nontoxic shot from their refuge-specific regulations.

Our Response: The Service is concerned about the impacts of spent lead ammunition on scavengers, especially bald eagles and ravens. Lead shot for waterfowl hunting has been illegal on refuges since 1998. We continue to look at options and ways to reduce the indirect impacts of toxic shot. Generally, we are and have been phasing out the use of lead shot by upland and big game hunters on refuge lands.

The Service continues to research this issue and engage with States and other partners to promote the use of non-lead ammunition. The Administration Act, as amended, directs the Service to make refuge regulations as consistent with State regulations as practicable. We share a strong partnership with the States in managing wildlife, and, therefore, we are proceeding with the phase-out of toxic ammunition in a coordinated manner with each respective State wildlife agency. Notably, as part of this rulemaking, 22 refuges have limited the use of toxic shot for hunting either upland game, big game, or both. None of these refuges is in the State of California, where lead ammunition is already banned under State law and is therefore banned on all refuges in California.

Currently, the State of Colorado does not require the use of nontoxic bullets for either rifles or muzzleloaders. As part of this rulemaking, Alamosa, Baca, and Monte Vista NWRs require nontoxic ammunition for migratory game bird and upland game hunting. The Service will continue to work with the State of Colorado to further phase-out toxic ammunition on these refuges.

We disagree that any use of lead shot related to the opening or expanding hunting and fishing on the 13 refuges in this rulemaking will harm endangered or threatened species. Each of the refuges carefully evaluated possible effects to endangered and threatened species as part of the NEPA process. In addition, each refuge complied with section 7 of the Endangered Species Act, which requires Federal agencies to ensure that the actions they carry out, fund, or authorize do not jeopardize the continued existence of endangered or threatened species (''listed species''). For each refuge, the Service determined that the proposed action was not likely to affect any listed species.

While the Service is concerned about the impacts of spent lead ammunition on scavengers, we can conclude without a detailed cumulative impacts analysis that the limited use of lead ammunition allowed on refuges will have an insignificant effect on refuge resources. We reach this conclusion because the amount of spent lead ammunition on refuges nationwide is so small compared to the amount of spent lead ammunition in the environment. Therefore, the Service has not revised the 2016–2017 Cumulative Impacts Report based on these comments. Lastly, for the comment about California refuges, under the Administration Act, as amended, refuge-specific regulations can be more restrictive, but not more liberal, than State regulations. We are removing the provisions regarding nontoxic shot from some California refuges' regulations to avoid redundancy and confusion now that the State has banned lead ammunition for hunting. The regulations for each of the refuges in question clearly state that State regulations apply. It would be confusing for the public to pick certain State provisions to repeat in our refuge-regulations and not others. It is important to note, however, that the refuges may still remind the public of the prohibition on lead ammunition through hunt brochures, announcements at meetings, postings at visitor's centers, and through interactions with refuge staff.

We made no changes to the rule as a result of these comments.

Comment (15): According to one commenter, in the proposed rule, the Service contends that on some occasions we must impose regulations regarding hunting on NWRs that conflict with State laws and regulations. The commenter stated that the Service

should not adopt or implement management strategies that lead to overreach and infringement on State prerogatives for refuges in Alaska or in any other State. The commenter added that the Service should defer to the States' expertise in managing their wildlife and should make every effort to conform refuge hunting regulations to the regulations already adopted and followed by State managers.

Our Response: The Service works closely with our State partners in managing hunt programs on refuge lands. Whenever possible, we defer to State regulations related to hunting and fishing. However, we may create refuge-specific regulations that are more restrictive than State regulations if necessary to meet the establishment purpose of the refuge or the mission of the NWRS. Our authority to do so stems from the Administration Act, as amended, which states: ''When the Secretary [of the Interior] determines that a proposed wildlife-dependent recreational use is a compatible use within a refuge, that activity should be facilitated, subject to such restrictions or regulations as may be necessary, reasonable, and appropriate'' (16 U.S.C. 668dd(a)(3)(D)), and ''Regulations permitting hunting or fishing of fish and resident wildlife within the System shall be, to the extent practicable, consistent with State fish and wildlife laws, regulations, and management plans'' (16 U.S.C. 668dd(m)). We also note that this final rule does not address refuges in the State of Alaska. We made no changes to the rule as a result of this comment.

Comment (16): One commenter was of the opinion that we failed to identify what species of migratory game birds and ''other big game'' would be open to hunting on Baca NWR.

Our Response: In the proposed rule, in the proposed entry for Baca NWR at 50 CFR 32.25, we specify that migratory game bird hunting at the refuge would be limited to the hunting of Eurasian collared-doves and mourning doves and that big game hunting would be limited to the hunting of elk. We do not have a category that authorizes the hunting of ''other big game.'' We did not make any changes to the rule as a result of this comment.

Comment (17): One commenter expressed concern that residents living near refuges might act prejudicially toward certain wildlife species, such as wolves, and that refuge managers would share these prejudices. The commenter asked how the Service can assure proper oversight of refuge managers.

Our Response: Allowing hunting on a refuge requires rigorous examination, State consultation, and multiple opportunities for public comment, as detailed in our response to *Comment (1),* above. This prevents an individual manager from prejudicing the process. In addition, the Service has a robust supervisory system in place to ensure that individual refuge managers execute their duties appropriately. Each refuge manager reports directly to a Supervisory Refuge Program Specialist (Refuge Supervisor), who exercises supervisory line authority in the management of refuges within a defined geographic area. Among other duties, the Refuge Supervisor conducts site-visits to evaluate whether refuges are being managed in accordance with relevant laws, regulations, and policies. Where necessary, the Refuge Supervisor is empowered to institute corrective actions for refuge staff. Beyond the Refuge Supervisor, there are additional lines of supervision. We did not make any changes to the rule as a result of this comment.

Comment (18): A commenter stated that if the refuge cannot be sustained financially, we should open it up to hunting and fishing and charge a daily permit fee. However, the commenter also stated that if the refuge can be supported financially without charging a daily permit fee, then hunting and fishing opportunities should not be expanded.

Our Response: The Federal Lands Recreation Enhancement Act (FLRA; 16 U.S.C. 6801–6814) authorizes the Secretary to establish, modify, charge, and collect recreation fees at Federal recreational lands and waters. FLRA also specifies how these recreation fees can be spent. The three types of recreation fees are entrance fees, amenity recreation fees, and special recreation permit fees. In addition, 36 CFR part 71 sets forth regulations for establishing recreation fees on a specific area. The intent of FLRA was not to generate revenue for public lands, but instead to reimburse agencies for the costs of administering recreational activity.

When developing the CCPs and step-down hunting plans for each refuge, the refuge manager takes into account budgetary needs for increased hunting opportunities. The refuge manager only proposes a hunt if he or she anticipates having sufficient funds to ensure compatibility and administer the activity appropriately. Typically, you can find this information under the ''Staffing and Funds'' section of each refuge's hunt plan, which were made publicly available when first issued, and remain available at each refuge's Web site. In some cases, refuges find some budgetary relief in user fees, which are sufficient to cover the cost of increased opportunities.

Finally, as discussed earlier in our response to *Comment (1),* with the passage of the Improvement Act in 1997, Congress mandated that hunting was one of the six priority public uses that refuge managers were to facilitate when compatible. We made no change to the rule as a result of this comment.

Comment (19): One commenter expressed support for opening and expanding hunting opportunities on refuges but requested sign-in sheets in parking lots and end-of-year surveys to account for the amount of big and small game taken.

Our Response: Individual refuges have a variety of options for collecting information about the number of hunters as well as hunter harvest. Refuges may require hunters to sign in using the Visitor Check-In Permit and Report (FWS Form 3–2405) or report harvest using the Big Game Harvest Report (FWS Form 3–2359), Migratory Bird Hunt Report (FWS Form 3–2361), or Upland Game Hunt Report (FWS Form 3–2362). The forms each refuge requires are indicated in the refuge-specific regulations in 50 CFR part 32. We did not make any changes to the rule as a result of this comment.

Comment (20): Two commenters suggested changing the name of National Wildlife Refuges to National Wildlife Management Areas.

Our Response: In 1966, the Administration Act consolidated various lands previously known as wildlife refuges, wildlife ranges, game ranges, wildlife management areas, or waterfowl production areas and designated them as part of the ''National Wildlife Refuge System.'' We made no changes to the rule as a result of these comments.

Comment (21): Several commenters expressed concern about expanding the number goose hunting days at Montezuma NWR from 3 to 7. According to one commenter, it is of greater benefit to the hunter to hunt 3 days a week because it manages hunting pressure better and the geese (as well as the ducks) will hold on the refuge longer.

Our Response: During the regular waterfowl season (October to December), we will allow waterfowl hunting on only 3 days a week: Tuesdays, Thursdays, and Saturdays. The 7-days-per-week hunting refers only to a limited set of seasons, including the September Canada goose hunting season, the late snow goose hunting season (January to March), and the Light Goose Conservation Order season

(March to mid-April). Expanding our program to include the September Canada goose season, the late snow goose season, and the Light Goose Conservation Order season is not only a recreational opportunity, but also a management tool for over-abundant geese. Service biologists and wildlife professionals, in consultation with the State, analyzed the goose population dynamics and considered refuge purposes and management objectives when designing this hunt program. The hunt plan, compatibility determination, and NEPA documentation were all made available for public comment. We made no changes to the rule as a result of these comments.

Comment (22): One commenter requested permanent tree stands in dedicated areas of Montezuma NWR to facilitate deer hunting. The commenter also requested that the refuge expand the number of blinds for waterfowl hunting.

Our Response: In order to meet habitat management objectives for migratory waterfowl, Montezuma NWR actively manipulates water levels throughout the refuge. Therefore, conditions in any given area of the refuge are likely to vary from year to year and throughout the year. For this reason, the refuge has not installed permanent structures such as tree stands and waterfowl blinds. However, the refuge does allow portable tree stands and blinds, which must be removed at the end of each day. We did not make any changes to the rule as a result of this comment.

Comment (23): Several commenters expressed interest in hunting upland game birds and webless migratory game birds at Montezuma NWR.

Our Response: The hunt plan for Montezuma is a result of the CCP process. As part of the CCP process, we invited the public to comment during the scoping period, as well as on the final draft plan. The refuge did not encounter a call for upland game or webless migratory game bird hunting during those comment periods, nor did we get requests for such hunting through our personal interactions with hunters. We appreciate the feedback but we cannot accommodate these requests in this final rule; adding new species to hunt would require us to update our hunt plan, compatibility determination, and NEPA documentation and allow for additional public comment. Therefore, we made no changes as a result of these comments. However, we may consider making these changes in a future regulatory proposal.

Comment (24): Several commenters requested the ability to hunt with dogs at Montezuma NWR.

Our Response: In response to these comments, we are adding in this final rule a provision to allow hunters to use dogs when hunting migratory game birds in Montezuma NWR. The Montezuma NWR CCP, compatibility determination, and environmental assessment all address hunting migratory game birds with dogs so we can accommodate this request in the present rulemaking.

Comment (25): According to one commenter, the regulations for Montezuma NWR state that the refuge manager reserves the right to restrict hunting implements beyond State restrictions based on hunter satisfaction and visitor safety. The commenter remarks that there is no definition in the regulations describing hunter satisfaction and visitor safety, and, therefore, this requirement is ambiguous. The commenter goes on to say that this provision gives too much discretion to the refuge manager, without any public or stakeholder input; hunters and other stakeholder groups should be given the opportunity to meet with the refuge manager and their input given significant weight to accept, provide plausible alternatives, or to refute the claims of the refuge manager.

Our Response: Refuge-specific hunting regulations can be more restrictive than State regulations and often are more restrictive in order to help meet specific refuge objectives. The refuge manager is best equipped to understand how regulations can help meet refuge objectives. However, Montezuma NWR welcomes feedback from the public through a variety of means, such as calling the refuge, writing a letter, or sending an email. Contact information for the refuge can be found at: *http://www.fws.gov/refuge/Montezuma/.* In response to this comment, we revised the language in paragraphs B.6 and C.11 for Montezuma NWR to be more consistent with other refuge-specific regulations.

Comment (26): One commenter took issue with the prohibition against ''use of silencers or any like device that alters the noise on a firearm,'' which appears in the proposed regulations for Buffalo Lake NWR. According to the commenter, using firearms-mounted hearing protection is good for the surrounding neighbors and for abatement of hearing loss to the hunter and hunting party (which may include youth). The commenter asks that we remove this provision from the regulations for Buffalo Lake NWR or change it to reflect most States' hunting laws that allow the use of hearing protection devices mounted to the firearm.

Our Response: The Administration Act, as amended, directs us to make refuge regulations as consistent with State regulations as practicable. Thirty-eight States currently allow the use of silencers for hunting, including Texas, where Buffalo Lake NWR is located. In response to this comment, we have removed the prohibition against the use of silencers or any like device that alters the noise on a firearm for the hunt in question, a youth hunt outside the general deer season.; however, the Service will continue to monitor the use of silencers on Service lands. If we find that silencers lead to an increase in illegal hunting activity, create a public safety problem, reduce high-quality hunting opportunities, or otherwise interfere with the purpose of the specific refuge or the mission of the NWRS, then we may prohibit their use.

Comment (27): One commenter questioned the motivation for allowing hunting on Baca, Monte Vista, and Alamosa NWRs. According to the commenter, calls for hunting on refuges at this time come from ranchers, farmers, hunters, and property owners; they are not to protect an ecosystem and its biodiversity. The commenter states that it appears that human/elk conflicts are part of the issue and that increased revenue from license sales motivated the Service and the State to allow the hunt. Finally, the commenter suggested that the refuge let natural predators do the work, instead of hunters.

Our Response: The San Luis Valley National Wildlife Refuge Complex, which includes Alamosa, Baca, and Monte Vista NWRs, recently completed a CCP and EIS, which complied with NEPA and included an affirmative compatibility determination for hunting on the three refuges. During this process, we received relatively few comments regarding proposed elk hunting on these refuges. Some comments were in opposition, while others greatly supported the proposed elk hunting opportunities.

Through sound professional judgment, as well as consultation with Colorado Parks and Wildlife, we found that the limited number of elk that will be harvested will not affect the sustainability of the population. We designed refuge-specific regulations to provide a safe and high-quality hunting experience, minimize wildlife disturbance, ensure wildlife conservation, and reduce or avoid conflicts with other refuge users. In addition to providing quality elk hunting opportunities, another objective

of the hunt is to redistribute elk, via hunting pressure, away from sensitive habitats, such as riparian areas, where intense elk browsing on willow and cottonwood plants is occurring. Reduced elk browsing on these plants will promote growth, providing improved nesting and foraging habitat for a variety of songbird species as well as other riparian dependent wildlife species.

There was no financial motivation behind opening the elk hunts in the San Luis Valley. The hunts will generate relatively little revenue, as only a limited number of elk hunters will be allowed. Moreover, these hunters would likely have purchased licenses anyway for hunts elsewhere, even if these particular hunts were not offered.

Currently, relatively few natural predators exist for elk on the refuges, with the exception of coyotes. There currently is no control of coyotes on any of the refuges. During the development of the CCP, the introduction of other natural predators was addressed, but was determined not to be a viable option based on substantial public opposition. We did not make any changes to the rule as a result of this comment.

Comment (28): Three commenters expressed a desire to have a dove hunt in New York State.

Our Response: By law, refuge-specific hunting and fishing regulations can be more restrictive than State regulations, but not more liberal. Refuges in New York State do not allow mourning dove hunting because the State does not allow mourning dove hunting. Allowing dove hunting in New York State is a State matter; therefore it is not germane to this rulemaking. We made no changes to the rule as a result of these comments.

Comment (29): One commenter drew attention to the fact that in the entry for Choctaw NWR, the requirement to use nontoxic shot is embedded in a provision that begins by allowing take of incidental species. The commenter stated that these two provisions are unrelated and should be separated so that the requirement to use nontoxic shot is clear and easy to find.

Our Response: We agree with the commenter that separating the two provisions would improve clarity. Therefore, we separated the two statements in this final rule.

Comment (30): One commenter stated that concerning sport fishing within the Billy Frank Jr. Nisqually NWR, the management of fishing activities is under the jurisdiction of the State. The commenter remarked that if the intent of the revisions in the proposed rule is to restrict access (versus fishing) on the refuge, then the wording in the entry should be specific to that. Also, the commenter stated that the reference to ''allowing'' shellfishing on the tideflats indicates where they allow access (*i.e.,* Luhr Beach); however, those wishing to take part in shellfish or fishing activities may access the tideflats from anywhere outside the refuge. In this case, the commenter believes that the language in the entry may be too specific, unintentionally inferring that Luhr Beach is the only access point to harvest these shellfish.

Our Response: In consultation with the State of Washington Department of Fish and Wildlife, in this final rule, we revised the language concerning sport fishing under the entry for the Billy Frank Jr. Nisqually National Wildlife Refuge to clarify where the Service has jurisdiction over fishing and clarify land access restrictions to fishing areas from refuge lands.

Comment (31): A commenter requested that we make information on access points, campsites, or lodging on or near NWRs readily available.

Our Response: Information on access points is routinely available on refuge maps and brochures. These maps and brochures can be found at the refuge headquarters or on the refuge's Web site. Some refuges may allow camping and that information can be found at refuge headquarters, or on the refuge's Web site. Some refuges may have information about lodging near the refuge. We encourage you to contact the refuge directly and inquire about lodging in the local area. We maintain a list of all of the NWRs on our National Wildlife Refuge System homepage at: *http://www.fws.gov/refuges/.* Look for the ''Find Your Refuge'' section on the first page and you can query the system by State, by zip code, alphabetically by refuge, or by certain other means. When you link to the refuge of interest, you will find its address, phone number, and a link to its individual Web site. We made no changes to the rule as a result of this comment.

Changes From the Proposed Rule

As discussed above, under Summary of Comments and Responses, based on comments we received on the proposed rule, we made changes to the regulatory text in this final rule from what we proposed for Montezuma NWR (in New York), Choctaw NWR (in Alabama), Buffalo Lake NWR (in Texas), and Billy Frank Jr. Nisqually NWR (in Washington). In general, we make these changes for clarity and consistency. Specifically, for Montezuma NWR, we removed reference to ''hunter satisfaction'' in the provisions concerning when the refuge manager may restrict hunting implements beyond State restrictions, and we allow dogs when hunting migratory game birds. For Choctaw NWR, we separated the provision concerning the use of nontoxic shot from the provision concerning the take of incidental species. For Buffalo Lake NWR, we removed the prohibition on the use of silencers or any like devices that alter noise on a firearm for the youth hunt, which is consistent with Texas' regulations. For Billy Frank Jr. Nisqually NWR, in consultation with the State of Washington Department of Fish and Wildlife, we revised the language concerning sport fishing to clarify where the Service has jurisdiction over fishing and how refuge users can access areas to fish.

We also made minor editorial changes to the entries for several refuges to clarify which forms or other documentation are required for certain activities. For example, for several refuges, in certain provisions, we stated that a hunter needs a valid permit, without specifying whether that permit is a State-issued or a refuge permit. We clarify those instances in this rule. As another example, for some refuges, we stated in the proposed rule that a hunter must obtain a refuge Special Use Permit (FWS Form 3–1383) to hunt in certain areas of a refuge or conduct certain other activities. FWS Form 3–1383 is, however, not a complete FWS form number, but a generic reference to the category of Special Use Permits used by the Service. In this final rule, we specify complete and exact Special Use Permit form numbers, such as FWS Form 3–1383–G, in those places of the proposed rule where we used the abbreviated form number.

Effective Date

This rule is effective upon publication in the **Federal Register** (see **DATES**, above). We have determined that any further delay in implementing these refuge-specific hunting and sport fishing regulations would not be in the public interest, in that a delay would hinder the effective planning and administration of the hunting and fishing programs. We provided a 30-day public comment period for the July 14, 2016, proposed rule. This rule does not impact the public generally in terms of requiring lead time for compliance. Rather, it relieves restrictions in that it allows activities on refuges that we would otherwise prohibit. Therefore, we find good cause under 5 U.S.C. 553(d)(3) to make this rule effective upon publication.

Amendments to Existing Regulations

This document adopts in the Code of Federal Regulations all of the Service's hunting and/or sport fishing regulations that we are updating since the last time we published a rule amending these regulations (80 FR 51878; August 26, 2015) and that are applicable at Refuge System units previously opened to hunting and/or sport fishing. We are taking this action to better inform the general public of the regulations at each refuge, to increase understanding and compliance with these regulations, and to make enforcement of these regulations more efficient. In addition to now finding these regulations in 50 CFR part 32, visitors to our refuges may find them reiterated in literature distributed by each refuge or posted on signs.

We cross-reference a number of existing regulations in 50 CFR parts 26, 27, 28, and 32 to assist hunting and sport fishing visitors with understanding safety and other legal requirements on refuges. This redundancy is deliberate, with the intention of improving safety and compliance in our hunting and sport fishing programs.

TABLE 1—CHANGES FOR 2016–2017 HUNTING/FISHING SEASON

Refuge/region (*)	State	Migratory bird hunting	Upland game hunting	Big game hunting	Sport fishing
Alamosa (6)	Colorado	D	Already open	B	Closed.
Anahuac (2)	Texas	C/D	Closed	Closed	Already open.
Atchafalaya (4)	Louisiana	Already open	Already open	D	Already open.
Baca (6)	Colorado	A	A	A	Closed.
Black Bayou Lake (4)	Louisiana	C	C	C	Already open.
Buffalo Lake (2)	Texas	Closed	Already open	B	Closed.
Detroit River NWR (3)	Illinois and Missouri	C	C	C	Closed.
Lake Andes (6)	South Dakota	Already open	Already open	Already open	B.
Monte Vista (6)	Colorado	D	Already open	B	Closed.
Montezuma (5)	New York	C/D	Closed	C/D	Already open.
Patoka River (3)	Indiana	C	C	C	C.
Waccamaw (4)	South Carolina	C	C	C	Already open.
Washita (2)	Oklahoma	Already open	Already open	D	Already open.

Key:
* Number in ( ) refers to the Region as defined in the preamble to this rule under Available Information for Specific Refuges.
A = New refuge opened.
B = New activity on a refuge previously open to other activities.
C = Refuge already open to activity, but added new lands/waters or modified areas open to hunting or fishing.
D = Refuge already open to activity but added new species to hunt.

The changes for the 2016–17 hunting/fishing season noted in the chart above are each based on a complete administrative record, which, among other detailed documentation, also includes a hunt plan, a compatibility determination, and the appropriate NEPA analysis, all of which were the subject of a public review and comment process. These documents are available upon request. In this rule, we are also adopting new names for two refuges, White River National Wildlife Refuge and Nisqually National Wildlife Refuge. The new name for White River National Wildlife Refuge is Dale Bumpers White River National Wildlife Refuge, and the new name for Nisqually National Wildlife Refuge is Billy Frank Jr. Nisqually National Wildlife Refuge.

Fish Advisory

For health reasons, anglers should review and follow State-issued consumption advisories before enjoying recreational sport fishing opportunities on Service-managed waters. You can find information about current fish-consumption advisories on the Internet at: *http://www.epa.gov/fish-tech.*

Plain Language Mandate

In this rule, we revise some regulations for individual refuge units to comply with a Presidential mandate to use plain language in regulations; these particular revisions do not modify the substance of the previous regulations. These types of changes include using ''you'' to refer to the reader and ''we'' to refer to the Refuge System, using the word ''allow'' instead of ''permit'' when we do not require the use of a permit for an activity, and using active voice (*e.g.*, ''We restrict entry into the refuge'' vs. ''Entry into the refuge is restricted'').

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rulemaking is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act [SBREFA] of 1996) (5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory

Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities.

This rule adds 1 national wildlife refuge to the list of refuges open to hunting and increases hunting or fishing activities on 12 additional national wildlife refuges. It adds one national wildlife refuge to the list of refuges open to fishing. As a result, visitor use for wildlife-dependent recreation on these NWRs will change. If the refuges establishing new programs were a pure addition to the current supply of those activities, it would mean an estimated increase of 4,045 user days (one person per day participating in a recreational opportunity, Table 2). Because the participation trend is flat in these activities since 1991, this increase in supply will most likely be offset by other sites losing participants. Therefore, this is likely to be a substitute site for the activity and not necessarily an increase in participation rates for the activity.

TABLE 2—ESTIMATED CHANGE IN RECREATION OPPORTUNITIES IN 2016/2017

[Dollars in thousands]

Refuge	Additional days	Additional expenditures
Alamosa	499	$19.4
Anahuac	350	13.6
Atchafalaya	200	7.8
Baca	970	37.8
Black Bayou Lake	200	7.8
Buffalo Lake	12	0.5
Detroit River	115	4.5
Lake Andes	0	0.0
Monte Vista	499	19.4
Montezuma	945	36.8
Patoka River	185	7.4
Waccamaw	10	0.4
Washita	60	2.3
Total	4,045	157.7

To the extent visitors spend time and money in the area of the refuge that they would not have spent there anyway, they contribute new income to the regional economy and benefit local businesses. Due to the unavailability of site-specific expenditure data, we use the national estimates from the 2011 National Survey of Fishing, Hunting, and Wildlife Associated Recreation to identify expenditures for food and lodging, transportation, and other incidental expenses. Using the average expenditures for these categories with the maximum expected additional participation of the Refuge System yields approximately $158,000 in recreation-related expenditures (Table 2). By having ripple effects throughout the economy, these direct expenditures are only part of the economic impact of these recreational activities. Using a national impact multiplier for hunting activities (2.27) derived from the report ''Hunting in America: An Economic Force for Conservation'' and for fishing activities (2.40) derived from the report ''Sportfishing in America'' yields a total economic impact of approximately $358,000 (2015 dollars) (Southwick Associates, Inc., 2012). Using a local impact multiplier would yield more accurate and smaller results. However, we employed the national impact multiplier due to the difficulty in developing local multipliers for each specific region.

Since we know that most of the fishing and hunting occurs within 100 miles of a participant's residence, then it is unlikely that most of this spending would be ''new'' money coming into a local economy; therefore, this spending would be offset with a decrease in some other sector of the local economy. The net gain to the local economies would be no more than $358,000, and most likely considerably less. Since 80 percent of the participants travel less than 100 miles to engage in hunting and fishing activities, their spending patterns would not add new money into the local economy and, therefore, the real impact would be on the order of about $72,000 annually.

Small businesses within the retail trade industry (such as hotels, gas stations, taxidermy shops, bait-and-tackle shops, and similar businesses) may be affected by some increased or decreased refuge visitation. A large percentage of these retail trade establishments in the local communities around NWRs qualify as small businesses (Table 3). We expect that the incremental recreational changes will be scattered, and so we do not expect that the rule will have a significant economic effect on a substantial number of small entities in any region or nationally. As noted previously, we expect approximately $158,000 to be spent in total in the refuges' local economies. The maximum increase at most would be less than one-tenth of 1 percent for local retail trade spending (Table 3).

TABLE 3—COMPARATIVE EXPENDITURES FOR RETAIL TRADE ASSOCIATED WITH ADDITIONAL REFUGE VISITATION FOR 2016/2017

[Thousands, 2015 dollars]

Refuge/county(ies)	Retail trade in 2012	Estimated maximum addition from new activities	Addition as % of total	Establishments in 2012	Establ. with <10 emp in 2012
Alamosa:					
Alamosa, CO	$320,858	$9.7	0.003	85	64
Costilla, CO	13,340	9.7	0.073	10	10
Anahuac:					
Chambers, TX	323,766	13.6	0.004	85	75
Atchafalaya:					
St. Martin, LA	638,981	3.9	0.001	142	101
Iberville, LA	319,242	3.9	0.001	88	61
Baca:					
Saguache, CO	26,605	37.8	0.142	16	13
Black Bayou Lake:					
Ouachita, LA	2,728,780	7.8	<0.001	710	498
Buffalo Lake:					
Randall, TX	2,063,425	0.5	<0.001	352	246
Detroit River:					
Monroe, MI	1,681,716	2.2	<0.001	377	264
Wayne, MI	19,901,061	2.2	<0.001	6,091	4,738
Monte Vista:					
Rio Grande, CO	114,102	19.4	0.017	48	41
Montezuma:					
Cayuga, NY	999,879	18.4	<0.001	260	195
Seneca, NY	559,990	18.4	<0.001	183	114
Wayne, NY	940,334	1.2	<0.001	267	181
Patoka River:					
Gibson, IN	637,370	3.7	0.001	120	84
Pike, IN	82,914	3.7	0.004	31	23
Waccamaw:					
Georgetown, SC	803,958	0.2	<0.001	303	230
Horry, SC	5,990,133	0.2	.....	1,666	1,185
Washita:					
Custer, OK	606,827	2.3	<0.001	149	102

With the small change in overall spending anticipated from this rule, it is unlikely that a substantial number of small entities will have more than a small impact from the spending change near the affected refuges. Therefore, we certify that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A regulatory flexibility analysis is not required. Accordingly, a small entity compliance guide is not required.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. We anticipate no significant employment or small business effects. This rule:

a. Will not have an annual effect on the economy of $100 million or more. The minimal impact will be scattered across the country and will most likely not be significant in any local area.

b. Will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions. This rule will have only a slight effect on the costs of hunting opportunities for Americans. If the substitute sites are farther from the participants' residences, then an increase in travel costs will occur. The Service does not have information to quantify this change in travel cost but assumes that, since most people travel less than 100 miles to hunt, the increased travel cost will be small. We do not expect this rule to affect the supply or demand for hunting opportunities in the United States, and, therefore, it should not affect prices for hunting equipment and supplies, or the retailers that sell equipment.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This rule represents only a small proportion of recreational spending at NWRs. Therefore, this rule will have no measurable economic effect on the wildlife-dependent industry, which has annual sales of equipment and travel expenditures of $72 billion nationwide.

Unfunded Mandates Reform Act

Since this rule applies to public use of federally owned and managed refuges, it will not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule will not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

In accordance with E.O. 12630, this rule will not have significant takings implications. This rule affects only visitors at NWRs and describes what they can do while they are on a refuge.

Federalism (E.O. 13132)

As discussed in Regulatory Planning and Review and Unfunded Mandates Reform Act, above, this rule will not have sufficient federalism implications

to warrant the preparation of a federalism summary impact statement under E.O. 13132. In preparing this rule, we worked with State governments.

Civil Justice Reform (E.O. 12988)

In accordance with E.O. 12988, the Department of the Interior has determined that this rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. The rule clarifies established regulations and will result in better understanding of the regulations by refuge visitors.

Energy Supply, Distribution or Use (E.O. 13211)

E.O. 13211 of May 18, 2001, requires agencies to prepare Statements of Energy Effects when undertaking certain actions that significantly affect energy supply, distribution, and use. Because this rule adds a new hunt at 1 NWR, increases hunting or fishing activities at 12 other NWRs, and adds fishing to 1 NWR, it is not a significant regulatory action under E.O. 12866, and we do not expect it to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

In accordance with E.O. 13175, we have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects. We coordinate recreational use on NWRs with Tribal governments having adjoining or overlapping jurisdiction before we propose the regulations.

Paperwork Reduction Act

This rule does not contain any information-collection requirements other than those already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and assigned OMB Control Numbers 1018–0102 (expires June 30, 2017), 1018–0140 (expires May 31, 2018), and 1018–0153 (expires December 31, 2018). 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.

Endangered Species Act Section 7 Consultation

We comply with section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), when developing comprehensive conservation plans and step-down management plans—which include hunting and/or fishing plans—for public use of refuges, and prior to implementing any new or revised public recreation program on a refuge as identified in 50 CFR 26.32. We have completed section 7 consultation on each of the affected refuges.

National Environmental Policy Act

We analyzed this rule in accordance with the criteria of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)), 43 CFR part 46, and 516 Departmental Manual (DM) 8.

A categorical exclusion from NEPA documentation applies to publication of amendments to refuge-specific hunting and fishing regulations because they are technical and procedural in nature, and the environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis (43 CFR 46.210 and 516 DM 8). Concerning the actions that are the subject of this rulemaking, we have complied with NEPA at the project level when developing each proposal. This is consistent with the Department of the Interior instructions for compliance with NEPA where actions are covered sufficiently by an earlier environmental document (43 CFR 46.120).

Prior to the addition of a refuge to the list of areas open to hunting and fishing in 50 CFR part 32, we develop hunting and fishing plans for the affected refuges. We incorporate these proposed refuge hunting and fishing activities in the refuge comprehensive conservation plan and/or other step-down management plans, pursuant to our refuge planning guidance in 602 Fish and Wildlife Service Manual (FW) 1, 3, and 4. We prepare these comprehensive conservation plans and step-down plans in compliance with section 102(2)(C) of NEPA, and the Council on Environmental Quality's regulations for implementing NEPA in 40 CFR parts 1500 through 1508. We invite the affected public to participate in the review, development, and implementation of these plans. Copies of all plans and NEPA compliance are available from the refuges at the addresses provided below.

Available Information for Specific Refuges

Individual refuge headquarters have information about public use programs and conditions that apply to their specific programs and maps of their respective areas. To find out how to contact a specific refuge, contact the appropriate Regional office listed below:

Region 1—Hawaii, Idaho, Oregon, and Washington. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Eastside Federal Complex, Suite 1692, 911 NE. 11th Avenue, Portland, OR 97232–4181; Telephone (503) 231–6214.

Region 2—Arizona, New Mexico, Oklahoma, and Texas. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, P.O. Box 1306, 500 Gold Avenue SW., Albuquerque, NM 87103; Telephone (505) 248–6937.

Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; Telephone (612) 713–5360.

Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the Virgin Islands. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, GA 30345; Telephone (404) 679–7166.

Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035–9589; Telephone (413) 253–8307.

Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 134 Union Blvd., Lakewood, CO 80228; Telephone (303) 236–8145.

Region 7—Alaska. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, AK 99503; Telephone (907) 786–3545.

Region 8—California and Nevada. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W–2606, Sacramento, CA 95825; Telephone (916) 414–6464.

Primary Author

Jillian Cohen, Division of Natural Resources and Conservation Planning, National Wildlife Refuge System, is the primary author of this rulemaking document.

List of Subjects in 50 CFR Part 32

Fishing, Hunting, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

Regulation Promulgation

For the reasons set forth in the preamble, we amend title 50, chapter I, subchapter C of the Code of Federal Regulations as follows:

PART 32—HUNTING AND FISHING

■ 1. The authority citation for part 32 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd–668ee, and 715i.

§ 32.7 [Amended]

■ 2. Amend § 32.7 by:
■ a. Adding, in alphabetical order, an entry for ''Dale Bumpers White River National Wildlife Refuge'' in the State of Arkansas;
■ b. Removing the entry for ''White River National Wildlife Refuge'' from the State of Arkansas;
■ c. Adding, in alphabetical order, an entry for ''Baca National Wildlife Refuge'' in the State of Colorado;
■ d. Adding, in alphabetical order, an entry for ''Billy Frank Jr. Nisqually National Wildlife Refuge'' in the State of Washington; and
■ e. Removing the entry for ''Nisqually National Wildlife Refuge'' in the State of Washington.
■ 3. Amend § 32.20, the entry for Choctaw National Wildlife Refuge, by:
■ a. Revising paragraph B;
■ b. Revising paragraphs C.1, C.2, and C.4;
■ c. Removing paragraph C.5; and
■ d. Revising paragraphs D.2, D.4, and D.7.

The revisions read as follows:

§ 32.20 Alabama.

* * * * *

Choctaw National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of squirrel and rabbit on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit access to closed areas and hunting within 100 yards (91.4 meters) of the fenced-in refuge work center area, designated hiking trails, and refuge boat ramps.

2. We prohibit leaving unattended personal property, including, but not limited to, boats or vehicles of any type, geocaches, lumber, and cameras, overnight on the refuge (see § 27.93 of this chapter). We prohibit marking trees and using flagging tape, reflective tacks, and other similar marking devices.

3. You may take incidental species (coyote, beaver, nutria, and feral hog) during any hunt with those weapons legal during those hunts as defined by the State of Alabama.

4. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

5. All persons age 15 or younger, while hunting on the refuge, must be in the presence and under direct supervision of a licensed or exempt hunter at least age 21. A licensed hunter supervising a youth must hold a valid State license for the species being hunted. One adult may supervise no more than two youth hunters.

6. The refuge is open daily from 1 hour before legal sunrise to 1 hour after legal sunset.

7. We require all hunters to record hours hunted and all harvested game on the Visitor Check-In Permit and Report (FWS Form 3–2405) at the conclusion of each day at one of the refuge check stations.

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

9. We prohibit equestrian use, domestic livestock, and use of all-terrain vehicles (ATVs) and utility-type vehicles (UTVs).

10. You must restrain all pets, except during squirrel and rabbit hunting, when you may hunt with unleashed dogs.

11. Public use information and hunting and fishing dates are available at refuge headquarters and specified in the refuge brochure.

12. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

13. We prohibit hunting with the aid of baits, salts, scent, or ingestible attractant (see § 32.2(h)).

14. For hunting, you may possess only approved nontoxic shot (see § 32.2(k)), .22 caliber rimfire or smaller rifles, or legal archery equipment according to State regulations.

C. * * *

1. Conditions B1 through B14 apply.

2. Deer hunters may place one portable stand or blind on the refuge for use while deer hunting, but only during the open deer season. The stand must be clearly labeled with the hunter's name, address, and phone number. You may leave the stand or blind on the refuge overnight in a non-hunting position at ground level.

* * * * *

4. We prohibit damaging trees, including driving or screwing any metal object into a tree or hunting from a tree in which a metal object has been driven or screwed to support a hunter (see § 32.2(i)).

D. * * *

2. Conditions B1, B2, B4, B6, B8 through B13, and C4 apply.

* * * * *

4. We prohibit the taking of frogs, turtles, and crawfish (see § 27.21 of this chapter).

* * * * *

7. We require a refuge Special Use Permit (FWS Form 3–1383–C) for commercial activities.

* * * * *

■ 4. Amend § 32.22, the entry for Havasu National Wildlife Refuge, by revising paragraphs A, B.2, C.1, D.3, and D.6 to read as follows:

§ 32.22 Arizona.

* * * * *

Havasu National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of mourning and white-winged dove, duck, coot, moorhen, goose, and common snipe on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit falconry.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. You may not hunt within 50 yards (45 meters) of any building or public road.

4. We prohibit target shooting.

5. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

6. We prohibit the construction or use of pits and permanent blinds (see § 27.92 of this chapter).

7. You must remove temporary blinds, boats, hunting equipment, and decoys from the refuge following each day's hunt (see §§ 27.93 and 27.94 of this chapter).

8. We prohibit retrieving game from closed areas. You may retrieve game from areas closed to hunting, but otherwise open to entry, as long as you possess no hunting firearms or other means of take.

9. Anyone hired to assist or guide hunter(s) must possess and carry a valid Special Use Permit (FWS Form 3–1383–C) issued by the refuge manager.

10. We prohibit hunting on those refuge lands within the Lake Havasu City limits.

11. The following conditions apply only to Pintail Slough (all refuge lands north of North Dike):

i. We require a fee for waterfowl hunting. You must possess proof of payment while hunting.

ii. Waterfowl hunters must hunt within 25 feet (7.5 meters) of the numbered post of their assigned blind.

iii. We limit the number of persons at each waterfowl hunt blind to three. Observers cannot hold shells or guns for hunting unless in possession of a valid State hunting license and stamps.

iv. We limit the number of shells a waterfowl hunter may possess to 25.

v. Waterfowl hunters must possess at least 12 decoys per blind.

vi. You may use only dead vegetation or materials brought from off refuge for making or fixing hunt blinds. We prohibit the cutting, pulling, marking or removing vegetation (see §§ 27.51 of this chapter).

vii. Waterfowl hunters must be at their blind at least 45 minutes before legal shoot time and not leave their blind until 10 a.m. MST.

viii. We allow waterfowl hunting on Wednesdays, Saturdays, and Sundays. Waterfowl hunting ends at 12 p.m. (noon) MST. Hunters must be out of the slough area by 1 p.m. MST.

ix. We allow qualifying youth to participate in the youth waterfowl hunt.

x. We allow dove hunting at Pintail Slough only during the September season.

12. The following conditions apply to all waters of the lower Colorado River within the refuge:

i. We close designated portions of Topock Marsh to all entry from October 1 through the last day of the waterfowl hunt season (including the State youth waterfowl hunt). These areas are indicated in refuge brochures and identified by buoys and/or signs.

ii. We prohibit hunting in the waters of the Colorado River and on those refuge lands within ¼ mile (.4 kilometer) of the waters of the Colorado River from and including Castle Rock Bay north to Interstate 40.

iii. We allow hunting on refuge lands and waters south of Castle Rock Bay to the north boundary of the Lake Havasu City limits.

13. We prohibit the use of all air-thrust boats and/or air-cooled propulsion engines, including floating aircraft.

14. Dogs must be under your immediate control at all times.

B. * * *

2. We prohibit the possession of rifles for hunting.

* * * * *

C. * * *

1. Conditions A2 through A9, and A12ii apply.

D. * * *

3. Anyone hired to assist or guide anglers must possess and carry a valid Special Use Permit (FWS Form 3–1383–C) issued by the refuge manager.

* * * * *

6. The following apply to improved areas within the refuge. Improved areas consist of the Mesquite Bay areas, Castle Rock, the Diving Cliffs, Catfish Paradise, Five Mile Landing and North Dike.

i. We prohibit entry of all motorized watercraft in all three bays of the Mesquite Bay areas as indicated by signs or regulatory buoys.

ii. Improved areas are day-use only and are open from ½ hour before legal sunrise to ½ hour after legal sunset. We allow fishing and launching water craft at these and other areas 24 hours a day.

iii. We prohibit the possession of open containers of alcohol or the possession of glass beverage containers in improved areas.

* * * * *

■ 5. Amend § 32.23 by:

■ a. Under the entry Bald Knob National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.2, A.9, A.11, and A.22;

■ ii. Revising paragraphs B.1 and B.3 through B.6;

■ iii. Revising paragraphs C.1, C.3, C.5, C.6, C.9, C.10, C.11, and C.17;

■ iv. Adding paragraph C.19; and

■ v. Revising paragraph D introductory text and paragraphs D.1 and D.2;

■ b. Under the entry Big Lake National Wildlife Refuge:

■ i. Revising paragraphs B.15, B.17, and C.7; and

■ ii. Adding paragraph C.12;

■ c. Under the entry Cache River National Wildlife Refuge:

■ i. Revising paragraphs A.2 and A.23; and

■ ii. Revising paragraph C introductory text and paragraph C.12;

■ d. Revising paragraphs B, C, and D under the entry Holla Bend National Wildlife Refuge;

■ e. Under the entry Wapanocca National Wildlife Refuge:

■ i. Revising paragraphs A.5, A.10, and A.11;

■ ii. Revising paragraph C.6; and

■ iii. Adding paragraph C.9; and

■ f. Under the entry White River National Wildlife Refuge:

■ i. Revising the heading of the entry to read, ''Dale Bumpers White River National Wildlife Refuge'' and moving the entry into alphabetical order within the section;

■ ii. Removing paragraph A.14;

■ iii. Redesignating paragraphs A.15 through A.26 as A.14 through A.25, respectively;

■ iv. Revising newly redesignated paragraphs A.16, A.17, A.20, and A.24;

■ v. Revising paragraphs B.1 and B.6;

■ vi. Revising paragraphs C.1, C.2, C.3, C.8, and C.10;

■ vii. Removing paragraph C.11;

■ viii. Redesignating paragraphs C.12 through C.20 as C.11 through C.19, respectively;

■ ix. Revising newly redesignated paragraphs C.18 and C.19; and

■ x. Revising paragraph D.5.

The revisions and additions read as follows:

§ 32.23 Arkansas.

* * * * *

Bald Knob National Wildlife Refuge

A. * * *

1. We require refuge hunting permits (signed brochure). The permits are nontransferable, and anyone on refuge land in possession of hunting equipment must possess a signed permit at all times.

2. We prohibit migratory game bird hunting on the refuge during the Quota Gun Deer Hunt.

* * * * *

9. We open the refuge to daylight use only, with the exception that hunters may enter the refuge beginning at 4 a.m. and must exit by 1 hour after legal shooting time ends.

* * * * *

11. You may possess only biodegradable materials to mark trails.

* * * * *

22. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, all-terrain vehicles (ATV) trails, boat ramps, observation platforms, and parking areas.

* * * * *

B. * * *

1. Conditions A1, A6, A9, A11 through A13, and A17 through A23 apply.

* * * * *

3. We allow squirrel hunting September 1 through February 28 on the Mingo Creek Unit and on the Farm Unit, except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

4. We allow rabbit hunting in accordance with the State season on the Mingo Creek Unit and on the Farm Unit, except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

5. We allow quail hunting in accordance with the State season except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

6. We allow daylight hunting of raccoon and opossum with dogs on all

refuge hunt units. Nighttime hunting of raccoon and opossum is allowed only on the Mingo Creek Unit with a Special Use Permit (FWS Form 3–1383–G). We require dogs for hunting raccoon/opossum at night. We list annual season dates in the refuge hunting brochure/permit. We prohibit field trials and organized training events.

* * * * *

C. * * *

1. Conditions A1, A6, A9, A11 through A13, A17 through A23, and B8 through B12 apply.

* * * * *

3. The archery/crossbow hunting season for deer begins on the opening day of the State season and continues throughout the State season in the Mingo Creek Unit and Farm Unit except for the season closure of the refuge during the Quota Gun Deer Hunt. We provide annual season dates and bag limits in the hunt brochure/permit (signature required).

* * * * *

5. The modern gun hunting season for deer will begin in November and continue for a period of up to 9 days in all hunting units with annual season dates and bag limits provided in the hunt brochure/permit.

6. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

9. Immediately record the zone (002) on your hunting license and check all harvested game according to State regulations.

10. You may use only shotguns with rifled slugs, muzzleloaders, and legal pistols for modern gun deer hunting on the Farm Unit.

11. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them from the waterfowl sanctuaries prior to November 15, except for stands used by Quota Gun Deer Hunt permit holders (signature required), which you must remove by the last day of the Quota Gun Deer Hunt. You must remove all stands on the remainder of the refuge within 7 days of the closure of archery season (see § 27.93 of this chapter).

* * * * *

17. We allow only Quota Gun Deer Hunt permit holders on the refuge during the Quota Gun Deer Hunt and only for the purposes of deer hunting. We close the refuge to all other entry and public use during the Quota Gun Deer Hunt.

* * * * *

19. You may enter the refuge at 4 a.m. and remain until 1 hour after legal shooting time.

D. Sport Fishing. We allow fishing in accordance with State regulations subject to the following conditions:

1. Conditions A9, A11, A19 through A23, B11, and C18 apply.

2. We close waterfowl sanctuaries to all entry from November 15 to February 28. We also close the refuge to all entry and fishing during the Quota Gun Deer Hunt.

* * * * *

Big Lake National Wildlife Refuge

* * * * *

B. * * *

15. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, trails, boat ramps, parking areas, fishing piers, observation decks, and photo blinds.

* * * * *

17. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle, or boat while under power. We define ''loaded'' as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. * * *

7. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them 7 days before the closure of archery season (see § 27.93 of this chapter).

* * * * *

12. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

Cache River National Wildlife Refuge

A. * * *

2. We prohibit migratory game bird hunting on the refuge during the Quota Gun Deer Hunt.

* * * * *

23. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle, ATV, or boat while under power. We define ''loaded'' as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

12. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

Dale Bumpers White River National Wildlife Refuge

A. * * *

16. We require hunters born after 1968 to carry a valid hunter-education card. We do not require hunters under age 16 to have a hunter-education card while under direct supervision (within arm's reach) of a holder of a valid hunting license who is at least age 21. Youth hunters under age 16 must remain within sight and normal voice contact of an adult age 21 or older, possessing a valid hunting license. An adult may supervise only one youth for big game hunting but may supervise up to two youths for waterfowl and small game hunting.

17. We allow take of beaver, nutria, and coyote, incidental to any daytime refuge hunt with weapons authorized for that hunt. We prohibit take of beaver, nutria, and feral hog with the aid of dogs or after the hunter has taken the daily bag limit for that hunt. We allow feral hog to be taken during modern gun and muzzleloader deer hunts.

* * * * *

20. We allow camping only in designated sites and areas identified in the refuge user brochure/permit, and we restrict camping to individuals involved in wildlife-dependent activities. Campers may stay no more than 14 days during any 30 consecutive-day period in any campground site or area and must occupy camps daily. We prohibit all disturbances, including use of generators, after 10 p.m.

* * * * *

24. We prohibit hovercraft, personal watercraft (*e.g.*, jet skis, etc.), and airboats.

* * * * *

B. * * *

1. Conditions A1, A9, A10, A11, A12, and A15 through A25 apply.

* * * * *

6. You may possess only approved nontoxic shot when hunting upland game (see § 32.2(k)).

* * * * *

C. * * *

1. Conditions A1, A9, A10, A11, A12, and A15 through A25 apply.

2. Archery deer seasons on the North Unit are from the beginning of the State

archery season until the end of January except for refuge-wide season closure during quota muzzleloader and quota gun deer hunts. We provide annual season dates and bag limits in the refuge user brochure/permit.

3. Archery deer seasons on the South Unit are from the beginning of the State archery season until the end of December except for refuge-wide season closure during quota muzzleloader and quota gun deer hunts. We provide annual season dates and bag limits in the refuge user brochure/permit.

* * * * *

8. If you harvest deer or turkey on the refuge, you must immediately record the zone number (Zone 146 South Unit and Zone 145 North Unit) on your hunting license and later check deer and/or turkey through State phone or online checking system.

* * * * *

10. You must follow refuge guidance regarding flood-zone closures during the deer hunt. Guidance is found in the refuge brochure, which you must carry at all times.

* * * * *

18. We prohibit hunting on the Kansas Lake Area after November 30.

19. We prohibit the possession of buckshot on the refuge.

D. * * *

5. We prohibit all commercial and recreational harvest of turtle on all property administered by Dale Bumpers White River National Wildlife Refuge.

* * * * *

Holla Bend National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of squirrel, rabbit, raccoon, opossum, beaver, armadillo, coyote, and bobcat on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require refuge hunting permits (name, address, signature required). The permits are nontransferable, and anyone on refuge land in possession of hunting equipment must sign, possess, and carry the permits at all times. Your hunt permit will also act as your entrance pass to the refuge.

2. During the refuge archery season, you may take only squirrel, rabbit, raccoon, opossum, beaver, armadillo, coyote, or bobcat.

3. We allow gun hunting of raccoon and opossum with dogs every Thursday, Friday, and Saturday until legal sunrise during the month of February. We prohibit field trails and organized training events (see § 26.21(b) of this chapter).

4. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice or nonhunting discharge of firearms (see § 27.42(a) of this chapter).

5. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, boat ramps, observation platforms, and parking areas.

6. We only allow all-terrain vehicles (ATVs) for hunters and anglers with disabilities. We require a refuge ATV permit (Special Use Permit; FWS Form 3–1383–G) issued by the refuge manager.

7. We prohibit the use of horses and mules.

8. We prohibit hunting from a vehicle.

9. We only allow vehicle use on established roads and trails (see § 27.31 of this chapter).

10. You must enter and exit the refuge from designated roads and parking areas. We prohibit accessing refuge waters and land from the Arkansas River. We prohibit boating over the dam at the Old River Channel from either direction.

11. We prohibit hunting within 150 feet (45 meters) of roads open to motor vehicle use and nature trails.

12. We prohibit marking trails with tape, ribbon, paint, or any other substance other than biodegradable materials.

13. We allow the use of nonmotorized boats during the refuge fishing/boating season (March 1 to October 31), but we prohibit hunters leaving boats on the refuge overnight (see § 27.93 of this chapter).

14. You must adhere to all public use special conditions and regulations in the annual public use regulations brochure/permit.

15. You may not possess live hogs or live coyotes.

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B4 through B15 apply.

2. We allow archery/crossbow hunting for white-tailed deer and turkey. We provide annual season dates in the public use regulations brochure/permit (name, address, signature required).

3. The refuge will conduct one youth-only (between ages 6 and 15 at the beginning of the gun deer season in Zone 7) quota gun deer hunt. Specific hunt dates and application procedures will be available at the refuge office in July. We restrict hunt participants to those selected for a quota permit, except that one nonhunting adult age 21 or older must accompany the youth hunter during the youth hunt.

4. We open spring and fall archery turkey hunting during the State spring and fall turkey season for this zone.

5. We close the refuge to all entry and public use during scheduled youth quota gun hunts, except for those allowed to participate in the youth quota gun hunt.

6. The refuge will conduct two youth-only (age 6 to 15 at the beginning of the spring turkey season) quota spring gun turkey hunts, each 2 days in length. Specific hunt dates and application procedures will be available at the refuge office in January. We restrict hunt participants to those selected for a quota permit (name, address, phone number required), except that one nonhunting adult age 21 or older must accompany the youth hunter during the youth hunt.

7. An adult age 21 or older must accompany and be within sight or normal voice contact of hunters age 15 and under. One adult may supervise no more than one youth hunter.

8. We allow only portable deer stands and blinds capable of being carried in their entirety by a single individual. You may erect stands 7 days before the start of the season and must remove the stands from the refuge within 7 days after the season ends (see §§ 27.93 and 27.94 of this chapter).

9. You must permanently affix the owner's name, address, and phone number to all tree stands, ground blinds, or game cameras on the refuge.

10. We prohibit the use of dogs during big game hunting.

11. We prohibit hunting from paved, graveled, and mowed roads and mowed trails (see § 27.31 of this chapter).

12. We prohibit hunting with the aid of bait, salt, or ingestible attractant (see § 32.2(h)).

13. We prohibit all forms of organized game drives.

14. You must check all game at the refuge check station.

15. We prohibit commercial hunting/guiding.

D. Sport Fishing. We allow sport fishing and frogging in accordance with State regulations and subject to the following conditions:

1. Conditions B6, B7, B9, and C5 apply.

2. Waters of the refuge are only open for fishing March 1 through October 31 during daylight hours.

3. We do not require a permit to fish but do require an entrance pass to the

refuge, which can be purchased at the entrance fee station or refuge office.

4. We limit free-floating fishing devices, trotlines, and tree limb devices to 20 per person. Each device must have the angler's name and address.

5. You must reset trotlines and limb lines when receding water levels expose them.

6. We prohibit leaving trotlines and other self-fishing devices overnight or unattended.

7. You must enter and exit the refuge from designated roads and parking areas. We prohibit accessing refuge waters and land from the Arkansas River. We prohibit boating over the dam at the Old River Channel from either direction.

8. We prohibit anglers from leaving their boats unattended overnight on any portion of the refuge (see § 27.93 of this chapter).

9. We require a Special Use Permit (FWS form 3–1383–C) for all commercial fishing activities on the refuge.

10. We prohibit the take and possession of turtles and/or mollusks (see § 27.21 of this chapter).

11. We prohibit airboats, hovercraft, and personal watercraft (Jet Skis, etc.) (see § 27.31 of this chapter).

* * * * *

Wapannoca National Wildlife Refuge

A. * * *

5. We prohibit all-terrain vehicles (ATVs).

* * * * *

10. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, trails, boat ramps, parking areas, fishing piers, observation decks, and photo blinds.

11. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle or boat while under power (see § 27.42(b) of this chapter). We define ''loaded'' as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. * * *

6. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them from the waterfowl sanctuaries by December 1. You must remove all stands on the remainder of the refuge within 7 days of the closure of archery season (see § 27.93 of this chapter).

* * * * *

9. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

■ 6. Amend § 32.24 by:

■ a. Under the entry Clear Lake National Wildlife Refuge:

■ i. Revising paragraphs A.1 and A.2;

■ ii. Removing paragraph A.3; and

■ iii. Revising paragraph C.1;

■ b. Revising paragraphs A.2 and A.3 under the entry Colusa National Wildlife Refuge;

■ c. Revising paragraphs A.2, A.3, and A.12 under the entry Delevan National Wildlife Refuge;

■ d. Under the entry Don Edwards San Francisco Bay National Wildlife Refuge:

■ i. Revising paragraphs A.2.iii, A.2.iv, A.3, A.4, A.5, A.6, and A.7;

■ ii. Removing paragraph A.8;

■ iii. Redesignating paragraphs A.9 and A.10 as A.8 and A.9, respectively; and

■ iv. Revising newly redesignated paragraph A.8;

■ e. Revising paragraph A.4 under the entry Lower Klamath National Wildlife Refuge;

■ f. Revising paragraphs A.2, A.3, and A.12 under the entry Sacramento National Wildlife Refuge;

■ g. Revising paragraph A under the entry Salinas River National Wildlife Refuge;

■ h. Revising paragraphs A.1, A.3, A.4, A.5, A.6, and A.8 under the entry San Pablo Bay National Wildlife Refuge;

■ i. Revising paragraphs A.2 and A.3 under the entry Sutter National Wildlife Refuge; and

■ j. Under the entry Tule Lake National Wildlife Refuge:

■ i. Revising paragraph A.4;

■ ii. Redesignating paragraphs A.5 through A.9 as A.6 through A.10; and

■ iii. Adding a new paragraph A.5.

The revisions and addition read as follows:

§ 32.24 California.

* * * * *

Clear Lake National Wildlife Refuge

A. * * *

1. We allow waterfowl hunting on designated areas of the refuge 7 days per week during the State regulated season.

i. You may hunt from the shoreline only.

ii. You may not use a boat of any kind while conducting waterfowl hunting activities.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

* * * * *

C. * * *

1. You may hunt only in the unit for 9 consecutive days beginning on the first Saturday following the third Wednesday in August.

* * * * *

Colusa National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A13.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

Delevan National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A14.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

12. We prohibit snipe hunting in the assigned pond/spaced blind areas.

* * * * *

Don Edwards San Francisco Bay National Wildlife Refuge

A. * * *

2. * * *

iii. Ponds AB1, A2E, AB2, A3N, and A3W in the Alviso Unit. These ponds are located on the west side of the Bay between Stevens Creek and Guadalupe Slough. You must obtain a refuge permit (name, address, phone number, and signature required) to hunt these ponds. Access to Ponds AB1 and A2E will be from the Crittenden Lane Trailhead in Mountain View. Access to Ponds A3W will be from the Carl Road Trailhead in Sunnyvale. Access to Ponds A3N and AB2 is by boat from the other ponds. We allow hunting only from existing hunting blinds. We allow hunting only on Wednesdays, Saturdays, and Sundays on these ponds.

iv. Ponds A5, A7, and A8N in the Alviso Unit. These ponds are located on the south end of the Bay between Guadalupe Slough and Alviso Slough. You must obtain a refuge permit (name, address, phone number, and signature required) to hunt these ponds. Access is via walking and bicycling from the Gold Street gate in Alviso. We allow hunting by boat and by walking pond levees. We allow hunting only on Wednesdays, Saturdays, and Sundays on these ponds.

3. During the 2 weeks before the opening of the hunt season, you may bring a boat into Ponds AB1, A2E, AB2, A3N, A3W, A5, A7, and A8N, and moor

it at a designated site. These boats will be used to access the hunting ponds and can stay on the refuge during the hunt season. You must remove your boat within 2 weeks following the close of the hunt season. We allow nonmotorized boats and motorized boats powered by electric, gasoline direct fuel injection 2-stroke, or 4-stroke gasoline motors only.

4. You may maintain an existing blind in the ponds open to hunting if you have a refuge permit (name, address, phone number, and signature required), but the blind will be open for general use on a first-come, first-served basis. We prohibit pit blinds or digging into the levees (see § 27.92 of this chapter).

5. You must remove all decoys and other personal property, except personal boats, from the refuge by legal sunset. You must remove all trash, including shotshell hulls, when leaving hunting areas (see §§ 27.93 and 27.94 of this chapter).

6. You may enter closed areas of the refuge to retrieve downed birds, provided you leave all weapons in a legal hunting area. We encourage the use of retriever dogs. We prohibit other domesticated animals or pets. You must keep your dog(s) under immediate control of the handler at all times (see § 26.21(b) of this chapter). Dogs must remain inside a vehicle or be on a leash until they are on the ponds or on the levees (Ponds R1, 2, A5, 7, and 8N only) as a part of the hunt.

7. You may possess shotshells in quantities of 25 or fewer when in the field.

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

* * * * *

Lower Klamath National Wildlife Refuge

A. * * *

4. Shooting hours end at 1 p.m. on all California portions of the refuge with the following exceptions:

i. The refuge manager may designate up to 6 afternoon special youth, ladies, veteran, or disabled hunter waterfowl hunts per season.

ii. The refuge manager may designate up to 3 days per week of afternoon waterfowl hunting for the general public after December 1.

* * * * *

Sacramento National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A14.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

12. We prohibit snipe hunting in the assigned pond/spaced blind areas.

* * * * *

Salinas River National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, coot, and moorhen on a hunt area along the Salinas River on the southeast portion of the refuge, as designated by posted signs, in accordance with State regulations and subject to the following conditions:

1. You may possess shotshells only in quantities of 25 or fewer.

2. Access to the hunt area is by foot traffic only. We prohibit bicycles and other conveyances. Mobility-impaired hunters should consult with the refuge manager for allowed conveyances.

3. We only allow dogs engaged in hunting activities on the refuge during the waterfowl season. You must keep dog(s) under your immediate control at all times (see § 26.21(b) of this chapter). We prohibit training of dogs on the refuge. We prohibit other domesticated animals or pets.

4. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

5. You must remove all decoys and other personal property from the refuge at the end of each day (see § 27.93 of this chapter). You must remove all trash, including shotshell hulls, when leaving hunting areas (see § 27.94 of this chapter).

* * * * *

San Pablo Bay National Wildlife Refuge

A. * * *

1. Unless posted in the field and/or noted below, we only allow hunting in the open waters of San Pablo Bay and its navigable sloughs. The following areas are closed to hunting:

i. Lower Tubbs Island;

ii. Lower Tubbs Setback;

iii. Cullinan Ranch Unit;

iv. Sonoma Baylands Unit; and

v. Within 300 feet (90 meters) of Highway 37.

* * * * *

3. You may possess shotshells only in quantities of 25 or fewer while in the field.

4. You must remove all decoys, boats, and other personal property from the refuge at the end of each day (see § 27.93 of this chapter). You must remove all trash, including shotshell hulls, when leaving hunting areas (see § 27.94 of this chapter).

5. We prohibit entry to closed areas of the refuge prior to the hunting season in order to scout for hunting sites.

6. We only allow dogs engaged in hunting activities on the refuge during waterfowl season. We prohibit other domesticated animals or pets. You must keep dog(s) under your immediate control at all times (see § 26.21(b) of this chapter). We prohibit training of dogs on the refuge.

* * * * *

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

* * * * *

Sutter National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A13.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

Tule Lake National Wildlife Refuge

A. * * *

4. Shooting hours end at 1 p.m. on all California portions of the refuge with the following exceptions:

i. The refuge manager may designate up to 6 afternoon special youth, ladies, veteran, or disabled hunter waterfowl hunts per season.

ii. The refuge manager may designate up to 3 days per week of afternoon waterfowl hunting for the general public after December 1.

5. You must be drawn daily to hunt all spaced blinds, including numbered blind areas, Sump 1B, and Frey's Island

units, from the first day of the regulated hunting season through November 30. Drawings are held at the hunter check station located on County Road 103. Beginning December 1 through the last day of the season, spaced blinds are first-come, first-served.

* * * * *

■ 7. Amend § 32.25 by:
■ a. Revising paragraphs A, B, and C under the entry Alamosa National Wildlife Refuge;
■ b. Adding, in alphabetical order, an entry for Baca National Wildlife Refuge; and
■ c. Revising paragraphs A, B, and C under the entry Monte Vista National Refuge.

The addition and revisions read as follows:

§ 32.25 Colorado.

* * * * *

Alamosa National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of geese, ducks, coots, snipe, Eurasian collared-doves, and mourning doves on designated areas of the refuge in accordance with State and Federal regulations, and subject to the following conditions:

1. We allow Eurasian collared-dove hunting only during the mourning dove season.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

3. The only acceptable methods of take are shotguns, hand-held bows, and hawking/falconry.

4. Persons possessing, transporting, or carrying firearms on national wildlife refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

B. Upland Game Hunting. We allow hunting of cottontail rabbit, and black-tailed and white-tailed jackrabbit, on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2, A3 and A4 apply.

C. Big Game Hunting. We allow hunting of elk on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A4 applies.

2. You must possess a valid State license and a refuge-specific permit from the State, or a valid State license issued specifically for the refuge, to hunt elk. State license selection will be made via the Colorado Parks and Wildlife hunt selection process.

* * * * *

Baca National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of Eurasian collared-doves and mourning doves only in designated areas of the refuge in accordance with State and Federal regulations, and subject to the following conditions:

1. We allow Eurasian collared-dove hunting only during the mourning dove season.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

3. The only acceptable methods of take are shotguns, hand-held bows, and hawking/falconry.

4. Persons possessing, transporting, or carrying firearms on national wildlife refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

B. Upland Game Hunting. We allow hunting of cottontail rabbit, and black-tailed and white-tailed jackrabbit, on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2 and A4 apply.

2. We prohibit handguns for hunting.

3. Shotguns, rifles firing rim-fire cartridges less than .23 caliber, hand-held bows, pellet guns, slingshots, and hawking/falconry are the only acceptable methods of take.

C. Big Game Hunting. We allow hunting of elk on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A4 applies.

2. You must possess a valid State license and a refuge-specific permit from the State, or a valid State license issued specifically for the refuge, to hunt elk. State license selection will be made via the Colorado Parks and Wildlife hunt selection process.

3. During firearms elk seasons, hunters must follow State law for use of hunter orange.

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■ 8. Amend § 32.27 by revising paragraph D under the entry Prime Hook National Wildlife Refuge to read as follows:

§ 32.27 Delaware.

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Prime Hook National Wildlife Refuge

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D. Sport Fishing. We allow fishing and crabbing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require all individuals fishing and/or crabbing on or from the refuge or within refuge waters to possess a signed refuge fishing/crabbing application (FWS Form 3–2358) and a valid form of government-issued photo identification.

2. Anglers using boats on Turkle and Fleetwood Ponds may propel them manually or with electric motors only.

3. We do not allow fishing or crabbing from water control structures.

4. You may use or possess only nontoxic terminal tackle, weights, sinkers, and/or split shot while fishing or crabbing within refuge boundaries.

5. You may use only hook-and-line tackle when fishing for finfish.

6. You may use only hand lines, crab dip nets, hoop crab nets, and/or manually operated crab traps (collapsible traps) for crabbing.

7. You must attend to your fishing and/or crabbing lines and gear at all times.

8. We do not allow commercial fishing and/or crabbing.

* * * * *

■ 9. Amend § 32.28 by:
■ a. Revising paragraphs C and D under the entry Lake Woodruff National Wildlife Refuge;
■ b. Under the entry Merritt Island National Wildlife Refuge:
■ i. Revising paragraph A introductory text and paragraphs A.1 through A.9, A.12, A.14, and A.15;
■ ii. Adding paragraph A.16;
■ iii. Revising paragraph C;
■ iv. Revising paragraph D introductory text and paragraphs D.1, D.3, D.4, D.5, D.8, D.11, D.14, D.15, D.16, and D.17; and
■ v. Removing paragraph D.18;
■ c. Revising paragraphs C.6 through C.9 and C.12 under the entry St. Marks National Wildlife Refuge; and
■ d. Revising paragraphs C.1, C.2, C.3, C.8, C.9, C.18 and D.6 under the entry St. Vincent National Wildlife Refuge.

The addition and revisions read as follows:

§ 32.28 Florida.

* * * * *

Lake Woodruff National Wildlife Refuge

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require Lake Woodruff hunt permits. The permits (signed annual hunt brochure) are free and nontransferable, and anyone on refuge land in possession of hunting equipment must sign, possess, and carry the permit at all times.

2. In addition to the valid, paid Lake Woodruff Quota Hunt Permit (Florida Fish and Wildlife Conservation Commission State Permit), which can be purchased through Florida Fish and Wildlife Conservation Commission (FWC), and a signed Lake Woodruff National Wildlife Refuge hunt permit (signed annual hunt brochure), hunters must have on their person all applicable Florida hunting licenses and permits. State requirements for hunter safety apply.

3. All hunters must be on stands or in blinds while hunting.

4. We prohibit stalking or movement through the hunt area while hunting.

5. We prohibit scouting in the hunt area, whether you hold a permit for the current hunt or a future hunt, during the quota hunt.

6. We prohibit possession of hunting weapons while scouting.

7. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and refuge-specific regulations in this part 32).

8. We close the hunt areas of the refuge to all public use except to permitted hunters. The refuge is closed between legal sunset and legal sunrise, except permitted hunters may access the refuge 2 hours prior to legal sunrise each hunting day. All hunters must be off the refuge 2 hours after legal sunset.

9. You may set up stands or blinds 2 days prior to the hunt for which you are permitted, and you must remove them on or before the last day of your permitted hunt. You must clearly mark stands with the hunter's name and address or the Florida Fish and Wildlife Conservation Commission (FWC) customer number found on your hunting license. No more than one stand or blind per person may be on the refuge at any time, unless a permitted hunter is accompanied by a youth hunter. Stands and/or blinds for youth hunters must be placed within sight and normal voice contact of the permitted hunter's stand and marked with the adult permitted hunter's name and address or the FWC customer number and the word ''YOUTH.''

10. If you use flagging or other trail marking material, you must print your name or FWC customer number on each piece or marker. You may set up flagging and trail markers 2 days prior to the permitted hunt, and you must remove them on or before the last day of the permitted hunt.

11. You must check out any game taken during the hunts at a self-check station.

12. We allow primitive gun hunting only in the Western Unit, which is only accessible by boat.

13. We prohibit hunting with dogs.

14. We prohibit accessing the refuge through the railroad right-of-way.

15. Hunters under age 16 do not need a quota permit, but must be accompanied by an adult age 18 or older. Each adult may supervise one youth hunter and must remain within sight and normal voice contact; the pair must share a single bag limit unless hunting during a designated Family or Youth Hunt.

16. Archery hunters must wear a vest or jacket containing back and front panels of at least 500 square inches (3,226 square centimeters) of solid-fluorescent-orange color when moving to and from their vehicle, to their deer stand or their hunting spot, and while tracking or dragging out their deer. We do not require archery hunters to wear solid-colored-fluorescent hunter orange when positioned in their stands to hunt.

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require a Florida Freshwater Fishing license, and we adhere to State regulations for bag and length limits.

2. Fishing on the refuge is by hook and line only. We prohibit cast nets.

3. We allow fishing from legal sunrise to legal sunset.

4. We prohibit the use of airboats on the refuge.

5. We prohibit commercial fishing and the taking of frogs, turtles, or any other wildlife without permit (see § 27.21 of this chapter).

6. We prohibit the use of snatch hooks in the refuge impoundments.

* * * * *

Merritt Island National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of ducks, mergansers, and coots in designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of Federal, State, and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

2. You must possess and carry a current, signed Merritt Island National Wildlife Refuge hunt permit (signed brochure, non-transferable) at all times while hunting waterfowl on the refuge.

3. You must carry a valid State-issued Merritt Island Waterfowl Quota Permit (Waterfowl Quota Permit), which can be purchased through the Florida Fish and Wildlife Conservation Commission (FWC) while hunting in areas 1 or 4 from the beginning of the regular waterfowl season through January 31.

4. We allow hunting on Wednesdays, Saturdays, Sundays, and Federal holidays, including Thanksgiving, Christmas, and New Year's Day, that fall within the State's waterfowl season.

5. We allow hunting in four designated areas of the refuge as delineated in the refuge hunting regulations map. We prohibit hunters entering the normal or expanded restricted areas of the Kennedy Space Center (KSC).

6. We only allow hunting of waterfowl on refuge-established hunt days from ½ hour before legal sunrise until 12 p.m. (noon). All equipment must be removed by 1 p.m. daily.

7. You may enter the refuge no earlier than 4 a.m. for the purpose of waterfowl hunting.

8. You must comply with State requirements for hunter-education courses.

9. We require an adult, age 18 or older, to supervise hunters age 15 and younger. The adult must remain within sight and normal voice contact of the youth hunter.

* * * * *

12. We prohibit hunting or shooting within 25 feet (7.6 meters), or shooting from any portion of, a dike, dirt road, or railroad grade.

* * * * *

14. You must stop at posted refuge waterfowl check stations and report statistical hunt information on the Migratory Bird Hunt Report (FWS Form 3–2361) to refuge personnel.

15. You may not possess more than 25 shells in 1 hunt day.

16. You may only use gasoline, diesel, or electric motors inside the impoundment perimeter ditch.

* * * * *

C. Big Game Hunting. We allow the hunting of white-tailed deer and feral hog in designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require a State-issued Merritt Island National Wildlife Refuge Big Game Quota Hunt Permit (Quota Hunt Permit), which can be purchased through the FWC. The Quota Hunt Permit is a limited entry quota permit, is zone-specific, and is nontransferable.

2. You must have a valid signed Big Game Hunt Permit (signed annual hunt brochure). The permits are free and

nontransferable, and anyone on refuge land in possession of hunting equipment must sign and carry the signed permit at all times.

3. You must also have on your person all applicable Florida hunting licenses and permits. State requirements for hunter safety apply.

4. Licenses, permits, all hunting equipment and effects, and vehicles and/or other conveyances are subject to inspection by law-enforcement officials.

5. We allow hunting as a 3-day weekend within the State's deer season. Legal shooting hours are ½ hour before legal sunrise to ½ hour after legal sunset.

6. We close the hunt areas of the refuge to all public use except to permitted hunters.

7. The refuge is closed between legal sunset and legal sunrise except permitted hunters may access the refuge no earlier than 2 hours before legal sunrise and must leave the refuge no later than 2 hours after legal sunset.

8. You are prohibited from entering the normal or expanded restricted areas of KSC. KSC maintains the right to close any portion of the refuge for any length of time. In that case, we will not refund or reissue any permits.

9. We prohibit hunting from refuge roads or within 100 yards of roads open to public vehicle traffic or within 200 yards of a building or KSC facility.

10. Persons possessing, transporting, or carrying firearms on a National Wildlife Refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

11. Hunters under age 16 do not need a Quota Hunt Permit, but must be accompanied by an adult age 18 or older. Each adult may supervise one youth hunter and must remain within sight and normal voice contact. The pair must share a single bag limit unless hunting during a designated Youth or Family hunt.

12. You may set up stands or blinds up to 2 days prior to the permitted hunt; you must remove them on the last day of your permitted hunt. You must clearly mark stands and blinds with your name and address or the FWC customer number found on your hunting license. You may have no more than one stand or blind per person on the refuge at any time. Stands or blinds for youth hunters must be placed within sight and normal voice contact of the supervisory hunter's stand and marked with the supervisory hunter's name and address or FWC customer number and the word ''YOUTH.''

13. We prohibit all scouting in the hunt area during the quota hunt.

14. If you use flagging or other trail-marking material, you must print your name or FWC customer number on each piece or marker. You may set out flagging and trail markers up to 2 days prior to the permitted hunt, and you must remove them on the last day of the permitted hunt.

15. We allow legally permitted hunters to scout within their permitted zones up to 7 days prior to their permitted hunts. You must carry your valid Quota Hunt Permit identifying the permitted hunt zone while scouting.

16. We allow parking for scouting and/or hunting only along State Road (SR) 3, not within the hunt areas.

17. You must be on your stand or in your blind while hunting.

18. We prohibit stalking or moving through the hunt area while hunting.

19. You must be at your vehicle within 1 hour after legal shooting time. If you wish to track wounded game beyond 1 hour after legal sunset, you must gain consent from a Federal Wildlife Officer to do so.

20. We prohibit hunting with dogs.

21. We prohibit using dogs for tracking unless authorized by a Federal Wildlife Officer. Dogs must remain on a leash and be equipped with a GPS tracking device.

22. You may field dress game; however, we prohibit cleaning game within 1,000 feet of any public area, road, game-check station, or gate. We prohibit dumping game carcasses on the refuge.

23. Archery hunters must wear at least 500 square inches (3,226 square centimeters) of solid fluorescent-orange color while moving to and from their vehicles, to their stands or hunting spots, and while tracking or dragging out game.

24. The bag limit and antler requirements for white-tailed deer on the refuge will follow State regulations but will not exceed two deer per hunt. Antlered and antlerless deer are defined per State regulations. It is illegal to take spotted fawns.

25. There is no bag limit or size limit for the take of feral hogs.

26. You must report all hunting activities at one of the two check stations, including both successful and non-successful hunts, prior to leaving the refuge.

D. Sport Fishing. We allow recreational fishing, crabbing, clamming, and shrimping in designated areas of the refuge as delineated in the refuge fishing regulations map in accordance with State regulations and subject to the following conditions:

1. You must possess a current, signed refuge fishing permit (signed brochure) and a Florida State Freshwater and/or Saltwater fishing license at all times while fishing on the refuge. All State regulations for bag and length limits apply.

* * * * *

3. We allow launching of boats for night fishing activities only from Bair's Cove, Beacon 42, and Biolab boat ramps.

4. We prohibit crabbing or fishing from Black Point Wildlife Drive or any side road connected to Black Point Wildlife Drive except from L Pond Road.

5. We prohibit launching boats, canoes, or kayaks from Black Point Wildlife Drive or any side road connected to Black Point Wildlife Drive except from L Pond Road.

* * * * *

8. We prohibit use of personal watercraft, kite surfing, kite boarding, wind surfing, sail boarding, use of air thrust boats, and use of hovercraft or any similar non-wildlife oriented watercraft on the refuge or in refuge waters.

* * * * *

11. We prohibit fishing within the normal or expanded restricted areas of the KSC, unless those areas are officially designated by KSC as special fishing opportunity sites.

* * * * *

14. We prohibit fishing from, or in the immediate vicinity of, the Manatee Viewing Deck on the northeast side of Haulover Canal.

15. We require all commercial fishing guides to purchase, possess, and carry a Special Use Permit (FWS Form 3–1383–C).

16. You may only use gasoline, diesel, or electric motors inside the impoundment perimeter ditch.

17. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of Federal, State, and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

* * * * *

St. Marks National Wildlife Refuge

* * * * *

C. * * *

6. There are two fall archery hunts: You may harvest either-sex deer, feral hog, and bearded turkey during the fall archery hunts. We will hold one hunt on the Panacea Unit and one hunt on the Wakulla Unit. See condition C8 for specific information on bag limits.

Contact the refuge office for specific dates.

7. There are two modern gun hunts. You may harvest deer, feral hog, and bearded turkey. Modern guns must meet State requirements. We will hold one hunt on the Panacea Unit and one hunt on the Wakulla Unit. See condition C8 for specific information on bag limits. Contact the refuge office for specific dates.

8. The bag limit for white-tailed deer is two deer per hunt, either two antlerless deer or one antlerless deer and one antlered deer. Antlerless deer are defined per State regulations as deer with no antler or antlers less than 5 inches (12.75 centimeters). Antlered deer must have at least three points, 1 inch (2.5 centimeters) or greater on one antler to be harvested.

9. There is one youth white-tailed deer hunt and one youth turkey hunt for youth ages 12 to 17, on the St. Marks Unit in an area we will specify in the refuge hunt brochure. Youth hunters age 12 to 15 may harvest two deer, either two antlerless deer or one antlerless and one antlered. There are no restrictions on antler size for youth age 12 to 15. Youth hunters age 16 to 17 may harvest two deer, either two antlerless or one antlerless and one antlered. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or greater on one antler to be harvested by youth age 16 to 17. Antlerless deer are defined in C8. The youth turkey hunt will be conducted in the St. Marks Unit in an area we will specify in the refuge hunt brochure. The limit will be one bearded turkey per hunter. Unlimited hogs may be harvested on both hunts. Only the youth hunter may handle or discharge firearms used for hunting. An adult age 21 or older must accompany and remain in sight and normal voice contact with each youth hunter. Contact the refuge office for specific dates.

* * * * *

12. Portions of the St. Marks Unit adjacent to Flint Rock Wildlife Management Area (as specified in the hunt brochure) will be open concurrent with Flint Rock Wildlife Management Area seasons and regulations except only white-tailed deer, feral hog, and turkey may be harvested. We require a refuge permit (signed brochure).

* * * * *

St. Vincent National Wildlife Refuge

* * * * *

C. * * *

1. We require refuge permits (State license—fee charged). The permits are nontransferable, and the hunter must possess them while hunting. Only signed permits are valid. We only allow people with a signed refuge hunt permit or the helpers of mobility-impaired hunters on the island during the hunt periods. Contact the refuge office for details on receiving a permit. We will charge fees for duplicate permits.

2. We restrict hunting to three periods: Primitive Weapons Sambar Deer (sambar deer, raccoon, and feral hog); Archery (white-tailed deer, raccoon, feral hog); and Primitive Weapons White-Tailed Deer (white-tailed deer, raccoon, and feral hog). Contact the refuge office for specific dates. You may check-in and set up camp sites and stands on the day prior to the scheduled hunt as specified in the brochure. You must leave the island and remove all equipment by the date and time specified in the brochure.

3. You must check-in at the check stations on the island. We restrict entry onto St. Vincent Island to the Indian Pass and West Pass Campsites. All access to hunt areas will be on foot or by bicycle from these areas.

* * * * *

8. You may retrieve game from the closed areas only if accompanied by a refuge staff member or a Federal Wildlife Officer.

9. We limit weapons to primitive weapons (bow and arrow and muzzleloader) on the primitive weapons sambar deer hunt and the primitive weapons white-tailed deer hunt. We limit the archery hunt to bow and arrow. Weapons must meet all State regulations. We prohibit crossbows during the white-tailed deer archery hunt except with a State disabled persons permit. You may take feral hog and raccoon only with the weapons allowed for that period.

* * * * *

18. Bag limits:

i. Primitive Weapons Sambar Deer Hunt: One sambar deer of either sex, no limit on feral hog or raccoon.

ii. Archery Hunt: One white-tailed deer of either sex. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or more on one antler to be harvested. Antlerless deer are defined per State regulations as deer with no antler or antlers less than 5 inches (12.75 centimeters). Youth age 15 or younger may harvest any deer except spotted fawn. We prohibit harvesting of spotted fawns. There is no limit on feral hog or raccoon.

iii. Primitive Weapons White-Tailed Deer Hunt: One white-tailed deer. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or more in length on one antler, to be harvested. We issue a limited number of either-sex tags. If you have an either-sex tag, the bag limit is one deer that may be antlerless or antlered with legal antler configuration. Antlerless deer are defined per State regulation as deer with no antler or antlers less than 5 inches (12.75 centimeters). Youth age 15 or younger may harvest any deer except spotted fawn. We prohibit harvesting of spotted fawns. There is no limit on feral hog or raccoon.

* * * * *

D. * * *

6. You may take only fish species, and you must comply with the fish limits, authorized by State regulations. We prohibit the taking of frog and/or turtle.

■ 10. Amend § 32.31 by:

■ a. Revising paragraphs A, C.2, C.7, C.8, D.1, and D.4 under the entry Deer Flat National Wildlife Refuge; and

■ b. Revising paragraph A introductory text and paragraphs A.4 and C under the entry for Kootenai National Wildlife Refuge.

The revisions read as follows:

§ 32.31 Idaho.

* * * * *

Deer Flat National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, coot, common snipe, and dove on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You may hunt only duck, coot, and mourning dove on the Lake Lowell Unit.

2. You may hunt duck and coot only within 200 yards (180 meters) of the shoreline.

3. Duck and coot hunting in the East Side Recreation Area is walk-in only. We prohibit using float tubes and boats. Duck and coot hunters in the South Side Recreation Area may use float tubes, nonmotorized boats, or boats equipped with electric motors within 200 yards (180 meters) of the shoreline. We prohibit the use or possession of gas-powered motors.

4. You may possess only 25 or fewer shotgun shells per day for hunting duck and coot.

5. You may only use portable and temporary blinds. We prohibit permanent structures (see § 27.92 of this chapter).

6. You must remove boats, decoys, blinds, other personal property, and any materials brought onto the refuge for blind construction at the end of each day (see §§ 27.93 and 27.94 of this chapter).

7. You may enter the refuge 1 hour before official shooting hours (½ hour before legal sunrise), and remain on the

refuge until 1 hour after official shooting hours (legal sunset).

8. You may use dogs for hunting. Dogs must be under the immediate control of the handler at all times.

9. From February 1 through June 14, we prohibit hunting on all islands in the Snake River Islands Unit. From June 15 through June 30, we prohibit hunting on islands used by nesting birds. You must comply with all posted signs.

* * * * *

C. * * *

2. Only the southern portion of the Lake Lowell Unit is open to deer hunting. We define the boundary of the deer hunting area on the north by the southern shoreline of Lake Lowell, on the east by the New York Canal, on the south by the southern boundary of the refuge, and on the west by Riverside Road.

* * * * *

7. You may enter the Lake Lowell Unit no earlier than 2 hours before official shooting hours (½ hour before legal sunrise) and must leave the area within 2 hours after official shooting hours (½ hour after legal sunset). Successful hunters may extend their departure time only as long as is necessary to retrieve dead deer.

8. A refuge employee, State Game Warden, or local law-enforcement officer must accompany hunters to retrieve a wounded or dead deer from any area that is closed to deer hunting.

D. * * *

1. From October 1 through April 14, we only allow ice fishing within 200 yards (180 meters) of the shoreline in front of both the Lower Dam (Fishing Area A) and the Upper Dam (Fishing Area B) on the Lake Lowell Unit, unless otherwise posted by the Bureau of Reclamation.

* * * * *

4. From February 1 through June 14, we prohibit fishing from all islands in the Snake River Islands Unit. From June 15 through June 30, we prohibit fishing from islands used by nesting birds. You must comply with all posted signs.

* * * * *

Kootenai National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, and coot on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

4. On waterfowl hunt days, we allow waterfowl hunters to access the waterfowl hunt area after 3 a.m.

* * * * *

C. Big Game Hunting. We allow hunting of deer, elk, black bear, moose, and mountain lion on that portion of the refuge that lies west of Lion's Den Road in accordance with State regulations and subject to the following conditions:

1. We allow hunting of white-tailed deer at the designated accessible blind for hunters with disabilities subject to the following conditions:

i. You may only participate in deer hunting at the accessible blind with a refuge permit (name/address/phone number), which is issued through a random drawing in early August. You may apply for a 7-day archery-only permit (name/address/phone number) or a 7-day archery/special weapons-only permit (name/address/phone number). A total of 4 weeks of archery-only permits and 6 weeks of archery/special weapon-only permits will be available.

ii. You must possess a valid State disabled hunting license and tag and provide proof of this prior to the drawing.

iii. We only allow deer hunting at the accessible blind using the following weapons: Muzzleloader, archery equipment, crossbow, shotgun, or handgun. For shotguns, you may only use slugs. For handguns, you may only use straight-walled cartridges not originally established for rifles.

iv. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

2. We prohibit the use of dogs to hunt big game.

* * * * *

■ 11. Amend § 32.32 by:

■ a. Under the entry Crab Orchard National Wildlife Refuge:

■ i. Removing paragraph B.6;

■ ii. Redesignating paragraphs B.3 through B.5 as B.4 through B.6, respectively;

■ iii. Adding a new paragraph B.3; and

■ iv. Revising paragraphs C.3. and D.10;

■ b. Under the entry Great River National Wildlife Refuge:

■ i. Revising paragraph C.5; and

■ ii. Removing paragraph C.7.iii;

■ c. Revising paragraphs B.1, C.1, C.2, and D.4 under the entry Middle Mississippi River National Wildlife Refuge; and

■ d. Under the entry Port Louisa National Wildlife Refuge:

■ i. Adding introductory text to the entry; and

■ ii. Revising paragraphs B.2 through B.5.

The revisions and additions read as follows:

§ 32.32 Illinois.

* * * * *

Crab Orchard National Wildlife Refuge

* * * * *

B. * * *

3. For hunting, you may possess only approved nontoxic shot shells while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)).

* * * * *

C. * * *

3. We allow the use of legal-sized lead ammunition (see current Illinois hunting digest) for the taking of deer.

* * * * *

D. * * *

10. Anglers may not submerge any poles or similar object to take or locate any fish.

* * * * *

Great River National Wildlife Refuge

* * * * *

C. * * *

5. On the Fox Island Division, we only allow deer hunting during the Statewide archery deer season and special managed hunts.

* * * * *

Middle Mississippi River National Wildlife Refuge

* * * * *

B. * * *

1. On the Wilkinson Island Division, you must comply with both Illinois and Missouri firearm blaze-orange safety requirements from October 1 to January 31.

* * * * *

C. * * *

1. Conditions A1, A2, and B1 apply. Condition A4 applies only to wild turkey.

2. On the Harlow, Crains, and Meissner Island Divisions, you may only use archery equipment to harvest white-tailed deer.

* * * * *

D. * * *

4. You must remove all fishing devices (see § 27.93 of this chapter) at the end of each day's fishing.

* * * * *

Port Louisa National Wildlife Refuge

Refer to § 32.34 (Iowa) for regulations regarding Iowa River Corridor Lands.

* * * * *

B. * * *

2. Condition A3 applies to upland game, including wild turkey. We allow shotgun slug or muzzleloading rifle for hunting coyotes.

3. We allow only squirrel hunting on the Keithsburg Division from the beginning of the State season to September 15. We prohibit hunting of any other upland game on the Keithsburg Division.

4. We allow hunting on the Horseshoe Bend Division from September 1 until

September 15, and December 1 until February 28. We allow spring turkey hunting.

5. We allow hunting on the Big Timber Division from September 1 until February 28. We allow spring turkey hunting.

* * * * *

■ 12. Amend § 32.33, the entry for Patoka River National Wildlife Refuge and Management Area, by:
■ a. Adding paragraph A.9; and
■ b. Revising paragraphs B.1, B.3, and C.6.

The addition and revisions read as follows:

§ 32.33 Indiana.

* * * * *

Patoka River National Wildlife Refuge and Management Area

A. * * *

9. We prohibit the use of trail and game cameras on the refuge.

B. * * *

1. You must register to hunt furbearers at the refuge office, record the number of furbearers harvested on the Upland Game Hunt Report (FWS Form 3–2362), and return the completed form to the refuge office after the hunting season.

* * * * *

3. Conditions A7 through A9 apply.

C. * * *

6. Conditions A6 through A9 apply. Condition A8 applies only to wild turkey.

* * * * *

■ 13. Amend § 32.34 by:
■ a. Revising the entry for Iowa Wetland Management District; and
■ b. Adding introductory text to the entry for Port Louisa National Wildlife Refuge.

The addition and revision read as follows:

§ 32.34 Iowa.

* * * * *

Iowa Wetland Management District

A. Migratory Game Bird Hunting. We allow hunting of migratory game birds throughout the district in accordance with State regulations and subject to the following conditions:

1. For hunting, you may possess only approved nontoxic shot shells while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)).

2. We prohibit leaving boats, decoys, or other personal property unattended at any time. You must remove all personal property, which includes boats, decoys, and blinds, brought onto the district at the end of each day (see §§ 27.93 and 27.94 of this chapter).

3. We allow boats or other floating devices. We restrict all watercraft motors to 15 horsepower (11.2 kW) or less.

B. Upland Game Hunting. We allow upland game hunting throughout the district in accordance with State regulations and subject to the following condition: Conditions A1 and A2 apply.

C. Big Game Hunting. We allow big game hunting throughout the district in accordance with State regulations and subject to the following conditions:

1. You may leave tree stands in an area for a continuous period of time beginning 7 days prior to the open season for hunting deer and ending 7 days after the final day of that season. You must clearly mark the stand with your name or Iowa hunting license number.

2. You do not have exclusive use of the tree stand when unattended or exclusive use of the tree stand site.

3. We prohibit driving nails, screws, spikes, or other metal objects into a tree (see § 32.2(i)).

D. Sport Fishing. We allow sport fishing throughout the district in accordance with State regulations and subject to the following conditions:

1. Condition A3 applies.

2. You must remove all ice fishing shelters and other personal property at the end of each day's fishing (see § 27.93 of this chapter).

* * * * *

Port Louisa National Wildlife Refuge

Refer to § 32.32 (Illinois) for Port Louisa National Wildlife Refuge fee title lands.

* * * * *

■ 14. Amend § 32.35 by:
■ a. Under the entry Flint Hills National Wildlife Refuge:
■ i. Redesignating paragraphs A.1 through A.9 as A.2 through A.10, respectively;
■ ii. Adding a new paragraph A.1;
■ iii. Revising newly redesignated paragraph A.10;
■ iv. Revising paragraphs B.1 and C.6; and
■ v. Adding paragraph C.7;
■ b. Under the entry Kirwin National Wildlife Refuge:
■ i. Removing paragraph A.8;
■ ii. Redesignating paragraphs A.9 through A.12 as A.8 through A.11, respectively;
■ iii. Removing paragraph B.3;
■ iv. Redesignating paragraphs B.4 through B.6 as B.3 through B.5, respectively;
■ v. Revising newly redesignated paragraph B.5; and
■ vi. Revising paragraphs C.9 and D.9; and
■ c. Under the entry Marais des Cygnes National Wildlife Refuge:
■ i. Redesignating paragraphs A.1 through A.4 as A.2 through A.5, respectively;
■ ii. Adding a new paragraph A.1;
■ iii. Revising paragraphs B.1, B.4, and C.1;
■ iv. Adding paragraphs C.4 and C.5; and
■ v. Revising paragraph D.

The revisions and additions read as follows:

§ 32.35 Kansas.

* * * * *

Flint Hills National Wildlife Refuge

A. * * *

1. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

* * * * *

10. We allow crow hunting on designated areas of the refuge subject to the following conditions:

i. We prohibit the use of centerfire rifles and pistols for hunting on the refuge.

ii. We close hunting areas on the north side of the Neosho River to all hunting from November 1 through March 1.

iii. Conditions A1, A3, A4, A7, and A8 apply.

B. * * *

1. Conditions A1, A3, A7, and A8 apply.

* * * * *

C. * * *

6. We prohibit the use of electronic or photographic trail-monitoring devices.

7. Conditions A1, A3, A7, A8, B3 and B4 apply.

* * * * *

Kirwin National Wildlife Refuge

* * * * *

B. * * *

5. Conditions A1, A8, A9, A10, and A11 apply.

C. * * *

9. Conditions A8 through A11 apply.

D. * * *

9. Conditions A8 through A11 apply.

Marais des Cygnes National Wildlife Refuge

A. * * *

1. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

* * * * *

B. * * *

1. Conditions A1 and A3 apply.

* * * * *

4. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

C. * * *

1. Conditions A1, A3, A4, A5, and B2 apply.

* * * * *

4. We prohibit the use of electronic or photographic trail monitoring devices.

5. You may possess only approved nontoxic shot for turkey hunting (see § 32.2(k)).

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following condition: Condition A2 applies.

* * * * *

■ 15. Amend § 32.36, the entry for Clarks River National Wildlife Refuge, by:

■ a. Revising paragraphs A.5, A.6, A.9, A.12, A.17, A.18, and A.19;

■ b. Removing paragraph A.20; and

■ c. Revising paragraphs C.2 and C.5.

The revisions read as follows:

§ 32.36 Kentucky.

* * * * *

Clarks River National Wildlife Refuge

A. * * *

5. You must possess and carry a signed refuge permit (signed brochure) while hunting and/or fishing on the refuge.

6. To retrieve or track game from a posted closed area of the refuge, you must first receive authorization from the refuge manager at 270–527–5770 or the law enforcement officer at 270–703–2836.

* * * * *

9. We prohibit discharge of firearms on or within 200 feet (90 meters) of any home, the abandoned railroad tracks, graveled roads, and hiking trails.

* * * * *

12. We allow trail cameras. Cameras may be used year-round. Cameras must have the owner's name, address, and phone number clearly displayed or they may be confiscated.

* * * * *

17. By 12 p.m. (noon) during the Statewide waterfowl season: you must cease hunting; unload firearms used for waterfowl hunting (see § 27.42(b) of this chapter); remove decoys, blinds, boats, and all other equipment (see § 27.93 of this chapter); and be out of the field daily.

18. We close to all entry of, as posted, the Clarks River Waterfowl Units from November 1 through March 31, with the exception of drawn permit holders (name/address/phone) and their guests.

19. We only allow waterfowl hunting on the Clarks River Waterfowl Units on specified days during the State waterfowl season. We only allow hunting by individuals in possession of a drawn permit and their guests. State regulations and the following conditions apply:

i. Application procedures and eligibility requirements are available from the refuge office.

ii. We allow drawn permit holders and up to four guests to hunt their assigned zone and/or provided blind on the designated date. We prohibit guests on the Clarks River Waterfowl Units without the attendance of the drawn permit holder.

iii. We prohibit selling, trading, or bartering of drawn permits. These permits are nontransferable.

iv. You may place decoys out the first morning of the drawn hunt, and you must remove them at the close of the drawn hunt (see § 27.93 of this chapter).

v. We prohibit watercraft on the Clarks River Waterfowl Units, except for drawn permit holders to access their blinds and retrieve downed birds as needed.

* * * * *

C. * * *

2. We only allow the use of portable and climbing stands. You may place stands in the field no earlier than 2 weeks prior to the opening of deer season, and you must remove them from the field within 1 week after the season closes (see §§ 27.93 and 27.94 of this chapter). The hunter's name, address, and phone number must appear on all stands left in the field.

* * * * *

5. Ground blinds used for the purpose of hunting any species during the deer modern gun, muzzleloader, and youth firearms seasons must display one square foot (144 square inches) of solid, unbroken, hunter orange visible from all sides. You must remove ground blinds when not in use.

* * * * *

■ 16. Amend § 32.37 by:

■ a. Revising the entry for Atchafalaya National Wildlife Refuge;

■ b. Under the entry Bayou Cocodrie National Wildlife Refuge:

■ i. Revising paragraph A;

■ ii. Revising paragraphs B.3, B.5, and B.6;

■ iii. Revising paragraphs C.2, C.3, C.4, and C.5;

■ iv. Redesignating paragraphs C.11 and C.12 as C.12 and C.13, respectively;

■ v. Adding a new paragraph C.11;

■ vi. Revising newly redesignated paragraph C.13; and

■ vii. Revising paragraph D;

■ c. Revising paragraph C.1 under the entry Bayou Teche National Wildlife Refuge;

■ d. Revising paragraphs A.15 and B.1 under the entry Big Branch Marsh National Wildlife Refuge;

■ e. Under the entry Black Bayou Lake National Wildlife Refuge:

■ i. Revising paragraphs A, B, and C;

■ ii. Removing paragraph D.8; and

■ iii. Redesignating paragraph D.9 as D.8;

■ f. Revising paragraphs A.7, A.11, and C.8 under the entry Bogue Chitto National Wildlife Refuge;

■ g. Under the entry Cat Island National Wildlife Refuge:

■ i. Revising paragraphs A, B.3, C.3, C.4, C.7, and C.8;

■ ii. Redesignating paragraphs C.9 and C.10 as C.10 and C.11, respectively;

■ iii. Adding a new paragraph C.9; and

■ iv. Revising paragraph D.8;

■ h. Revising paragraphs A, B, C, D.1, and D.3 under the entry D'Arbonne National Wildlife Refuge; and

■ i. Revising paragraphs A, B, C, D.2, and D.4 under the entry Upper Ouachita National Wildlife Refuge.

The additions and revisions read as follows:

§ 32.37 Louisiana.

* * * * *

Atchafalaya National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory game birds on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Hunting must be in accordance with State-issued Sherburne Wildlife Management Area regulations.

2. Feral hogs are incidental take species. You may take feral hog during any open hunting season, only with the weapon allowed for that season, and only if you are a hunter with proper licenses and State permits for that season. There is no bag limit on feral hog.

B. Upland Game Hunting. We allow hunting of upland game on designated areas of the refuge in accordance with State regulations and subject to the following conditions: A1 and A2 apply.

C. Big Game Hunting. We allow hunting of white-tailed deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions: A1 and A2 apply.

D. Sport Fishing. We allow finfishing and shellfishing year-round in accordance with Sherburne Wildlife Management Area regulations and subject to the following condition: We prohibit all commercial finfishing and shellfishing without a Special Use Permit (FWS Form 3–1383–C).

Bayou Cocodrie National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, coot, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require that all hunters and anglers age 16 and older purchase an annual public use permit (name/address/telephone number). We waive the fee for individuals age 60 and older. You must sign the permit, certifying that you understand and will comply with all regulations. You must carry this permit at all times while on the refuge.

2. We allow migratory game bird hunting on Wednesdays, Saturdays, and Sundays until 12 p.m. (noon) during the State season. We do not open for the special teal season or the State youth waterfowl hunt.

3. We prohibit hunting within 150 feet (45 meters) of the maintained rights-of-way of roads, refuge roads or designated trails, buildings, residences, or designated public facilities.

4. You must remove harvested waterfowl, temporary blinds, and decoys (see § 27.93 of this chapter) used for duck hunting by 1 p.m. daily.

5. We only allow dogs to locate, point, and retrieve when hunting for migratory game birds.

6. While hunting, all persons age 16 or younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

7. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

8. We prohibit use or possession of any type of trail-marking material.

9. Coyote, beaver, feral hog, and raccoon are incidental take species and you may take them during any open hunting season only with the weapon allowed for that season if you are a hunter having the required licenses and permits. There is no bag limit on coyote, feral hog, and beaver. State regulations apply on other incidental species.

10. You must check all game taken on the refuge before leaving the refuge at one of the self-clearing check stations indicated on the map in the refuge Hunting and Fishing Regulations Brochure.

11. We allow all-terrain vehicles (ATVs) and utility vehicles in accordance with State Wildlife Management Area (WMA) regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches (66 cm) by 12 inches (30.5 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

12. You may possess only approved nontoxic shot while hunting on the refuge (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

13. You must obtain a daily use reporting card (one per person) and place it on the dashboard of your vehicle or in your boat so that your personal information (name/city/State/zip code) is readable and in plain view. You must complete all the information requested (name/address/phone number) and return the cards to the refuge kiosk/check stations upon departure from the refuge.

14. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset except that raccoon and opossum hunters during the month of February may use the refuge at night.

15. Waterfowl hunters are allowed no more than 25 shotshells per person.

B. * * *

3. We allow the use of dogs to hunt squirrel and rabbit during that portion of the season designated as small game with dogs. We list specific season dates in the refuge brochure.

* * * * *

5. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset.

6. While hunting, all persons age 16 and younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

C. * * *

2. The bag limit is one deer per day. The State tagging regulations apply.

3. You must check all deer on the same day taken during lottery deer hunts at the nearest refuge check station.

4. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken hunter orange. You must wear the solid-hunter-orange items while in the field.

5. You may place stands up to 2 days prior to established hunting season dates. You must remove stands by 2 days after the hunting season closes. You must mark your name and phone number on your stand. You are allowed one portable stand or blind on the refuge.

* * * * *

11. We prohibit the use of trail cameras.

* * * * *

13. There is an application fee per person for the lottery gun hunt application (name/address/phone number). We waive the fee for youth and special access applications.

D. Sport Fishing. We allow fishing on the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A11 through A15 apply.

2. We prohibit commercial fishing.

3. We prohibit the taking of alligator snapping turtle (see § 27.21 of this chapter).

4. We only allow fishing during daylight hours.

5. The refuge boat ramp is open for daylight use only, except during specified hunting seasons when the ramp is open from 4 a.m. until 2 hours after legal sunset.

6. We prohibit wire traps, slat traps, wire nets, hoop nets, trotlines, yo-yos, and jug lines on the refuge.

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Bayou Teche National Wildlife Refuge

* * * * *

C. * * *

1. We allow hunting of deer only with firearms (see § 27.42 of this chapter) during 5 specific days during October and November. A youth gun hunt will occur during the last weekend of October. The general gun hunt will occur during the final full weekend in November. The youth gun hunt includes both Saturday and Sunday. The general gun hunt includes the Friday immediately before the weekend.

* * * * *

Big Branch Marsh National Wildlife Refuge

A. * * *

15. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs).

* * * * *

B. * * *

1. We allow upland game hunting during the open State season. When hunting, you may possess only approved nontoxic shot (see § 32.2(k) of this chapter), shot size 4 or smaller, or 0.22 caliber rimfire rifles or smaller.

* * * * *

Black Bayou Lake National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. We prohibit accessing the hunting area by boat from Black Bayou Lake.

5. You may enter the refuge no earlier than 4 a.m.

6. We prohibit hunting within 100 feet (30 meters) of the maintained right-of-way of roads and from or across all-terrain vehicle (ATV) trails (see § 27.31 of this chapter). We prohibit hunting within 50 feet (15 meters), or trespassing on above-ground oil, gas, or electrical transmission facilities.

7. We prohibit leaving boats, blinds, and decoys overnight.

8. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

9. Youths are generally defined as those individuals age 17 or younger, except that for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

10. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

11. We only allow ATVs on trails (see § 27.31 of this chapter) designated for their use and marked by signs. ATV trails are closed March 1 through August 31. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 lbs. (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 25 inches by 12 inches (62.5 cm by 30 cm) with a maximum of 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge as indicated in the annual Public Use Regulations brochure and in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A4, A6, A9, A10, and A11 apply.

2. Specific open dates and open areas to small game hunting will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 1 hour after legal shooting hours end.

5. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting on the refuge. This requirement only applies to the use of shotgun ammunition.

C. Big Game Hunting. We allow archery hunting of white-tailed deer on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A4, A6, A9, A10, A11, and B4 apply.

2. Specific open dates and open areas will appear in the annual Public Use Regulations brochure.

3. We prohibit gun deer hunting.

4. The daily bag limit is one deer of either sex. The State season limit applies.

5. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

6. An adult at least age 21 must supervise youth hunters under age 16 during all hunts. One adult may supervise two youths during small game and migratory bird hunts but may supervise only one youth during big game hunts. Youth must remain within normal voice contact of the adult who is supervising them. Parents or adult guardians are responsible for ensuring that hunters under age 16 do not violate refuge regulations.

7. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or any nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

* * * * *

Bogue Chitto National Wildlife Refuge

A. * * *

7. We prohibit hunting within 150 feet (45 meters) from the centerline of any public road, refuge road, designated or maintained trail, building, residence, designated public facility, or from or across aboveground oil or gas or electric facilities. We prohibit hunting in refuge-designated closed areas, which we post on the refuge and identify in the refuge hunt permits (signed brochure).

* * * * *

11. We prohibit horses, trail cameras, all-terrain vehicles (ATVs), and utility-type vehicles (UTVs).

* * * * *

C. * * *

8. You may take hog as incidental game while participating in the refuge archery, primitive weapon, and general gun deer hunts and where otherwise specified. We list specific dates for the special hog hunts in January, February, and March in the refuge hunt permit (signed brochure). During the special hog hunts in February, you must use trained hog-hunting dogs to aid in the take of hog. During the special hog hunts, you may take hog from ½ hour before legal sunrise until ½ hour after legal sunset. You may possess only approved nontoxic shot or pistol or rifle ammunition not larger than .22 caliber rimfire to take the hog after it has been caught by dogs. During the special hog hunt in March, you may use any legal firearm. A8 applies during special hog hunts in February.

* * * * *

Cat Island National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, coot, and woodcock on designated areas of the refuge as shown on the refuge hunt brochure map in accordance with State regulations and subject to the following conditions:

1. We require that all hunters and anglers age 16 and older purchase an annual public use permit (name/address/telephone number). We waive the fee for hunters age 65 and older. The refuge user is required to sign, certifying that you understand and will comply

with all regulations, and carry this permit at all times while on the refuge.

2. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset.

3. You may possess only approved nontoxic shot while hunting on the refuge (see § 32.2(k)). This requirement applies only to the use of shotgun ammunition.

4. Waterfowl hunters may possess no more than 25 shotshells per person.

5. While hunting, all persons age 17 or younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

6. We allow take of beaver, feral hog, nutria, raccoon, and coyote incidental to any refuge hunt with weapons legal for that hunt until you take the daily bag limit of game.

7. You must check all game (name) taken prior to leaving the refuge at one of the self-clearing check stations indicated on the map in the refuge public use brochure.

8. We allow all-terrain vehicles (ATVs) and utility-type vehicle (UTVs) in accordance with State Wildlife Management Area regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches by 12 inches (66 cm by 30 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

9. We prohibit hunting within 150 feet (45 meters) of any public road, refuge road, trail or ATV trail, building, residence, or designated public facility.

10. We prohibit the possession or use of any type of trail-marking material.

11. We prohibit horses or mules.

12. We prohibit camping or overnight parking on the refuge.

13. We prohibit air-thrust boats on the refuge.

14. We prohibit all other hunting during refuge lottery deer hunts.

15. We allow waterfowl hunting on Wednesdays, Saturdays, and Sundays until 12 p.m. (noon) during the designated State duck season.

16. You must remove harvested waterfowl, temporary blinds, and decoys (see § 27.93 of this chapter) used for duck hunting by 1 p.m. daily.

17. We allow dogs to only locate, point, and retrieve when hunting for migratory game birds.

18. We prohibit accessing refuge property by boat from the Mississippi River.

19. We prohibit trapping.

20. We prohibit the possession of saws, saw blades, or machetes.

21. We prohibit the use or possession of alcohol while hunting (see § 32.2(j)).

22. We prohibit all commercial activities (including, but not limited to, guiding).

B. * * *

3. We allow the use of squirrel and rabbit dogs during designated small game with dog seasons. We allow up to two dogs per hunting party for squirrel hunting.

* * * * *

C. * * *

3. There is no application fee per person for each lottery hunt application (name/address/phone number).

4. You may place stands up to 2 days prior to established hunting season dates, and you must remove them no more than 2 days after the hunting season closes. You must mark your name and phone number on your stand. You are allowed one portable stand or blind on the refuge.

* * * * *

7. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken-hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken-hunter orange.

8. We prohibit nailing deer stands or steps to trees. We prohibit attaching any blind or stand to a tree by using any metal object inserted into the tree.

9. We prohibit the use of trail cameras.

* * * * *

D. * * *

8. We prohibit boat launching by trailer from all refuge roads and parking lots except at designated boat ramps.

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D'Arbonne National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory game bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. You may enter the refuge no earlier than 4 a.m.

5. We prohibit hunting within 100 feet (30 meters (m)) of the maintained rights-of-way of roads. We prohibit hunting within 50 feet (15 m) or trespassing on above-ground oil, gas, or electrical transmission facilities.

6. We prohibit leaving boats, blinds, and decoys overnight.

7. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

8. Youths are generally defined as those individuals age 17 or younger, except that for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

9. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

10. We prohibit motorized boats in the No Gun Hunting Area (the ''Beanfield'') from November 1 through January 31.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, and A10 apply.

2. Specific open dates and open areas to small game hunting will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 2 hours after legal shooting hours.

5. You may possess only approved nontoxic shot for hunting (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

6. We allow hunting dogs only to locate, point, and retrieve when hunting for upland game species.

C. Big Game Hunting. We allow hunting of white-tailed deer on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, A10, and B4 apply.

2. Specific open dates and open areas will appear in the annual Public Use Regulations brochure.

3. You must check all deer taken during general Gun Deer Hunts at a refuge check station on the same day taken.

4. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

5. Deer hunters must wear hunter orange in accordance with State deer hunting regulations in Wildlife Management areas.

6. We prohibit hunters from placing or hunting from stands on pine trees with white-painted bands or rings.

7. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or any nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

8. We prohibit the hunting of big game species with dogs.

D. * * *

1. We prohibit leaving boats and other personal property on the refuge overnight.

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3. We prohibit commercial fishing. For recreational fishing using commercial gear (slat traps, etc.) we require you to carry a Special Use Permit (FWS Form 3–1383–G), which is available at the refuge office.

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Upper Ouachita National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory game bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. You may enter the refuge no earlier than 4 a.m.

5. We prohibit hunting within 100 feet (30 meters (m)) of the maintained rights-of-way of roads and from or across all-terrain vehicle (ATV) trails. We prohibit hunting within 50 feet (15 m), or trespassing on aboveground oil, gas, or electrical transmission facilities.

6. We prohibit leaving boats, blinds, and decoys overnight.

7. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

8. Youths are generally defined as those individuals age 17 or younger; for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

9. We prohibit any person or group to act as a hunting guide or outfitter, or in any other capacity that receives payment directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

10. We allow ATVs only on trails (see § 27.31 of this chapter) designated for their use and marked by signs. ATV trails are closed March 1 through August 31. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 lbs. (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 25 inches by 12 inches (62.5 cm by 30 cm) with a maximum of 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, and A10 apply.

2. Specific open dates and open areas to hunt small game will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 2 hours after legal shooting hours.

5. You may possess only approved nontoxic shot for hunting (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

C. Big Game Hunting. We allow hunting of certain species of big game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, A10, and B4 apply.

2. Specific open dates and open areas will appear in the Annual Public Use Regulations Brochure.

3. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

4. Deer hunters must wear hunter orange in accordance with State deer hunting regulations in Wildlife Management Areas.

5. We prohibit hunters from placing stands or hunting from stands on pine trees with white-painted bands and/or rings.

6. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

7. We prohibit the use of dogs for hog hunting.

D. * * *

2. We prohibit outboard motors in the Wigeon Ponds (only trolling motors allowed).

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4. We prohibit leaving boats and other personal property on the refuge overnight (see § 27.93 of this chapter).

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■ 17. Amend § 32.38 by:

■ a. Revising paragraph C.15 under the entry Moosehorn National Wildlife Refuge; and

■ b. Revising paragraphs B.3 and C.3 under the entry Umbagog National Wildlife Refuge.

The revisions read as follows:

§ 32.38 Maine.

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Moosehorn National Wildlife Refuge

* * * * *

C. * * *

15. We prohibit hunting in the following areas:

i. The South Magurrewock Area: The boundary of this area begins at the intersection of the Charlotte Road and U.S. Route 1; it follows the Charlotte Road in a southerly direction to a point just south of the fishing pier and observation blind, where it turns in an easterly direction, crossing the East Branch of the Magurrewock Stream, and proceeds in a northerly direction along the upland edge of the Upper and Middle Magurrewock Marshes to U.S. Route 1 where it follows Route 1 in a southerly direction to the point of origin.

ii. The North Magurrewock Area: The boundary of this area begins where the northern exterior boundary of the refuge and Route 1 intersect; it follows the boundary line in a westerly direction to the railroad grade where it follows the main railroad grade and refuge boundary in a southwest direction to the upland edge of the Lower Barn Meadow Marsh; then it follows the upland edge of the marsh in a southerly direction to U.S. Route 1 where it follows Route 1 to the point of origin.

iii. The posted safety zone around the refuge headquarters: The boundary of this area starts where the snowmobile trail intersects with Charlotte Road. The boundary follows the southern edge of the field, across the abandoned Maine Central Railroad grade, where it follows the snowmobile trail in a northwesterly direction to Barn Meadow Road. It proceeds across Barn Meadow Road to the South Fireline, where it follows the South Fireline to the Headquarters Road. It follows the Headquarters Road in a southerly direction to Two Mile Meadow Road. It follows the westerly side of Two Mile Meadow Road to the intersection with Mile Bridge Road. It then follows Mile Bridge Road to the intersection with Hanson Pit Road, then along Hanson Pit Road leaving the road in an easterly direction at the site of the old crossing, across the abandoned Maine Central Railroad grade to Charlotte Road (directly across from the Moosehorn Ridge Road gate). The line follows Charlotte Road in a northerly direction to the point of origin.

iv. The Southern Gravel Pit: The boundary of this area starts at a point where Cranberry Brook crosses the Charlotte Road and proceeds south along the Charlotte Road to the Baring/Charlotte Town Line, east along the Town Line to a point where it intersects the railroad grade where it turns in a northerly direction, and follows the railroad grade to Cranberry Brook, following Cranberry Brook in a westerly direction to the point of origin.

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Umbagog National Wildlife Refuge

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B. * * *

3. We open the refuge to hunting during the hours stipulated under State hunting regulations. You must unload all hunting firearms (see § 27.42 of this chapter) and nock no arrows outside of legal hunting hours.

* * * * *

C. * * *

3. We allow prehunt scouting of the refuge; however, we prohibit dogs and hunting firearms (see § 27.42 of this chapter) during prehunt scouting.

* * * * *

■ 18. Amend § 32.39 by:

■ a. Revising paragraphs A.1, A.3, and C.13 under the entry Blackwater National Wildlife Refuge;

■ b. Revising paragraph C.12 under the entry Eastern Neck National Wildlife Refuge; and

■ c. Under the entry Patuxent Research Refuge:

■ i. Revising paragraphs A.12, B.2, C.6, C.7, and C.8;

■ ii. Removing paragraph C.16;

■ iii. Redesignating paragraphs C.17 through C.20 as C.16 through C.19, respectively;

■ iv. Revising newly redesignated paragraphs C.17, C.18, and C.19; and

■ v. Revising paragraphs D.15.iv and D.15.v.

The revisions read as follows:

§ 32.39 Maryland.

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Blackwater National Wildlife Refuge

A. * * *

1. We require you to obtain a refuge waterfowl hunting permit using the Waterfowl Lottery Application (FWS Form 3–2355) or a signed refuge permit (signed brochure) while hunting on refuge property.

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3. We allow only hunters possessing a valid refuge waterfowl hunting permit issued by the refuge to participate in the waterfowl hunt during designated days.

* * * * *

C. * * *

13. Disabled persons may have an assistant during the hunt in designated areas of the refuge. Persons assisting disabled hunters must be at least age 18 and obey all refuge, State, and Federal laws and regulations. Non-hunting assistants assisting disabled hunters must not be afield with a hunting firearm, bow, or other hunting device. Assistants who wish to hunt must abide by the conditions in C1 and C3. Assistants may not enter a designated disabled hunting area unless they are accompanied by a certified disabled hunter. All refuge-provided hunt blinds are reserved for disabled hunters only; however, when a certified disabled hunter and their assistant occupy the same blind, both may take game.

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Eastern Neck National Wildlife Refuge

* * * * *

C. * * *

12. Disabled persons may have an assistant during the hunt on designated areas of the refuge. Persons assisting disabled hunters must be at least age 18 and obey all refuge, State, and Federal laws and regulations. Non-hunting assistants assisting disabled hunters must not be afield with a hunting firearm, bow, or other hunting device. Assistants who wish to hunt must abide by the conditions in C1 and C3. Assistants participating in a disabled hunt must be accompanied by a hunter certified by the State as being disabled.

* * * * *

Patuxent Research Refuge

A. * * *

12. Goose, duck, and dove hunting is suspended during the muzzleloader and firearms seasons, with the exceptions that waterfowl hunting will remain open during the 2-day January firearms season, during the early muzzleloader season, and waterfowl hunters are restricted to hunting only Blue Heron Pond, Lake Allen, and Area Z.

* * * * *

B. * * *

2. You may possess only approved nontoxic shot while hunting in the field (see § 32.2(k)), except for the use of .22-caliber rimfire rifles during the months of December and January only to hunt squirrel.

* * * * *

C. * * *

6. We require turkey hunters to pattern their hunting weapons prior to going afield. Contact refuge headquarters for more information.

7. Prior to issuing a hunt permit, we require you to pass a yearly proficiency test with each hunting weapon used. See A1 for issuing information.

8. We only allow the use of a hunting shotgun, muzzleloader, or bow and

arrow according to refuge hunting regulations.

* * * * *

17. North Tract: We allow shotgun, muzzleloader, and bow hunting in accordance with the following: Conditions C1 through C16 apply.

18. Central Tract: Headquarters/Mills Race (MR) Lottery Hunt: We only allow shotgun and bow hunting in accordance with the following: Conditions C1 through C15 apply (except C8).

19. South Tract: We allow shotgun, muzzleloader, and bow hunting in accordance with the following: Conditions C1 through C16 apply.

D. * * *

15. * * *

iv. Anglers may fish from April 1 until mid-October, as posted. We also reserve the right to close Cash Lake at any time.

v. We allow fishing from legal sunrise to legal sunset.

* * * * *

■ 19. Amend § 32.40 by:

■ a. Revising paragraphs A.4, A.5, A.9, C.9, and D.1 under the entry Assabet River National Wildlife Refuge;

■ b. Revising paragraphs A.5, A.10, and C.8 under the entry Great Meadows National Wildlife Refuge;

■ c. Revising paragraphs D.1 and D.3 under the entry Nantucket National Wildlife Refuge; and

■ d. Revising the heading of paragraph A, and paragraphs A.6, A.11, C.7, and C.9 under the entry Oxbow National Wildlife Refuge.

The revisions read as follows:

§ 32.40 Massachusetts.

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Assabet River National Wildlife Refuge

A. * * *

4. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

5. During any season when it is legal to hunt deer with a shotgun or muzzleloader, we require all hunters, including archers and small game hunters, to wear a minimum of 500 square inches (3,226 square centimeters) of solid-orange clothing or material in a conspicuous manner on their chest, back, and head. During all other times, if you are engaged in woodcock hunting on the refuge, you must wear a minimum of a solid-orange hat.

* * * * *

9. You may begin scouting hunting areas 1 month prior to the opening day of your permitted season. We require possession of refuge permits (Migratory Bird Hunt Application, FWS Form 3–2357) while scouting.

* * * * *

C. * * *

9. We prohibit construction or use of permanent structures while hunting.

* * * * *

D. * * *

1. We allow fishing from designated locations on the banks of Puffer Pond. We prohibit the use of motorized and non-motorized boats on Puffer Pond.

* * * * *

Great Meadows National Wildlife Refuge

A. * * *

5. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

* * * * *

10. You may begin scouting hunting areas beginning 1 month prior to the opening day of your permitted season. We require possession of refuge permits (FWS Form 3–2357) while scouting. We prohibit the use of dogs during scouting.

* * * * *

C. * * *

8. We prohibit construction or use of permanent structures while hunting.

* * * * *

Nantucket National Wildlife Refuge

* * * * *

D. * * *

1. We reserve the right to close the refuge shoreline and beach area to surf fishing and over-sand vehicle use during the period of April 1 through mid-September annually, based on biological needs and beach conditions. Seasonal closures are delineated with posted signs. A portion of the northernmost area of the shoreline, commonly referred to as the point, is posted closed from April 1 through mid-September.

* * * * *

3. We require a permit obtained from the Trustees of Reservations for the use of over-sand, surf-fishing vehicles on the refuge.

* * * * *

Oxbow National Wildlife Refuge

A. Migratory Game Bird Hunting.

* * *

6. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

* * * * *

11. You may begin scouting hunting areas 1 month prior to the opening day of your permitted season. We require possession of refuge permits while scouting. We prohibit the use of dogs during scouting.

* * * * *

C. * * *

7. You may use decoys to hunt turkey.

* * * * *

9. We prohibit construction or use of permanent structures while hunting.

* * * * *

■ 20. Amend § 32.41, the entry for Detroit River International Wildlife Refuge, by revising paragraphs A.4, B.1, B.2, and C to read as follows:

§ 32.41 Michigan.

* * * * *

Detroit River International Wildlife Refuge

A. * * *

4. For hunting, you may possess only approved nontoxic shot while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)). Discarded shells are considered litter.

* * * * *

B. * * *

1. Conditions A1, A2, A3, A5, A6, A7, A8, and A9 apply.

2. You may possess only approved nontoxic shot (see § 32.2(k)) while in the field with the following exception: While hunting fox, coyotes, and raccoons in units where we allow it, you may use single projectile shot such as bullets, slugs, or muzzleloader bullets containing lead. We prohibit the use of buckshot for any hunting on the refuge. Discarded shells are considered litter.

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A3, A4, A5, A6, A8, and A9 apply.

2. We prohibit the distribution of bait or hunting with the aid of bait, salt, minerals, or other ingestible attractant (see § 32.2(h)).

3. For deer hunting, you may use only single projectile shot. We prohibit the use of buckshot for any hunting on the refuge. Discarded shells are considered litter.

4. We allow portable tree stands for deer hunting.

5. We allow only one tree stand per hunter per refuge unit.

6. We do not require hunters to remove tree stands at the end of each day's hunt, but we strictly enforce State rules on tree stands.

7. For Humbug Marsh Only:

i. You must obtain State-issued permits for this unit by entering the Michigan Department of Natural Resources annual drawing.

ii. You must possess a valid State-issued permit for the date you are hunting in the Humbug Marsh Unit.

iii. We will provide fixed hunting platforms and blinds for selected hunters.

8. The Fix Unit is closed to firearm deer hunting. We allow only archery deer hunting in the Fix Unit.

* * * * *

■ 21. Amend § 32.43 by:

■ a. Revising paragraphs A, D.1, D.2, and D.8 under the entry Coldwater River National Wildlife Refuge;

■ b. Revising paragraphs A, B, C, D.1, D.2, and D.7 under the entry Dahomey National Wildlife Refuge;

■ c. Revising paragraphs A.2, A.3, A.13, and A.14 under the entry Hillside National Wildlife Refuge;

■ d. Revising paragraphs B.2, B.3, and B.9 under the entry Holt Collier National Wildlife Refuge;

■ e. Revising paragraphs A.2, A.3, and A.12 under the entry Mathews Brake National Wildlife Refuge;

■ f. Revising paragraphs A.2, A.3, A.13, and A.14 under the entry Morgan Brake National Wildlife Refuge;

■ g. Revising paragraphs A.2, A.3, and A.13 under the entry Panther Swamp National Wildlife Refuge;

■ h. Revising the entry for Sam D. Hamilton Noxubee National Wildlife Refuge;

■ i. Under the entry St. Catherine Creek National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.9, A.11, A.12, and A.14;

■ ii. Revising paragraphs B.3.iii and B.6;

■ iii. Revising paragraphs C.3, C.4, C.7, and C.9;

■ iv. Adding paragraph C.13; and

■ v. Revising paragraph D introductory text and paragraphs D.1 and D.5;

■ j. Revising the entry for Tallahatchie National Wildlife Refuge; and

■ k. Revising paragraphs A.2, A.3, A.10, and A.13 under the entry Yazoo National Wildlife Refuge.

The addition and revisions read as follows:

§ 32.43 Mississippi.

* * * * *

Coldwater River National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must possess and carry a valid, signed refuge hunting permit (Visitor Check-In Permit and Report, FWS Form 3–2405). While hunting on the refuge, all persons younger than age 16 (''youth hunter'') must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 (''licensed hunter''). A hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359), available at each refuge information station, and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the reverse side of the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report ''0.'' We prohibit hunters possessing more than one Big Game Harvest Report at a time.

5. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with ''No Hunting'' or ''Area Closed'' signs.

6. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

7. During the refuge deer firearm season (to include primitive weapons and youth gun hunt) all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge's general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

8. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

9. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94 of this chapter) from the hunting area following each morning's hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit all-terrain vehicles (ATVs, see § 27.31(f) of this chapter), horses, and mules on the refuge. We prohibit the overnight storage of boats on the refuge.

11. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

12. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

13. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

14. You are allowed no more than 25 shotshells per person in the field.

* * * * *

D. * * *

1. Condition A12 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

* * * * *

8. We allow take of frog only with a Special Use Permit (FWS Form 3–1383–G).

Dahomey National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must carry a valid, signed refuge hunting permit

(Visitor Check-In Permit and Report, FWS Form 3–2405). While hunting on the refuge, all persons younger than age 16 (''youth hunter'') must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 (''licensed hunter''). A hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359), available at each refuge information station, and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report ''0.'' We prohibit hunters possessing more than one Big Game Harvest Report (FWS Form 3–2359) at a time.

5. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with ''No Hunting'' or ''Area Closed'' signs.

6. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

7. During the refuge deer firearm season (to include primitive weapons and youth gun hunt) all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge's general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

8. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

9. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94 of this chapter) from the hunting area following each morning's hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) (see § 27.31(f) of this chapter), horses, and mules on the refuge.

11. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

12. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

13. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

14. You are allowed no more than 25 shotshells per person in the field.

B. Upland Game Hunting. We allow hunting of quail, squirrel, rabbit, and raccoon (raccoon by general Special Use Permit [FWS Form 3–1383–G] only) on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A7, and A10 through A13 apply.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting small game with a shotgun. Small game also may be hunted with .22 magnums, .17 calibers, and .22 caliber rimfire rifles and archery equipment using arrows with points other than broadheads.

3. You may use dogs, but dogs must remain under the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

4. We prohibit the cutting or removal of trees and other vegetation (see § 27.51 of this chapter).

5. We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A7, and A10 through A13 apply.

2. We prohibit dogs for any big game hunt.

3. We prohibit possession of any drug on any arrow for bow hunting (see § 32.2(g)).

4. We prohibit organized drives for deer.

5. We prohibit hunting or shooting across any open, fallow, or planted field from ground level.

6. We prohibit the construction of, and hunting from, any permanent stands or blinds on the refuge. We allow valid permit holders to possess and hunt from one portable stand or blind on the refuge. You must permanently and legibly write your name and phone number on all stands on the refuge. Stands left in the area do not reserve the hunting locations. You may place stands up to 2 days prior to the hunt, and you must remove them no more than 2 days after the refuge's deer season closes. We may confiscate and dispose of stands not in compliance with these regulations. Ground blinds must display a minimum 400 square inches (2,581 square centimeters) of fluorescent orange that is visible from all sides. We prohibit nailing deer stands and/or steps to trees and attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

7. Hunters using a climbing tree stand must use a fall-arrest system manufactured to Treestand Manufacturers Association standards.

8. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter).

9. We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit the use of buckshot on the refuge.

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A11 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

* * * * *

7. We allow take of frog only by Special Use Permit (FWS Form 3–1383–G).

* * * * *

Hillside National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form

3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

14. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) only on designated trails (see § 27.31 of this chapter; see refuge brochure map) from September 15 through February 28. We prohibit horses and mules.

* * * * *

Holt Collier National Wildlife Refuge

B. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

9. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Mathews Brake National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

12. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Morgan Brake National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

14. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) only on designated trails (see § 27.31 of this chapter; see refuge brochure map) from September 15 through February 28. We prohibit horses and mules.

* * * * *

Panther Swamp National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid T R Complex Annual Public Use Permit (name/address/phone number)holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Sam D. Hamilton Noxubee National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, woodcock, and coot on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must purchase a refuge waterfowl permit (Waterfowl Lottery Application; FWS Form 3–2355) for waterfowl hunting in addition to meeting other applicable State and Federal requirements. No more than two companions may accompany each permitted hunter, and we do not require these companions to purchase permits. Permits are nontransferable and only issued to hunters ages 16 and older. Permit holders can hunt as standby hunters for any date for which waterfowl hunting is open. Youth age 15 or younger are not required to obtain a refuge waterfowl permit and can obtain a free permit from the refuge's office.

2. Information on hunts and hunt dates are available at refuge headquarters, on the refuge Web site, and as specified in the refuge brochure.

3. You must remove all decoys, blind material, and harvested game and return to the check station by 1 p.m. each day (see §§ 27.93 and 27.94 of this chapter).

4. All youth hunters age 15 and younger must remain within sight and normal voice contact of an adult age 21 or older. One adult may supervise not more than two youth hunters.

5. All waterfowl hunters must check-in and check-out at the refuge's duck check station both before and after a day's hunt.

6. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

7. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

8. You may possess only approved nontoxic shot while hunting within wetlands and green-tree reservoirs (see § 32.2(k)). Waterfowl hunters are limited to 25 shotshells per person.

9. We prohibit leaving any personal property, including, but not limited to, boats or vehicles of any type, geocaches, and cameras, overnight on the refuge (see § 27.93 of this chapter). You may not bring any mechanized equipment into the Noxubee Wilderness Area, and you must remove all personal property daily from the Noxubee Wilderness Area. Outside the Noxubee Wilderness Area, you may leave properly labeled tree stands used for deer hunting and trotlines and jugs used for fishing overnight.

10. During the deer firearm (primitive or modern gun) hunts, any person hunting species other than waterfowl,

accompanying another person hunting species other than waterfowl, or walking off-trail within areas open to deer hunting must wear at least 500 square inches (3,226 square centimeters (cm)) of unbroken fluorescent-orange material visible above the waistline as an outer garment at all times. Ground blinds when occupied must display a minimum of 400 square inches (2,581 square cm) of unbroken fluorescent-orange material.

11. We allow unleashed dogs for retrieval of migratory and upland game only. Livestock is prohibited, and pets must remained restrained and under the owner's control.

12. We prohibit marking trees and using flagging tape, reflective tacks, and other similar marking devices.

13. We require all hunters and anglers to record hours active and game harvested using the Visitor Check-In Permit and Report (FWS Form 3–2405).

14. We require all users to possess and display a valid Entrance Pass. You may use a current Federal Recreational Lands Pass or valid Federal Migratory Bird Hunting and Conservation Stamp (Federal Duck Stamp) as the Entrance Pass.

15. Waterfowl hunters must stay within 100 feet (30.5 meters (m)) of the assigned hunt location. You may exceed 100 feet (30.5 m) when retrieving downed birds.

16. We prohibit using real or artificial agricultural grain baits, salts and other minerals, scents, and other food-like attractants (see § 32.2(h)). We allow you to use baited lines for fishing on the refuge.

17. We prohibit off-road vehicle use including the use of all-terrain vehicles (ATVs), utility-type vehicles (UTVs), and livestock, including horses and mules.

B. Upland Game Hunting. We allow hunting of squirrel, rabbit, quail, opossum, and raccoon on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. When waterfowl hunting is actively taking place, we prohibit all public use other than waterfowl hunting within the designated areas for waterfowl hunting.

2. We allow hunting of squirrel, raccoon, rabbit, quail, and opossum with unleashed dogs during designated hunts. All pets must remain restrained and within the immediate control of the owner.

3. We allow raccoon and opossum hunting between the hours of legal sunset and legal sunrise.

4. Conditions A2, A4, A6 through A14, A16, and A17 apply.

5. We prohibit hunting or entry into areas designated as being ''closed'' (see refuge brochure map).

6. You may take incidental species (coyote, beaver, nutria, and feral hog) during any hunt with those weapons legal during those hunts.

7. Bobwhite quail and rabbit hunters are required to wear at least a solid hunter orange vest or cap.

C. Big Game Hunting. We allow hunting of white-tailed deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2, A4, A6 through A14, A16, A17, B1, B2, B5 and B6 apply.

2. You must purchase a refuge quota deer permit (Quota Deer Hunt Application; FWS Form 3–2354) in addition to meeting State requirements for all refuge deer hunts. Permits are nontransferable. Youth age 15 or younger are not required to a purchase a refuge quota deer permit and can obtain a free permit from the refuge's office.

3. We prohibit organized drives for deer.

4. You may place one portable tree stand or ground blind for deer hunting on the refuge only during the open deer season. You must clearly label the stand or blind with the name, address, and phone number of the hunter. When not in use and left on the refuge, you must place stands in a non-hunting position at ground level.

5. While climbing a tree, installing a tree stand that uses climbing aids, or hunting from a tree stand on the refuge, you must use a fall-arrest system (full body harness) that is manufactured to the Treestand Manufacturer's Association's standards.

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. The general sport fishing, boating, and bow fishing season extends from March 1 through October 31, except for the shoreline of Bluff Lake from the Bluff Lake Boardwalk to the visitor center, the entire Noxubee River, and all borrow pit areas along Highway 25 that are open year-round to fishing.

2. Conditions A2, A6, A7, A9 through A14, A16, A17, B1, and B5 apply.

3. Anglers must keep boat travel at idle speed, and they must not create a wake when moving.

4. We prohibit limb lines, jug fishing, trotlines, snag lines, and hand grappling in Ross Branch, Bluff, and Loakfoma Lakes as well as areas within 100 yards of refuge water and transportation structures.

5. When left unattended, anglers must tag fishing gear with their name, address, and phone number. Anglers must check all gear within 24 hours each day or remove these devices.

6. Trotlining:

i. Anglers must label each end of the trotline floats with the owner's name, address, and phone number.

ii. We limit trotlines to one line per person, and we allow no more than two trotlines per boat.

iii. Anglers must tend all trotlines every 24 hours and remove them when not in use.

iv. Trotlines must possess at least 6-inch (15.2-centimeter) cotton string leads.

7. Jug fishing:

i. Anglers must label each jug with their name, address, and phone number.

ii. Anglers must check all jugs every 24 hours and remove them when not in use.

8. We prohibit nighttime bow fishing.

9. We prohibit fishing tournaments on all refuge waters.

10. We prohibit the taking of frogs, turtles, and crawfish (see § 27.21 of this chapter).

11. We prohibit the use of airboats, sailboats, hovercrafts, and inboard-water-thrust boats such as, but not limited to, personal watercraft, watercycles, and waterbikes.

12. We prohibit using nets of any type to capture free-roaming fish or wildlife. Fishing nets can be used to recover fish caught by hook and line.

St. Catherine Creek National Wildlife Refuge

A. * * *

1. We allow hunting in Butler Lake, Salt Lake, and Gillard Lake from ½ hour before legal sunrise until 12 p.m. (noon) on Wednesdays, Saturdays, and Sundays.

* * * * *

9. Waterfowl hunters are allowed no more than 25 shotshells per person.

* * * * *

11. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) in accordance with State WMA regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches (66 cm) by 12 inches (30 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire

pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

12. You must be age 16 or older to operate an ATV or UTV on the refuge.

* * * * *

14. We prohibit the following acts: Use or possession of alcohol while hunting (see § 32.2(j)); entering the refuge from private property; hunters entering the refuge from public waterways; overnight parking; parking or hunting within 150 feet (45 meters) of any petroleum facility or equipment, or refuge residences and buildings; parking by hunters in refuge headquarters parking lot; and use of handguns for hunting on the refuge.

B. * * *

3. * * *

iii. We prohibit the use of boats, ATVs, and UTVs.

* * * * *

6. We prohibit the following acts: Target practice; and the possession of any trail-marking material.

C. * * *

3. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken hunter orange. You must wear the solid-hunter-orange items while in the field.

4. While hunting, all persons under age 16 must be in the presence and under direct supervision of a licensed or exempt hunter at least age 21.

* * * * *

7. We prohibit nailing deer stands and/or steps to trees. We prohibit attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

* * * * *

9. You may place stands up to 2 days prior to established hunting season dates, and you must remove them no more than 2 days after the hunting season closes. You must mark your stand with your name and phone number. We allow each hunter one portable stand or blind on the refuge.

* * * * *

13. We prohibit the use of trail cameras.

D. * * *. We allow fishing during daylight hours only from February 1–November 15 in accordance with State regulations and subject to the following conditions:

1. We prohibit the use of ATVs and UTVs (see § 27.31(f) of this chapter).

* * * * *

5. We prohibit taking alligator gar.

* * * * *

Tallahatchie National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must possess and carry a signed North Mississippi NWR hunting permit (code 606, available from the Mississippi Department of Wildlife, Fisheries, and Parks). While hunting on the refuge, all persons younger than age 16 (''youth hunter'') must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 (''licensed hunter''). A licensed hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. We prohibit public hunting north of Mississippi Highway 8.

5. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359) available at each refuge information station and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report ''0.'' We prohibit hunters possessing more than one Big Game Harvest Report at a time.

6. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with ''No Hunting'' or ''Area Closed'' signs.

7. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

8. During the refuge deer firearm season (to include primitive weapons and youth gun hunt), all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge's general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

9. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

10. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94) from the hunting area following each morning's hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

11. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) (see § 27.31(f) of this chapter), horses, and mules on the refuge.

12. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

13. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

14. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

15. You are allowed no more than 25 shotshells per person in the field.

B. Upland Game Hunting. We allow hunting of quail, squirrel, rabbit, and raccoon (raccoon by general Special Use Permit [FWS Form 3–1383–G] only) on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A8, and A10 through A14 apply.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting for small game with a shotgun. Small game also may be hunted with .22 magnums, .17 calibers, and .22 caliber rimfire rifles and archery equipment using arrows with points other than broadheads.

3. You may use dogs, but they must remain under the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in

accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A8, and A10 through A13 apply.

2. We prohibit dogs for any big game hunt.

3. We prohibit possession of any drug on any arrow for bow hunting (see § 32.2(g)).

4. We prohibit organized drives for deer.

5. We prohibit hunting or shooting across any open, fallow, or planted field from ground level.

6. We prohibit the construction of, and hunting from, any permanent stands or blinds on the refuge. We allow valid permit holders to possess and hunt from one portable stand or blind on the refuge. You must permanently and legibly write your name and phone number on all stands on the refuge. Stands left on the area do not reserve the hunting locations. You may place stands up to 2 days prior to the hunt, and you must remove them no more than 2 days after the refuge's deer season closes. We may confiscate and dispose of stands not in compliance with these regulations. Ground blinds must display a minimum 400 square inches (2,581 square centimeters) of fluorescent orange that is visible from all sides. We prohibit nailing deer stands and/or steps to trees and attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

7. Hunters using a climbing tree stand must use a fall-arrest system manufactured to Treestand Manufacturers Association standards.

8. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

9. We prohibit the use of buckshot on the refuge.

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A12 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

3. We only allow bank or boat sport fishing south of Mississippi Highway 8.

4. We prohibit possession or use of jugs, seines, nets, hand-grab baskets, slat traps/baskets, or any other similar devices and commercial fishing of any kind.

5. We only allow trotlines, yo-yos, limb lines, crawfish traps, or any other similar devices for recreational use. You must tag or mark them with the angler's full name and full residence address, including zip code written with waterproof ink, legibly inscribed or legibly stamped on the tag, and you must attend the devices a minimum of once daily. When not attended, you must remove these devices (see § 27.93 of this chapter) from the refuge.

6. We prohibit snagging or attempting to snag fish.

7. We allow crawfishing.

8. We allow take of frog only with a Special Use Permit (FWS Form 3–1383–G).

Yazoo National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

10. For hunting, you may possess only approved nontoxic shot (see § 32.2(k)).

* * * * *

13. Valid T R Complex Annual Public Use Permit (name/address/phone number) holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

■ 22. Amend § 32.44 by:

■ a. Revising the entry for Great River National Wildlife Refuge; and

■ b. Revising the entry for Middle Mississippi River National Wildlife Refuge.

The revisions read as follows:

§ 32.44 Missouri.

* * * * *

Great River National Wildlife Refuge

Refer to § 32.32 (Illinois) for regulations.

Middle Mississippi River National Wildlife Refuge

Refer to § 32.32 (Illinois) for regulations.

* * * * *

■ 23. Amend § 32.46 by revising paragraphs C.1, C.2, C.4, and C.9 under the entry Fort Niobrara National Wildlife Refuge to read as follows:

§ 32.46 Nebraska.

* * * * *

Fort Niobrara National Wildlife Refuge

* * * * *

C. * * *

1. We require the submission of a Big/Upland Game Hunt Application (FWS Form 3–2356). You must possess and carry a signed refuge hunt permit (signed brochure) when hunting. We require hunters to complete a Big Game Harvest Report (FWS Form 3–2359) and return it to the refuge at the conclusion of the hunting season.

2. We allow hunting with muzzleloader and archery equipment. We prohibit hunting with firearms capable of firing cartridge ammunition.

* * * * *

4. We allow hunting in the area defined as those refuge lands situated north and west of the Niobrara River. We allow access to this area only from designated refuge parking areas and the Niobrara River.

* * * * *

9. We prohibit permanent tree stands, nails, screw-in steps, or other items that penetrate the outer bark of a tree (see § 32.2(i)). We prohibit leaving tree stands and ground blinds in the same location for more than 7 consecutive days. You must label unattended tree stands, elevated platforms, and ground blinds with your name and address; the label must be legible from the ground. You may put up tree stands, elevated platforms, and ground blinds, but no earlier than opening day of deer season; you must remove them by the last day of deer season.

* * * * *

■ 24. Amend § 32.48, the entry for Umbagog National Wildlife Refuge, by revising paragraphs A.1 and C.3 to read as follows:

§ 32.48 New Hampshire.

* * * * *

Umbagog National Wildlife Refuge

A. * * *

1. You must wear hunter-orange clothing or material in accordance with State of Maine regulations for the season and/or species you are hunting; one article of hunter-orange clothing is required during moose season, and two articles are required during firearm and muzzleloader season for deer.

* * * * *

C. * * *

3. We allow prehunt scouting of the refuge; however, we prohibit dogs and hunting firearms during prehunt scouting.

* * * * *

■ 25. Amend § 32.51, the entry for Montezuma National Wildlife Refuge, by revising paragraphs A, B, and C.11 to read as follows:

§ 32.51 New York.

* * * * *

Montezuma National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow waterfowl, Canada goose, and snow goose hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. For the regular waterfowl season:

i. We require daily refuge permits (Migratory Bird Hunt Report, FWS Form 3–2361) and reservations. You must possess and carry refuge permits while in the field and present them upon request to any law-enforcement officer.

ii. We allow hunting only on Tuesdays, Thursdays, and Saturdays during the established refuge season set within the State western zone season. We allow a youth waterfowl hunt during the Saturday of the State's established youth waterfowl hunt dates each year.

iii. Except for opening day, we take telephone reservations from 8:30 a.m. to 9 a.m. on Tuesdays, Thursdays, and Saturdays for the next hunt day.

iv. We take opening day reservations between 8:30 a.m. and 9 a.m. on the Thursday of the week before the season opener (Note: This is not the Thursday directly before the opener). We take youth hunt reservations between 8:30 a.m. and 9 a.m. on the Thursday of the week before the youth hunt (Note: This is not the Thursday directly before the youth hunt.).

v. The reservation telephone number is 315–568–4136.

vi. All telephone reservations are on a first-come, first-served basis.

vii. If you have a reservation for Tschache Pool, you may bring one companion; we will determine party limits for other areas annually.

viii. You may request the parking area of your choice when making reservations; parking areas are given on a first-come, first-served basis.

ix. Only refuge personnel may move parking signs and blinds.

x. All hunters with reservations and their hunting companions must check-in at the Route 89 Hunter Check Station area at least 1 hour before legal shooting time or forfeit their reservation.

xi. You must set up in your chosen hunting spot before legal shooting time.

xii. Forfeited reservations become available on a first-come, first-served basis to standby hunters at the Route 89 Hunter Check Station.

xiii. In Tschache Pool, you must use motorless boats to hunt, and we limit hunters to one boat per reservation. We also limit hunters to one motor vehicle in the Tschache Pool area per reservation.

xiv. We prohibit shooting from any dike or within 50 feet (15.2 meters) of any dike or road, or from within 500 feet (152.4 meters) of the Tschache Pool observation tower. We do not limit hunting to specific blind sites.

xv. We will announce selection procedures for hunting sites on areas other than Tschache Pool annually.

xvi. You may possess a maximum of 15 nontoxic shot shells for hunting while in the field (see § 32.2(k)); you may not take more than 15 shot shells per hunter into the hunting area.

xvii. You must stop hunting at 12 p.m. (noon), and you must check-out and be out of the hunting area by 1 p.m.

xviii. We require proof of successful completion of the New York State Waterfowl Identification Course, the Montezuma Nonresident Waterfowl Identification Course, or a suitable nonresident State Waterfowl Identification Course to hunt in the refuge; all hunters must show proof each time they hunt, in addition to showing their valid hunting license and signed Federal Migratory Bird Hunting and Conservation Stamp (Federal Duck Stamp).

xix. You must possess, carry, and present upon request to any law enforcement officer a valid daily hunt permit card (Migratory Bird Hunt Report, FWS Form 3–2361). We also require you to return the daily hunt permit card at the end of hunting. You can obtain a permit at the Hunter Check Station during the check-in process, and you can return it to the Hunter Check Station or at the box located at the north end of the Tschache Pool dike.

2. For Canada goose and snow goose hunting:

i. We allow hunting of Canada goose during the New York State September (or ''early'') season and of snow goose during portions of the New York State snow goose season and portions of the period covered by the Light Goose Conservation Order according to New York State regulations and any special postings or publications set forth by the refuge manager.

ii. Canada goose and snow goose hunting will be permitted 7 days per week during the refuge's set hunting dates. Hunting hours are in accordance with New York State regulations for Canada goose and snow goose seasons.

iii. You must possess, carry, and present upon request to any law enforcement officer a valid daily hunt permit card (Migratory Bird Hunt Report, FWS Form 3–2361). We also require you to return the daily hunt permit card at the end of hunting or at the end of the day. You can obtain a permit at the Hunter Check Station on State Route 89 and return it to the same location; obtaining a permit will be on a first-come, first-served basis each hunt day until the day's permits are all taken.

3. We allow hunting with dogs.

B. Upland Game Hunting. We allow hunting of wild turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must carry and present upon request to any law-enforcement officer a valid daily hunt permit card (Big/Upland Game Hunt Application, FWS Form 3–2356). We also require you to return the daily hunt permit card at the end of hunting or at the end of the day. You can obtain a permit at the Hunter Check Station on State Route 89 and return it to the same location; obtaining a permit during the fall season will be on a first-come, first-served basis each hunt day until the day's permits are all taken.

2. We only allow hunting from legal sunrise to legal sunset during the fall season and from ½ hour before legal sunrise to noon during the youth hunt weekend. We prohibit night hunting.

3. We allow hunting within the New York State fall turkey season. We prohibit hunting during the New York State spring turkey season.

4. We allow youth hunting during the New York State youth wild turkey hunt weekend, depending on whether mentors for youth hunters are available. Participants must make a reservation to hunt; each year, the refuge manager will set the date and time that we will accept reservations by phone. The reservation phone number is (315) 568–4136.

5. Youth hunters and their mentors must attend an orientation program conducted by refuge staff.

6. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting with a shotgun. The refuge manager reserves the right to restrict hunting implements beyond State restrictions (*e.g.,* based on visitor safety).

7. We prohibit hunting with dogs.

8. You may use portable blinds and decoys, but you must remove all equipment (see § 27.93 of this chapter) at the conclusion of each day.

9. We prohibit parking and walking along the Wildlife Drive for the purpose of hunting, unless otherwise posted by refuge personnel.

10. We prohibit use of all-terrain vehicles (ATVs) (see § 27.31(f) of this

chapter), dirt bikes, bicycles, snowmobiles, and watercraft for the purpose of turkey hunting.

C. * * *

11. Hunting weapon restrictions follow New York State regulations; successful harvest with a bow or other hunting weapon during firearms season requires use of a State-issued firearms season tag. The refuge manager reserves the right to restrict hunting implements beyond State restrictions (*e.g.,* based on visitor safety).

* * * * *

■ 26. Amend § 32.52, the entry for Pocosin Lakes National Wildlife Refuge, by:
■ a. Revising paragraphs A.4 and A.9;
■ b. Removing paragraphs A.12 and B.9;
■ c. Revising paragraphs C.2 and C.5;
■ d. Removing paragraph C.8; and
■ e. Redesignating paragraph C.9 as C.8.

The revisions read as follows:

§ 32.52 North Carolina.

* * * * *

Pocosin Lakes National Wildlife Refuge

A. * * *

4. We open the refuge for daylight use only (½ hour before legal sunrise to ½ hour after legal sunset), except that we allow hunters to enter and remain in hunting areas from 2 hours before legal sunrise until 2 hours after legal sunset when we allow hunting in those areas.

* * * * *

9. You may possess only approved nontoxic shot (see § 32.2(k)) while migratory game bird hunting.

* * * * *

C. * * *

2. You may hunt turkey only if you carry a valid permit (General Activities Special Use Permit Application, FWS Form 3–1383–G). These permits are valid only for the dates and areas shown on the permit. We require an application and a fee for those permits and hold a drawing, when necessary, to select the permittees. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting turkeys west of Evans Road and on the Pungo Unit.

* * * * *

5. We allow hunters to take feral hogs in any area that is open to hunting deer using only those weapons authorized for taking deer. On the Frying Pan tracts, we also allow hunters to take feral hogs, using only those weapons authorized for taking deer, whenever we open those tracts to hunting any game species with firearms.

* * * * *

■ 27. Amend § 32.53 by:
■ a. Under the entry Arrowwood National Wildlife Refuge:
■ i. Revising paragraphs C.2, C.5, D.2, and D.3;
■ ii. Removing paragraphs D.4, D.5, and D.6; and
■ iii. Redesignating paragraphs D.7 through D.9 as D.4 through D.6, respectively;
■ b. Revising paragraph B introductory text and paragraphs B.3 and C.6 under the entry Des Lacs National Wildlife Refuge;
■ c. Revising paragraphs B and C under the entry Lake Zahl National Wildlife Refuge; and
■ d. Revising paragraphs B and C under the entry Lostwood National Wildlife Refuge.

The revisions read as follows:

§ 32.53 North Dakota.

* * * * *

Arrowwood National Wildlife Refuge

* * * * *

C. * * *

2. We allow deer hunting on the refuge during the State Youth Deer Season except in select closed areas as posted.

* * * * *

5. We prohibit permanent tree stands. We allow temporary tree stands, blinds, and game cameras for daily use; you must remove them by the end of the day. You may clamp, rope, or chain stands, steps, and cameras to trees; you may not nail, wire, screw, or bolt them to trees (see § 32.2(i)).

* * * * *

D. * * *

2. We allow shore fishing, archery, and spearfishing along major road rights-of-way and interior portions of the refuge and by-pass channel during the entire State fishing season. We only allow walk-in access, except in designated areas.

3. We allow ice fishing and dark house spearfishing. We allow fish houses, cars, and trucks on the ice as conditions allow. You may leave fish houses on the ice overnight until March 15; after March 15 you must remove fish houses from the refuge before leaving for the day.

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Des Lacs National Wildlife Refuge

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B. * * *. You may hunt sharp-tailed grouse, Hungarian partridge, turkey, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

3. Upland game bird season opens on the day following the close of the regular deer gun season through the end of the State season.

* * * * *

C. * * *

6. Conditions B6 through B9 apply.

* * * * *

Lake Zahl National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of sharp-tailed grouse, Hungarian partridge, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We open the refuge daily from 5 a.m. to 10 p.m.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. Upland game bird season opens on the day following the close of the regular deer gun season through the end of the State season.

4. You may use hunting dogs to retrieve upland game. Dogs must be under your direct control at all times.

5. You may only enter the refuge by foot.

6. We prohibit the use of snowmobiles, all-terrain vehicles (ATVs), off-highway vehicles (OHVs), utility-type vehicles (UTVs), bicycles, or similar vehicles on the refuge.

7. We prohibit the use of horses, mules, or similar livestock on the refuge during all hunting seasons.

C. Big Game Hunting. We allow deer hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B5 through B7 apply.

2. You may only use portable tree stands and ground blinds. We prohibit leaving stands and blinds overnight (see § 27.93 of this chapter). We prohibit driving nails, screws, spikes, or other objects into a tree or otherwise injuring a tree (see § 32.2(i)).

3. We prohibit entry to the refuge before 12 p.m. (noon) on the first day of the respective archery, gun, or muzzleloader deer hunting season.

4. We prohibit the use of flagging, trail markers, paint, reflective tacks, or other types of markers (see § 27.93 of this chapter).

5. We prohibit the use of trail cameras.

* * * * *

Lostwood National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of sharp-tailed grouse,

Hungarian partridge, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We open the refuge daily from 5 a.m. to 10 p.m.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. We prohibit upland game hunting on the portion of the refuge south of Highway 50 during regular deer gun season.

4. We allow upland game hunting on the portion of the refuge north of Highway 50 on the day following the close of the regular deer gun season through the end of the State season.

5. You may use hunting dogs to retrieve upland game. Dogs must be under your direct control at all times.

6. You must comply with all ''Closed to Hunting'' signs.

7. You may only enter the refuge by foot.

8. We prohibit the use of snowmobiles, all-terrain vehicles (ATVs), off-highway vehicles (OHVs), utility-type vehicles (UTVs), bicycles, or similar vehicles on the refuge.

9. We prohibit the use of horses, mules, or similar livestock on the refuge during all hunting seasons.

C. Big Game Hunting. We allow deer hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B6 through B9 apply.

2. You may only use portable tree stands and ground blinds. We prohibit leaving stands and blinds overnight (see § 27.93 of this chapter). We prohibit driving nails, screws, spikes, or other objects into a tree or otherwise injuring a tree (see § 32.2(i)).

3. We prohibit entry to the refuge before 12 p.m. (noon) on the first day of the respective archery, gun, or muzzleloader deer hunting season.

4. We prohibit the use of flagging, trail markers, paint, reflective tacks, or other types of markers (see § 27.93 of this chapter).

5. We prohibit the use of trail cameras.

* * * * *

■ 28. Amend § 32.55, the entry for Washita National Wildlife Refuge, by revising paragraphs A.1, A.2, and C to read as follows:

§ 32.55 Oklahoma.

* * * * *

Washita National Wildlife Refuge

A. * * *

1. We require permits (signed brochure) and payment of a fee to hunt goose, duck, and sandhill crane.

2. Goose, duck, and sandhill crane hunters must hunt from designated pit blinds.

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer, feral hog, and Rio Grande wild turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow deer and feral hog hunting during the special refuge season in accordance with the refuge hunt information sheet. We will hold turkey hunts during the State spring turkey season.

2. We allow shotguns and lawful archery equipment for turkey hunting.

3. You must obtain a refuge hunt permit from the State and pay a fee (fee waived for youth hunters and mentors during the youth hunt).

4. You must check in and out of hunt areas daily at the refuge office or check station.

5. You must take bagged deer, hog, and/or turkey to the refuge check station.

6. We will determine bag limits on deer and turkey annually.

7. We prohibit the use of bait (see § 32.2(h)).

8. A non-hunting mentor age 21 or older must accompany, and be in the immediate presence of, youth hunters participating in the youth hunt. Youth hunters must be age 17 or younger. Both youth hunters and mentors must wear hunter orange clothing meeting or exceeding the minimum State requirements.

9. We prohibit using handguns for hunting.

* * * * *

■ 29. Amend § 32.56 by:

■ a. Revising paragraph A.8 under the entry Bandon Marsh National Wildlife Refuge;

■ b. Revising paragraphs A.5, A.6, and A.7 under the entry Lower Klamath National Wildlife Refuge;

■ c. Removing paragraph A.6 under the entry Nestucca Bay National Wildlife Refuge; and

■ d. Adding paragraph A.8 under the entry Siletz Bay National Wildlife Refuge.

The revisions and addition read as follows:

§ 32.56 Oregon.

* * * * *

Bandon Marsh National Wildlife Refuge

A. * * *

8. You may enter posted retrieval zones while retrieving downed birds and when traveling to and from the hunting areas. We prohibit discharging firearms while in a retrieval zone.

* * * * *

Lower Klamath National Wildlife Refuge

A. * * *

5. You may not set decoys in retrieving zones.

6. We prohibit the use of air-thrust and water-thrust boats.

7. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

* * * * *

Siletz Bay National Wildlife Refuge

A. * * *

8. You may enter posted retrieval zones while retrieving downed birds and when traveling to and from the hunting areas. We prohibit discharging firearms while in a retrieval zone.

* * * * *

■ 30. Amend § 32.60 by:

■ a. Under the entry Cape Romain National Wildlife Refuge:

■ i. Revising paragraphs B.11, B.15, D.11, and D.12; and

■ ii. Adding paragraphs D.14, D.15, and D.16;

■ b. Under the entry Carolina Sandhills National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.3, and A.5 through A.9;

■ ii. Adding paragraph A.10;

■ iii. Revising paragraph B.1 and C.1;

■ iv. Removing paragraph C.11;

■ v. Redesignating paragraphs C.13 through C.19 as C.11 through C.17, respectively; and

■ vi. Revising paragraph D.9;

■ c. Revising paragraphs B, C, and D under the entry Santee National Wildlife Refuge; and

■ d. Revising the entry for Waccamaw National Wildlife Refuge.

The additions and revisions read as follows:

§ 32.60 South Carolina.

* * * * *

Cape Romain National Wildlife Refuge

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B. * * *

11. We prohibit camping on the refuge except for designated archery hunters on Bulls Island and individuals obtaining a Special Use Permit (FWS Form 3–1383–G) from the refuge manager.

* * * * *

15. We prohibit overnight parking at Garris Landing, except for archery

hunters during the designated refuge archery white-tailed deer season and individuals obtaining a Special Use Permit (FWS Form 3–1383–G) from the refuge manager. We require individuals parking vehicles at Garris Landing to obey all posted signs.

* * * * *

D. * * *

11. We prohibit the commercial transport of passengers to any refuge island for any purpose without a Special Use Permit (FWS Form 3–1383–C) from the refuge manager.

12. We prohibit feeding or harassing any marine mammal.

* * * * *

14. We prohibit any amphibious vehicle, hovercraft, airboat, or vessel from landing upon refuge islands.

15. We prohibit the use of any amphibious vehicle or vessel upon refuge lands or waters.

16. We prohibit any personal watercraft, as defined at 33 CFR 174.3, from landing upon refuge islands.

Carolina Sandhills National Wildlife Refuge

A. * * *

1. All hunters must carry a signed refuge General Hunt Permit (signed brochure) and government-issued picture identification.

* * * * *

3. Each youth hunter (younger than age 16) must remain within sight and normal voice contact and under supervision of an adult age 21 or older with a valid license and General Hunt Permit (signed brochure). Each adult may supervise no more than two youth hunters. Each youth hunter must carry evidence of successful completion of a State-approved hunter-education course.

* * * * *

5. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

6. We prohibit discharge of weapons for any purpose other than to take or attempt to take legal game animals during established hunting seasons.

7. We prohibit the use of outdoor recreational vehicles (ORVs) except by mobility-impaired hunters with a Special Use Permit (FWS Form 3–1383–G) to use ORV in designated areas during specified hunts. Mobility-impaired hunters must have a State Disabled Hunting license in order to receive the Special Use Permit. Companions assisting disabled hunters must possess required State license(s) and refuge permit(s) and be listed on the Special Use Permit.

8. For hunting, you may possess shotguns with shot no larger than No. 5.

9. Legal shooting hours for September dove hunts are 12 p.m. (noon) to 6 p.m.

10. We prohibit the possession of more than 50 shotgun shells during the September dove hunts.

B. * * *

1. Conditions A1 through A7 apply.

* * * * *

C. * * *

1. Conditions A1 through A7 apply (with the following exception for condition A3: Each adult may supervise no more than one youth hunter).

* * * * *

D. * * *

9. We prohibit the use or possession of alcoholic beverages while fishing on the refuge (see § 32.2(j)).

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Santee National Wildlife Refuge

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B. Upland Game Hunting. We allow hunting of raccoon and opossum on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow hunters to use only weapons, firearms, and ammunition specifically authorized for each hunt.

2. All refuge hunters under age 16 must show proof of successfully completing a hunter-education/safety course. A properly licensed adult at least age 21 must directly supervise (within sight and normal voice contact) hunters under age 16. An adult may supervise only one youth.

3. We require hunters to possess a refuge hunt permit (signed refuge hunt brochure), a valid State hunting license, and government-issued picture identification while hunting. The refuge hunt permit is not valid until signed by the hunter.

4. Before hunting, each individual participant must obtain from a designated check station and display their completed User Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. After checking a harvested animal at a check station, the hunter must record species harvest information on reporting card. You must return all cards upon completion of the activity and before leaving the refuge.

5. You must check all animals taken on the refuge before removing the animal from the refuge and prior to 8:30 p.m. at the check station.

6. We require hunters to make a reasonable effort to retrieve wounded game. You must obtain permission from refuge personnel to enter a ''No Hunting Zone'' or ''Closed Area'' for any purpose.

7. We allow vehicles only on established roads marked open for vehicular traffic. You may travel roads marked ''Closed to all vehicles'' on foot or by bicycle. The speed limit for all roads is 15 mph. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) or other off-road vehicles. You may park vehicles alongside roads but only in a manner that will not block gates, roads, or fire lanes or interfere with the normal flow of traffic.

8. Hunting firearms being transported in vehicles and boats during refuge hunts must be unloaded and cased or locked in a secure compartment (*e.g.,* toolbox or trunk). We define a loaded firearm as having ammunition in the chamber or magazine. Muzzleloaders will be considered unloaded if the percussion cap is not seated in the chamber.

9. We prohibit hunting with poison tip arrows (pods), exploding arrows, center fire rifles, and handguns (see § 32.2(g)).

10. We prohibit possession of bait, baiting, and/or hunting in the vicinity of bait (see § 32.2(h)).

11. We prohibit camping, overnight parking, fires, and littering (see §§ 27.95(a) and 27.94 of this chapter).

12. We prohibit the possession of remote photography, videography, or any other remote device and trail-monitoring/counting devices.

13. We prohibit entry beyond ''Closed Area'' or ''No Hunting Zone'' signs. We prohibit discharging weapons within, into, or across a ''No Hunting Zone'' or ''Closed Area.''

14. We prohibit discharging a firearm from, on, or across any refuge road, or designated refuge foot trail.

15. We prohibit hunting from within 100 feet (30 meters (m)) of any roadway, whether open or closed to vehicular traffic, or from or within 300 yards (270 m) of any designated hunter check station or residence.

16. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

17. We prohibit man or dog drives, stalk hunting, and/or hunting from artificially pruned trees for deer and feral hogs.

18. We allow hunting on each refuge unit only within specified hunt periods and only for raccoon or opossum, and white-tailed deer (see paragraph C, Big Game Hunting, of this entry).

19. We allow unlimited harvest of feral hog as an incidental take while hunting during the day.

20. We will open hunting areas from 5 a.m. until 8:30 p.m. during designated hunt periods.

21. We allow use of dogs only for raccoon and opossum hunting. The dogs must wear a collar displaying the owner's name, address, and telephone number.

22. We allow take of raccoon and opossum only during night hunting from the hours of 6 p.m. to 6 a.m. We prohibit hunting on Saturday nights and Sunday nights. Special State regulations apply for night hunting.

23. We allow take of raccoon and opossum with a shotgun using nontoxic shot size no larger than #4 or a .22-caliber rimfire rifle. We prohibit possession of buckshot or slugs. We prohibit the use of all other weapons for hunting.

C. Big Game Hunting. We allow hunting of white-tailed deer on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 through B20 apply.

2. We prohibit the use of dogs during deer hunts.

3. We prohibit night hunting of deer and feral hogs. On the refuge, nighttime is defined from ½ hour after legal sunset to ½ hour before legal sunrise.

4. We prohibit driving nails, screws, spikes, or other metal objects into a tree, and we prohibit hunting from a tree into which those objects have been driven (see § 32.2(i)).

5. We prohibit destroying or cutting vegetation (see § 27.51 of this chapter). We prohibit the possession of axes, saws, machetes, or other tools used for cutting vegetation on the refuge while scouting or hunting.

6. We prohibit trail flagging. You may use clothes pins with reflective tape/tack or commercially made reflective orange glow or trail clips to mark the path to the tree. You must mark all clips and pins with your full name, and you must remove them at the end of the hunt period. We will consider any clips or pins found without a hunter's name or any found after the end of a hunt period to be littering (see § 27.94 of this chapter), and we will remove them immediately.

7. We require hunters to wear an outer garment visible above the waist that contains a minimum of 500 square inches (3,226 square centimeters) of unbroken, solid fluorescent orange (hunter orange) material at all times during firearms and muzzleloader hunts. This does not apply to dove, raccoon, and turkey hunts.

8. Deer and feral hog hunting must occur from portable elevated hunting stands. A safety belt or harness must be used while using a hunting stand. We prohibit ground blinds. We allow only one stand per hunter, and each hunter must clearly mark stands with his or her full name, date, and phone number. We will confiscate any stands found without the hunter's name, date, and phone number marked on them.

9. We allow scouting on both the Pine Island and Cuddo Units during periods when these units are open to general public access. We allow vehicles only on roads designated as open for vehicular traffic. All other roads and trails are open to walk-in or bicycle traffic. We prohibit hunting weapons and dogs during scouting activities.

10. We will open access roads, closed to the general public for driving, only during each deer hunt and on the Friday, Saturday, and Sunday prior to each hunt.

11. You may place stands, clothes pins, or clips, only on open hunt areas on the Friday, Saturday, and Sunday immediately prior to each hunt (from 7 a.m. until 5 p.m.) and must remove them by 8:30 p.m. on the last day of each hunt period. We will confiscate any stands found outside of allowed periods.

12. We open the Plantation Islands (Cuddo Unit) to deer and feral hog hunting only from 5 a.m. until 2:30 p.m.

13. Shooting hours are from ½ hour before legal sunrise until ½ hour after legal sunset.

14. The refuge conducts one lottery draw hunt (Quota Deer Hunt Application, FWS Form 3–2354) for the Family, Friends, and Kids (Family Friendly) hunts conducted on the Bluff Unit of the refuge. Contact the refuge office for dates, application information, and more information about this special hunt opportunity.

15. We allow the use of non-motorized boats for accessing the unit's interior canals to inland areas open to hunting.

D. Sport Fishing. We allow fishing on the refuge in accordance with State regulations and subject to the following conditions:

1. A valid State fishing license, a signed refuge fishing permit (signed brochure), and government-issued picture identification must be in each angler's possession while fishing on the refuge. A signed refuge permit must be in each fisherman's possession while fishing on the refuge, except all recreational fishing boat operators are only required to have one refuge fishing permit per boat. A refuge fishing permit is not valid until signed.

2. We allow public fishing on all four refuge units. We open waters of Lake Marion within refuge boundaries for fishing 24 hours a day, except in areas posted as ''Closed Areas'' or closed for migratory bird management (sanctuaries). We allow fishing only on the inland ponds and canals during times the refuge units are open for general public access or as posted. We prohibit fishing at night, to include bank fishing, except by boat in Lake Marion.

3. Cantey Bay (Bluff Unit), Black Bottom (Cuddo Unit), and Savannah Branch (Pine Island Unit) are only open to public access, including boating and fishing, from March 1 through October 31.

4. We limit access to the interior freshwater canals and ponds to canoes or kayaks, or by foot or bicycle travel only. We prohibit use of internal combustion engines on interior ponds and canals.

5. We prohibit littering, camping and/or overnight parking, open fires, swimming or wading, collecting or searching for or taking of any items of antiquity, and overnight mooring of boats (see §§ 27.62, 27.94, and 27.95(a) of this chapter). We allow pets only in designated areas, and they must remain on a leash or within vehicles/vessels.

6. We prohibit fishing or boating within 100 feet (30 meters) of any nesting bird or bird rookeries within refuge boundaries.

7. We prohibit nighttime access to boat-launching areas.

8. We prohibit commercial fishing.

9. We prohibit attaching trotlines, bush/limb lines, fishing devices, signs, or any other objects to trees, posts, or markers within refuge boundaries.

10. We prohibit shellfishing of all mollusks, including Asian clams.

11. We prohibit mooring or attaching boats to any refuge boundary marker, post, or navigational post within refuge waters.

12. We prohibit air-thrust boats, hovercraft, airboats, and personal watercraft (jet skis) within the waters of and/or boundary of the refuge.

* * * * *

Waccamaw National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, dove, woodcock, and snipe on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must possess and carry at all times while hunting a signed, current refuge hunting regulations brochure, which serves as the hunt permit. The hunt permit is invalid until signed by the hunter.

2. Each youth hunter age 15 and younger must remain within sight, within normal voice contact, and under the supervision of an adult age 21 or older, except when participating in the Federal Youth Days waterfowl hunt,

when the youth hunter must be under the supervision of an adult age 18 or older. We do not require youth hunters to have a hunter-education card for migratory gamebird hunting, but they must possess a signed refuge hunting regulations brochure. The supervising adult must comply with all State and Federal hunting license requirements and also possess a signed refuge hunting regulations brochure. Each supervising adult may supervise no more than two youths.

3. We allow waterfowl hunting only until 12 p.m. (noon) each Saturday and Wednesday during the State waterfowl season. Hunters may enter the refuge no earlier than 5 a.m. on hunt days and must be off the refuge by 2 p.m.

4. We allow scouting Monday through Friday during the waterfowl season. Hunters must be off the refuge by 2 p.m.

5. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting all species of migratory birds on the refuge.

6. We prohibit permanent blinds (see § 27.93 of this chapter). Hunters must remove portable blinds and decoys at the end of each day's hunt.

7. We allow use of dogs only while hunting. We require dogs to wear a collar displaying the owner's name, address, and phone number.

8. We do not require hunter check-in and check-out, with the exception of special lottery hunts. There is no quota on the number of hunters for general hunting.

9. We prohibit discharge of weapons for any purpose other than to take or attempt to take legal game animals during established hunting seasons (see § 27.42(a) of this chapter).

10. We prohibit hunting on any unit for wildlife species not officially opened to hunting or posted as ''No Hunting Zones.'' We prohibit entering any unit or area posted as ''Closed.''

11. We require individuals parking vehicles in the refuge to obey all posted signs.

12. Access into all refuge hunt areas for hunting and scouting is by foot, bicycle, or boat. We prohibit ATVs (see § 27.31(f) of this chapter) and air boats on the refuge.

B. Upland Game Hunting. We allow hunting of gray squirrel, raccoon, and opossum on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, and A8 through A12 apply.

2. We allow hunting only in designated areas and only on days designated annually by the refuge within the State season.

3. You may possess only nontoxic shot no larger than #2 in shotguns for hunting. We allow .22-caliber rimfire rifles.

4. We prohibit shooting any game from a boat except waterfowl.

5. We require the use of dogs for hunting raccoon and opossum.

6. The refuge prohibits upland game hunting during refuge Big Game Hunts.

C. Big Game Hunting. We allow hunting of white-tailed deer, feral hog, and turkey on designated areas of the refuge. The State of South Carolina does not classify feral hog as big game; however, for the purpose of these regulations, we include feral hog in the big game category. We allow big game hunting on the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A8 through A12, B2 and B4 apply.

2. We only allow hunting for designated species on days designated annually by the refuge, within the State season and limits, and according to refuge unit-specific regulations annually listed in the refuge hunting regulations brochure.

3. We close areas open to hunting to the general public during big game hunts.

4. We allow archery, muzzleloading (black powder), rifles (centerfire larger than .22 caliber), and shotguns according to refuge unit-specific regulations.

5. We prohibit blow guns and drugged arrows (see § 32.2(g)). We allow muzzleloading rifles that use only a single projectile on the muzzleloader hunts. We prohibit buckshot, rimfire ammunition, and full-metal-jacketed military ammunition.

6. Access into all refuge hunt areas for hunting and scouting is by foot or boat. We may open some refuge roads on hunt days. We prohibit ATVs (see § 27.31(f) of this chapter) and air boats on the refuge.

7. We allow scouting all year during daylight hours except during the State waterfowl season. During the waterfowl season, the same regulations that apply to scouting for waterfowl (see condition A4) apply to scouting for big game species. We prohibit the use of trail cameras and other scouting devices.

8. Hunters may enter the refuge no earlier than 5 a.m. on hunt days and must leave the refuge no later than 1 hour after legal sunset.

9. We do not require hunter check-in and check-out, with the exception of special lottery hunts.

10. The refuge limit on antlered deer is one antlered buck per hunt session that must have at least three antler points on one side. We define a ''point'' as an antler projection of at least 1 inch (2.5 centimeters) or more in length. Hunters can harvest two antlerless deer per year during coinciding State doe days or by using personal doe tags.

11. You may take feral hogs during refuge deer hunts. There is no size or bag limit on hogs. We may offer special hog hunts during and after deer season to further control this invasive species. You must dispatch all feral hogs before removing them from the refuge.

12. We prohibit hunting on or within 100 feet (30 meters) of all routes marked as roads or trails on the hunt brochure map.

13. You must hunt deer and feral hog from an elevated hunting stand.

14. We allow only one portable tree stand per hunter, and you must clearly mark it with your full name and phone number. We prohibit placing deer stands on the refuge more than 3 days prior to the opening day of a hunting session. Hunters must remove stands from the refuge no later than 3 days after each refuge big game hunt (see § 27.93 of this chapter).

15. We allow hunters to use flagging to mark the site of hunter entry from roads or trails and again at the stand site. We allow hunters to use clothes pins with reflective tape between entry and stand sites to mark the route to the stand. You must label all pins with your full name and remove them at the end of the hunt.

16. We require hunters to wear an outer garment visible above the waist that contains a minimum of 500 square inches (3,226 square centimeters) of solid, fluorescent-orange material at all times during big game hunts except for wild turkey.

17. We prohibit the use of organized drives, including the use of boats, as an aid in the taking or attempting to take big game species.

18. We prohibit possession of bait, distribution of bait, or hunting over a baited area (see § 32.2(h)).

19. We allow crossbows only during the big game hunting sessions, when we allow muzzleloaders and modern weapons. We may also allow crossbows during special hunts if determined to be appropriate.

20. Each youth hunter age 15 and younger must remain within sight, within normal voice contact, and under supervision of an adult age 21 or older, and must possess a signed refuge hunting regulations brochure. We do not require youth hunters who are sitting in the same hunting stand as the supervising adult to possess a hunter-education card. We require youth hunters who are sitting in a hunting

stand by themselves to possess a valid hunter-education card. The supervising adult must comply with all State and Federal hunting license requirements and possess a signed refuge hunting regulations brochure. Each supervising adult may supervise a maximum of one youth.

21. We only allow deer and hog hunting on the uplands of Sandy Island during a special archery-only lottery hunt. Hunters must apply for lottery entry (name/address/phone number) and are chosen by a random selection process. There is a quota on the number of hunters selected for this hunt.

22. We have special hunts for youth and mobility-impaired hunters on the Normandy Tract. You may obtain information about the drawing from the refuge office or Web site.

D. Sport Fishing. We allow fishing in accordance with State regulations.

■ 31. Amend § 32.61, the entry for Lake Andes National Wildlife Refuge, by revising paragraph D to read as follows:

§ 32.61 South Dakota.

* * * * *

Lake Andes National Wildlife Refuge

* * * * *

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must remove all boats, motor vehicles, fishing equipment, and other personal property, excluding ice houses, by the end of each day (see §§ 27.93 and 27.94 of this chapter).

2. We allow fishing on the Center and South units of Lake Andes.

* * * * *

■ 32. Amend § 32.62 by:

■ a. Under the entry Cross Creeks National Wildlife Refuge:

■ i. Revising paragraphs A.2, A.3, A.8, B.2, B.3, and B.8;

■ ii. Removing paragraph B.9; and

■ iii. Revising paragraphs C.4. and D.1;

■ b. Revising paragraphs A.6, B.1, B.4, and D.8 under the entry Hatchie National Wildlife Refuge; and

■ c. Under the entry Tennessee National Wildlife Refuge:

■ i. Revising paragraphs A.2, A.8, B.2, and B.9;

■ ii. Removing paragraph B.10; and

■ iii. Redesignating paragraph B.11 as B.10.

The revisions read as follows:

§ 32.62 Tennessee.

* * * * *

Cross Creeks National Wildlife Refuge

A. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

3. We set and publish season dates and bag limits annually in the Refuge Hunting and Fishing Regulations available at the refuge office.

* * * * *

8. Youth hunters under age 17 must remain in sight and normal voice contact with an adult hunter age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

B. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

3. We set and publish season dates and bag limits annually in the Refuge Hunting and Fishing Regulations available at the refuge office.

* * * * *

8. Each youth hunter under age 17 must remain within sight and normal voice contact of an adult age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

C. * * *

4. Each youth hunter younger than age 17 must remain within sight and normal voice contact of an adult age 21 or older. One adult hunter may supervise no more than one youth hunter.

* * * * *

D. * * *

1. We allow fishing on the refuge pools and reservoirs from March 16 through November 14 from ½ hour before legal sunrise to ½ hour after legal sunset.

* * * * *

Hatchie National Wildlife Refuge

A. * * *

6. Mourning dove, woodcock, and snipe seasons close during all deer archery, quota deer gun, and youth deer gun hunts. In the area west of Interstate 40 we follow the State seasons, except we close during youth deer gun and quota deer gun hunts.

* * * * *

B. * * *

1. Conditions A1 through A4, A6, and A8 through A12 apply.

* * * * *

4. We close all small game hunts during the refuge deer archery, quota, and youth gun hunts, except in the area west of Interstate 40, where small game reopens after the second quota deer gun hunt in accordance with State seasons.

* * * * *

D. * * *

8. We allow the use of nonmotorized boats and boats with electric motors only; we prohibit the use of gas and diesel motors on refuge lakes except in the waterfowl hunting area.

* * * * *

Tennessee National Wildlife Refuge

A. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

* * * * *

8. Youth hunters under age 17 must remain in sight and normal voice contact with an adult hunter age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

B. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must possess and carry a valid refuge hunt permit while hunting on the refuge.

* * * * *

9. Each youth hunter (under age 17) must remain within sight and normal voice contact and under supervision of an adult age 21 or older. One adult may supervise no more than two youth hunters.

* * * * *

■ 33. Amend § 32.63 by:

■ a. Revising paragraph A introductory text and paragraphs A.1 through A.4 under the entry Anahuac National Wildlife Refuge;

■ b. Revising paragraphs B.1 and C under the entry Buffalo Lake National Wildlife Refuge;

■ c. Under the entry Hagerman National Wildlife Refuge:

■ i. Revising paragraphs A.10, A.12, A.13, and A.14;

■ ii. Removing paragraphs A.15 through A.17; and

■ iii. Revising paragraphs B, C.1 through C.4, C.6, and D;

■ d. Under the entry Laguna Atascosa National Wildlife Refuge:

■ i. Revising paragraph C.7; and

■ ii. Adding paragraph C.19; and

■ e. Under the entry Lower Rio Grande Valley National Wildlife Refuge:

■ i. Revising paragraph A.6;

■ ii. Adding paragraph A.23; and

■ iii. Revising paragraphs C.1 and C.4.

The revisions and additions read as follows:

§ 32.63 Texas.

* * * * *

Anahuac National Wildlife Refuge

A. * * *. We allow hunting of goose, duck, coot, white-winged dove, mourning dove, Eurasian collared-dove, and rock pigeon on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must carry a current signed refuge hunting permit (signed brochure) while waterfowl hunting on all refuge hunt units.

2. Season dates for waterfowl will be concurrent with the State, except as specified in the refuge hunting permit (signed brochure).

3. For waterfowl hunting, you may enter the refuge hunt units no earlier than 4 a.m. Hunting starts at the designated legal shooting time and ends at 12 p.m. (noon). You must leave refuge hunt units by 12:30 p.m. For dove hunting, you may enter the refuge an hour before legal sunrise and must leave the refuge by ½ hour after legal sunset. We close refuge hunt units on Thanksgiving, Christmas, and New Year's Day.

4. For waterfowl hunting, we allow hunting in portions of the East Unit on Saturdays, Sundays, and Tuesdays during the regular waterfowl seasons. We require payment of a $10 per day or $40 per year to hunt on the East Unit. All hunters must check in and out through the check station when accessing the East Unit by vehicle. We will allow a limited number of parties to access the East Unit by vehicle. All hunters entering the East Unit through the check station will designate a hunt area on a first-come, first-served basis (special duck hunt areas will be assigned through a random drawing). We will require hunters to remain in an assigned area for that day's hunt. We allow hunters to access designated areas of the East Unit by boat from Jackson Ditch, East Bay Bayou, or Onion Bayou. We require hunters accessing the East Unit by boat from Jackson Ditch, East Bay Bayou, or Onion Bayou to pay the $40 annual fee. We prohibit access to the East Unit Reservoirs from Onion Bayou via boat. We prohibit the use of motorized boats on the East Unit, except on ponds accessed from Jackson Ditch via Onion Bayou. We prohibit motorized boats launching from the East Unit. For dove hunting, you are allowed to access and hunt the designated areas on the East Unit by vehicles via Farm Market Road 1985 only. Hunters are required to follow rules published annually by TPWD relating to the TPWD AHP.

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Buffalo Lake National Wildlife Refuge

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B. * * *

1. We require hunters to pay a fee and obtain a Special Use Permit (FWS Form 3–1383–G).

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer, mule deer, and feral hogs on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit recreational shooting and target practice or any non-hunting discharge.

2. We prohibit shooting or hunting of all animals except deer and feral hogs during the hunt.

3. We prohibit any use of all-terrain vehicles (ATVs).

4. We prohibit the use of dogs for big game hunting.

5. We prohibit the use of horses.

6. We prohibit the use or possession of alcoholic beverages while hunting on refuge lands (see § 32.2(j)).

7. We prohibit the use of tree stands or any devices such as nails, tacks, and scaffolding used to climb trees, tripod types of blinds, or other elevated blinds.

8. You are not allowed on the refuge after dark except in designated camping areas.

9. Youth hunt:

i. We define youth hunters as ages 9 to 16 years of age. To participate in the youth hunt, youth hunters must be no younger than age 9 and no older than age 16 at the time they apply for a permit to hunt (see condition A.10.iv) and when the hunt occurs.

ii. A Texas-licensed, adult supervisor age 18 or older who has successfully completed a Hunter Education Certification Course (''adult supervisor'') must accompany youth hunters. Adult supervisors born prior to September 2, 1971, are exempt from the hunter-education requirement.

iii. When hunting, each adult supervisor may supervise only one youth hunter. A youth hunter may have up to two supervisors.

iv. All youth hunters must carry a valid Special Use Permit (FWS Form 3–1383–G) when hunting. Special Use Permits are available at the refuge office.

v. You must provide proof of the youth hunter's or supervisor's successful completion of a State hunter-safety course to refuge staff at the time of the hunt or the youth hunter will not be allowed to hunt. Adult supervisors born prior to September 2, 1971, are exempt from the hunter-safety course requirement.

vi. When hunting, the adult supervisor must be within normal voice control of the youth hunter at all times.

vii. Adult supervisors are not allowed to hunt during the youth hunt.

10. We may close hunting areas at any time due to fire dangers, inclement weather, or other unforeseen circumstances.

* * * * *

Hagerman National Wildlife Refuge

A. * * *

10. We prohibit airboats, hovercraft, and personal watercraft (Jet Skis, wave runner, jet boats, etc.) year-round on refuge waters.

* * * * *

12. We prohibit all-terrain vehicles (ATVs).

13. We prohibit horses.

14. We prohibit glass containers.

B. Upland Game Hunting. We allow hunting of squirrel and rabbit in the months of February and September on designated areas of the refuge in accordance with State regulations and subject to the following conditions: Conditions A1 through A14 apply.

C. * * *

1. We require a limited hunt permit (name) for archery deer, feral hog, and spring turkey hunts. In partnership with Texas Parks and Wildlife Department, we allow a special youth hunt as listed on the refuge hunt information sheet. For additional information on how to apply, contact the refuge headquarters at 903–786–2826.

2. Conditions A2, A5 through A7, and A10 through A14 apply.

3. We restrict hunt participants for limited hunts to those drawn for and in possession of a limited hunt permit (name). The permits are nontransferable. Hunt dates and application procedures will be available annually at the refuge headquarters.

4. We allow limited hunts for feral hog, archery deer, and spring turkey. We allow muzzleloaders, bow and arrow, and shotguns for feral hog and spring turkey hunts. You may possess only lead-free, nontoxic (steel, bismuth, copper, or tungsten) bullets, slugs, and shot (00 buck for hogs, no shell larger than No. 4 shot size for turkey).

* * * * *

6. We limit each hunter to one stand, which the hunter may place on the refuge during the day preceding each hunt. You must remove all stands by legal sunset on the last day of each hunt.

* * * * *

D. Sport Fishing. We allow fishing on designated areas of the refuge in

accordance with State regulations and subject to the following conditions:

1. Lake Texoma and connected streams are open to fishing year-round. We require a valid State of Texas or Lake Texoma fishing license in accordance with State regulations.

2. Conditions A10, and A12 through A14 apply.

3. You may bank fish on Lake Texoma with pole and line, rod and reel, or hand line year-round.

4. We allow wade fishing in refuge ponds March 15 through October 1 annually from all areas except Refuge Road, Wildlife Drive, Plover Road, Tern Road, and Egret Road.

5. We allow fishing in refuge ponds March 15 through September 30 annually. We require a valid State of Texas or Lake Texoma fishing license in accordance with State regulations.

6. Anglers may not use any glass containers, plastic jugs, or plastic bottles as floats.

7. We prohibit discarding any type of fishing line.

8. You may only take bait for personal use while fishing in refuge waters in accordance with Texas State law. We prohibit removal of bait from the refuge for commercial sales or use.

9. We prohibit fishing from bridges.

10. We allow the use of bow and arrow to take nongame fish on refuge waters except from Refuge Road, Wildlife Drive, Plover Road, Tern Road, and Egret Road.

11. We prohibit limb line, throw lines, jug lines, seine nets, noodling, and yo-yos.

12. We prohibit taking frog, turtle, and mussel from refuge lands and waters (see § 27.21 of this chapter).

13. We prohibit taking any fish or bait for any purpose from refuge impoundments year-round.

14. We prohibit entry into refuge impoundments and ponds by any means (*i.e.,* foot, boat, other floating device) for any purpose year-round.

Laguna Atascosa National Wildlife Refuge

* * * * *

C. * * *

7. Hunting means and methods, including use of firearms, archery, and crossbows, will be in accordance with State regulations unless otherwise designated. We publish this information in the refuge hunting sheet.

* * * * *

19. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

* * * * *

Lower Rio Grande Valley National Wildlife Refuge

* * * * *

A. * * *

6. We require hunters to pay a fee to obtain a refuge hunt permit (signed brochure) and to possess and carry that permit at all times during your designated hunt period. Hunters must also display the refuge-issued vehicle placard (part of the hunt permit) while participating in the designated hunt period. Hunters, including youth hunters, must also have a valid hunting license, proof of hunter's education certification, and picture identification in order to obtain a refuge hunt permit and must possess the items listed in this condition (A6) while on the refuge hunt.

* * * * *

23. Persons, possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

* * * * *

C. * * *

1. Conditions A4 through A13, and A16 through A23 apply.

* * * * *

4. Hunters must follow the Hunting Means and Methods of Firearms, Archery and Crossbows outlined in the Texas Wildlife and Parks Department's (TPWD's) regulations unless otherwise designated. We will publish changes from the TPWD regulations that are applicable to hunting on the refuge in the refuge hunting tear sheet, which is available at the refuge office.

* * * * *

■ 34. Amend § 32.64 by revising paragraph B.4 under the entry Ouray National Wildlife Refuge to read as follows:

§ 32.64 Utah.

* * * * *

Ouray National Wildlife Refuge

* * * * *

B. * * *

4. We allow turkey hunting for youth hunters only.

* * * * *

■ 35. Amend § 32.66 by:

■ a. Revising paragraph C.15 under the entry Back Bay National Wildlife Refuge; and

■ b. Under the entry Great Dismal Swamp National Wildlife Refuge:

■ i. Revising paragraph C.6;

■ ii. Removing paragraph C.7;

■ iii. Redesignating paragraph C.8 as C.7;

■ iv. Removing paragraph C.9;

■ v. Redesignating paragraphs C.10 and C.11 as C.8 and C.9, respectively; and

■ vi. Revising paragraph D.1.

The revisions read as follows:

§ 32.66 Virginia.

* * * * *

Back Bay National Wildlife Refuge

* * * * *

C. * * *

15. We prohibit use of tree stands except on Long Island (Zone 1).

* * * * *

Great Dismal Swamp National Wildlife Refuge

*C.** * *

6. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

* * * * *

*D.** * *

1. During daylight hours, we allow fishing in Lake Drummond and in the Feeder Ditch from boat, and from the piers at Washington Ditch and Interior Ditch.

* * * * *

■ 36. Amend § 32.67 by:

■ a. Under the entry Little Pend Oreille National Wildlife Refuge:

■ i. Revising paragraphs A.2 and B; and

■ ii. Removing paragraph C.3;

■ b. Revising the entry Nisqually National Wildlife Refuge to read, ''Billy Frank Jr. Nisqually National Wildlife Refuge'', moving the entry into alphabetical order within the section, and revising paragraph D; and

■ c. Revising paragraph A.3 under the entry Ridgefield National Wildlife Refuge.

The revisions read as follows:

§ 32.67 Washington.

* * * * *

Billy Frank Jr. Nisqually National Wildlife Refuge

* * * * *

D. Sport Fishing. We allow fishing and shellfishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. In concurrence with the State, we allow fishing from boats outside the

Sanctuary Area and outside the Research Natural Area.

2. We prohibit bank fishing within the refuge along the Nisqually River and McAllister Creek.

3. We prohibit shellfishing (clams, oysters, mussels) on the tideflats.

4. We prohibit boat launching on the refuge.

5. We prohibit tidal flat and marsh access from refuge trails.

* * * * *

Little Pend Oreille National Wildlife Refuge

* * * * *

*A.** * *

2. We allow hunting during approved State hunting seasons occurring from September through December. We prohibit hunting and discharging firearms during all other periods.

* * * * *

B. Upland Game Hunting. We allow hunting of upland game and other small game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow hunting during approved State hunting seasons occurring September through December, and during the State spring wild turkey season. We prohibit hunting and discharge of firearms during all other periods.

2. During the State spring turkey season, we prohibit hunting of all species except wild turkey.

3. We prohibit raccoon hunting with dogs.

4. Condition A3 applies.

* * * * *

Ridgefield National Wildlife Refuge

*A.** * *

3. We limit or prohibit hunting of dusky Canada goose in accordance with State regulations. The State defines dusky Canada goose as a dark-breasted Canada goose, as determined by a Munsell color chart 10 YR, 5 or less, with a culmen (bill) length of 40 to 50 millimeters (1.6 to 2 inches). In addition, we will close the refuge goose season early if the dusky Canada goose harvest reaches a quota adopted by the refuge.

* * * * *

Michael J. Bean

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–23190 Filed 10–3–16; 8:45 am]

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FEDERAL REGISTER

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No. 192 October 4, 2016

Part V

The President

Federal Register
Vol. 81, No. 192
Tuesday, October 4, 2016

Presidential Documents

Title 3—

The President

Presidential Determination No. 2016–05 of January 13, 2016

Unexpected Urgent Refugee and Migration Needs

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States, including section 2(c)(1) of the Migration and Refugee Assistance Act of 1962 (the ''Act'') (22 U.S.C. 2601(c)(1)), I hereby determine, pursuant to section 2(c)(1) of the Act, that it is important to the national interest to furnish assistance under the Act, in an amount not to exceed $70 million from the United States Emergency Refugee and Migration Assistance Fund, for the purpose of meeting unexpected urgent refugee and migration needs related to the U.S. Refugee Admissions Program, through contributions and other assistance to international and nongovernmental organizations funded through the Bureau of Population, Refugees, and Migration of the Department of State. Funds will be used by the Department of State to meet the unexpected urgent need for additional resources within the U.S. Refugee Admissions Program, in light of the unprecedented number of refugees in need of resettlement.

You are authorized and directed to publish this memorandum in the *Federal Register.*

THE WHITE HOUSE,
Washington, January 13, 2016

[FR Doc. 2016–24165
Filed 10–3–16; 11:15 am]
Billing code 4710–10–P

Presidential Documents

Memorandum of April 12, 2016

Delegations of Authority Under Sections 610, 614(a)(1), and 506(a)(2)(A)(i)(II) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

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 following authorities, subject to fulfilling the requirements of sections 614(a)(3) and 652 of the Foreign Assistance Act of 1961 (FAA) and section 7009(d) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Public Law 111–117), in order to provide assistance for Iraq:

(1) the authority under section 610 of the FAA to make the determination necessary for and to execute the transfer of up to $50 million of Fiscal Year (FY) 2010 supplemental International Narcotics Control and Law Enforcement (INCLE) funds to the Economic Support Fund account;

(2) the authority under section 614(a)(1) of the FAA to determine whether it is important to the security interests of the United States to furnish assistance using up to $50 million of FY 2010 supplemental INCLE funds without regard to any other provision of law within the purview of section 614(a)(1) of the FAA; and

(3) the authority under section 506(a)(2)(A)(i)(II) of the FAA to make the determination required and direct the drawdown of up to $33.9 million in articles and services from the inventory and resources of any agency of the United States Government and military education and training from the Department of Defense for the purposes and under the authorities of chapter 9 of part I of the FAA.

You are authorized and directed to publish this memorandum in the *Federal Register.*

THE WHITE HOUSE,
Washington, April 12, 2016

[FR Doc. 2016–24168
Filed 10–3–16; 11:15 am]
Billing code 4710–10–P

FEDERAL REGISTER

Vol. 81 Tuesday,
No. 192 October 4, 2016

Part VI

The President

Proclamation 9506—Child Health Day, 2016

Federal Register
Vol. 81, No. 192
Tuesday, October 4, 2016

Presidential Documents

Title 3—

The President

Proclamation 9506 of September 29, 2016

Child Health Day, 2016

By the President of the United States of America

A Proclamation

Today's youth will shape our Nation's narrative and drive our progress, and it is our duty to ensure our young people are given every opportunity to live full, healthy lives. Securing a bright future for America's daughters and sons requires us to continue expanding access to quality health care and working to foster cleaner, safer, and more supportive environments. On Child Health Day, we renew our strong commitment to protecting and empowering our children by giving them the tools, resources, and knowledge they need to grow into healthy and productive adults.

My Administration has made children's health a top priority throughout the past 8 years. Through First Lady Michelle Obama's *Let's Move!* initiative, we have worked to bring parents, schools, and communities together to reduce childhood obesity by increasing access to affordable and nutritious food, and by encouraging physical activity early on in life. Parents and guardians serve as role models when it comes to forming healthy habits, and they can help their children learn to make smart choices that will shape their lifestyles for years to come.

Thanks to the Affordable Care Act, no child can be denied coverage because of a pre-existing condition, and millions of young people are able to remain on a parent's insurance plan until age 26. Cancer touches the lives of millions of Americans, and pediatric cancer remains the leading cause of death by disease among children. Earlier this year, I called on Vice President Joe Biden to lead the White House Cancer Moonshot Task Force—a collaborative effort that is striving to make a decade's worth of progress in preventing, diagnosing, and treating cancer in just 5 years and is dedicated to ending cancer as we know it.

Supporting our children's emotional and mental health is just as critical as protecting their physical health. Bullying touches the lives of young people across our country and can affect their mental health, and we are committed to providing parents and schools with the support they need to address harassment—because no child should be hurt, and no child should feel ashamed because of who they are.

As we face growing environmental threats, it is our responsibility to combat climate change and protect our planet for future generations. That is why we have taken concrete steps to address carbon pollution and advocate for cleaner energy options. Through the Paris Climate Agreement, we are joining with nearly 200 countries to adopt ambitious measures that will reduce carbon pollution across the globe. By taking unprecedented action to protect the air we breathe and the water we drink, we are striving to reduce the harmful effects that climate change can have on our children, including the potential for higher incidence of asthma attacks, and other health problems exacerbated by dirty air.

This Child Health Day, we are reminded that the well-being of America's children is in our hands and that it is our responsibility to keep building a society that will allow them to thrive. Let us reaffirm our belief in the notion that all children should be able to live a healthy and happy life—no matter where they come from or what they look like—and let us continue

reaching for a future where all our children are limited by nothing but the size of their dreams.

The Congress, by a joint resolution approved May 18, 1928, as amended (36 U.S.C. 105), has called for the designation of the first Monday in October as Child Health Day and has requested that the President issue a proclamation in observance of this day.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim Monday, October 3, 2016, as Child Health Day. I call upon families, educators, health professionals, faith-based and community organizations, and all levels of government to help ensure America's children are healthy.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–24171
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FEDERAL REGISTER PAGES AND DATE, OCTOBER

CFR PARTS AFFECTED DURING OCTOBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *http://www.archives.gov/federal-register/laws*.

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S. 2040/P.L. 114–222

Justice Against Sponsors of Terrorism Act (Passed over the President's veto: Sept. 28, 2016; 130 Stat. 852)

H.R. 5325/P.L. 114–223

Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act (Sept. 29, 2016; 130 Stat. 857)

H.R. 2615/P.L. 114–224

Virgin Islands of the United States Centennial Commission Act (Sept. 29, 2016; 130 Stat. 921)

H.R. 5252/P.L. 114–225

To designate the United States Customs and Border Protection Port of Entry located at 1400 Lower Island Road in Tornillo, Texas, as the ''Marcelino Serna Port of Entry''. (Sept. 29, 2016; 130 Stat. 925)

H.R. 5936/P.L. 114–226

West Los Angeles Leasing Act of 2016 (Sept. 29, 2016; 130 Stat. 926)

H.R. 5937/P.L. 114–227

To amend title 36, United States Code, to authorize the American Battle Monuments Commission to acquire, operate, and maintain the Lafayette Escadrille Memorial in Marnes-la-Coquette, France, and for other purposes. (Sept. 29, 2016; 130 Stat. 934)

H.R. 5985/P.L. 114–228

Department of Veterans Affairs Expiring Authorities Act of 2016 (Sept. 29, 2016; 130 Stat. 935)

Last List September 27, 2016

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